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

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1260

[Doc. No. AMS–LP–22–0002]

Beef Promotion and Research Order; Reapportionment and Technical Amendment

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule adjusts representation on the Cattlemen's Beef Promotion and Research Board (Board), established under the Beef Promotion and Research Act of 1985 (Act), to reflect changes in domestic cattle inventories as well as changes in levels of imported cattle, beef, and beef products that have occurred since the Board was last reapportioned in July 2020. These adjustments are required by the Beef Promotion and Research Order (Order) and will result in a decrease in Board membership from 101 to 99, effective with the Secretary of Agriculture's (Secretary) appointments from nominees requested in Spring of 2023. This final rule also updates the list of Qualified State Beef Councils (QSBCs) in the Order by removing the Maryland Beef Industry Council which voted to dissolve their State beef council.

DATES: This rule is effective December 6, 2023.

FOR FURTHER INFORMATION CONTACT: Lacey Heddlesten, Agricultural Marketing Specialist, Research and Promotion Division, Telephone: (620) 717–3834; or Email: *Lacey.Heddlesten@usda.gov.*

SUPPLEMENTARY INFORMATION:

Executive Orders 12866, 14094 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. Executive Order 14094 reaffirms, supplements, and updates Executive Order 12866 and further directs agencies to solicit and consider input from a wide range of affected and interested parties through a variety of means. This rule is not a significant regulatory action within the meaning of Executive Order 12866. Accordingly, this action has not been reviewed by the Office of Management and Budget (OMB) under section 6 of the Executive Order.

Executive Order 12988

This rule has been reviewed under E.O. 12988, Civil Justice Reform and it is not intended to have retroactive effect.

Section 11 of the Act (7 U.S.C. 2910) provides that nothing in the Act may be construed to preempt or supersede any other program relating to beef promotion organized and operated under the laws of the U.S. or any State. There are no administrative proceedings that must be exhausted prior to any judicial challenge to the provisions of this rule.

Executive Order 13175

This 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 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.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*) the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

Paperwork Reduction Act

In accordance with OMB regulations (5 CFR part 1320) that implement the Paperwork Reduction Act of 1995 (44 U.S.C. 35), the information collection and recordkeeping requirements contained in the Order and accompanying Rules and Regulations have previously been approved by OMB and were assigned OMB control number 0581–0093.

Background

The Board was initially appointed on August 4, 1986, pursuant to the provisions of the Act (7 U.S.C. 2901–2911), and the Order issued thereunder. Domestic representation on the Board is based on cattle inventory numbers, while importer representation is based on the conversion of the volume of imported cattle, beef, and beef products into live animal equivalencies.

Reapportionment

Section 1260.141(b) of the Order provides that the Board shall be composed of cattle producers and importers appointed by the Secretary from nominations submitted by certified producer and importer organizations. A producer may only be nominated to represent the State or unit in which that producer is a resident.

Section 1260.141(c) of the Order provides that at least every 3 years, but not more than every 2 years, the Board shall review the geographic distribution of cattle inventories throughout the United States and the volume of imported cattle, beef, and beef products and, if warranted, shall reapportion units and/or modify the number of Board members from units in order to reflect the geographic distribution of cattle production volume in the United States and the volume of cattle, beef, or beef products imported into the United States. Further, § 1260.141(d) allows the board to recommend to the Secretary a modification in the number of cattle per unit necessary for representation of Board seats.

Section 1260.141(e)(1) provides that each geographic unit or State that includes a total cattle inventory equal to or greater than 500,000 head of cattle shall be entitled to one representative on the Board. Section 1260.141(e)(2) provides that States that do not have total cattle inventories equal to or greater than 500,000 head shall be

grouped, to the extent practicable, into geographically contiguous units, each of which have a combined total inventory of not less than 500,000 head. Such grouped units are entitled to at least one representative on the Board. Each unit is entitled to an additional Board member for each additional 1 million head of cattle within the unit, as provided in § 1260.141(e)(4). Further, as provided in § 1260.141(e)(3), importers are represented by a single unit, with their number of Board members based on a conversion of the total volume of imported cattle, beef, or beef products into live animal equivalencies.

Section 1260.141(f) of the Order states in determining the volume of cattle within the units, the Board and the Secretary shall utilize the information received by the Board pursuant to §§ 1260.201 and 1260.202 industry data and data published by USDA. The producer representation is based on an average of the inventory of cattle in the various States on January 1 in 2020, 2021, and 2022 as reported by USDA's National Agricultural Statistics Service (NASS). The importer representation is based on a combined total average of the 2019, 2020, and 2021 live cattle imports as published by USDA's Economic Research Service (ERS) and the average of the 2019, 2020, and 2021 live animal equivalents for imported beef and beef products.

In considering reapportionment, the Board reviewed cattle inventories as of January 1 in 2020, 2021, and 2022, as well as cattle, beef, and beef product import data for the period of January 1, 2019, to December 31, 2021. The Board determined that an average of the inventory of cattle on January 1 in 2020, 2021, and 2022 best reflect the number of cattle in each State or unit since publication of the last reapportionment rule in 2020 (85 FR 39461). The Board reviewed data published by ERS to determine proper importer representation. The Board recommended the use of the average of a combined total of the 2019, 2020, and 2021 cattle import data and the average of the 2019, 2020, and 2021 live animal equivalents for imported beef products. The method used to calculate the total number of live animal equivalents was the same as that used in the previous reapportionment of the Board. The live animal equivalent weight was changed in 2006 from 509 pounds to 592 pounds (71 FR 47074).

As discussed in the proposed rule, the Board's recommended reapportionment plan would decrease the number of representatives on the Board from 101 to 100. Based on the Board's recommendation, Idaho would gain one seat, Montana would lose one seat, Pennsylvania would lose one seat, and Wisconsin would maintain their four seats. This final rule, however, results in Wisconsin losing one seat. The States and units affected by the reapportionment plan and the current and revised representation per unit are as follows:

State/unit	Increase/decrease	Current representation	Revised representation
Idaho	+1	2	3
Montana	−1	3	2
Pennsylvania	−1	2	1
Wisconsin	−1	4	3
Net Change	−2		

The Board reapportionment takes effect in the 2023 nomination process and the number of board members the Secretary appointments to fill positions early in the year 2024 will reduce from 101 to 99.

Technical Amendment

The final rule updates the list of QSBCs in the Order by removing the Maryland Beef Industry Council which unanimously voted to dissolve their State beef council during the September 14, 2022, board meeting.

Summary of Comments

AMS published the proposed rule for public comment on May 1, 2023 (88 FR 27415). The comment period ended on June 1, 2023. AMS received 12 timely comments. AMS conducted a review of the comments and determined that three of the twelve comments were outside the scope of the rulemaking. Of the remaining nine comments, AMS analyzed the comments and grouped them into the below categories.

Unforeseen Events

Several of the comments mentioned the COVID–19 pandemic and the drought's impact on the beef industry. The majority of the comments received were a form letter opposing Wisconsin losing a seat and arguing several factors including that the pandemic caused record low milk prices. During the early part of the pandemic, dairy producers in Wisconsin faced a surplus of milk because of the rapid decrease in price. In addition, three producers and seven cattle, dairy, and farm associations in Wisconsin, stated that the average milk prices paid to Wisconsin farmers in 2020 were $18.90, in 2021 it was $17.10, and by May of 2022 the price of milk was up to $25.21. Further the commenters stated that due to increases in milk price, dairy cow numbers are expected to continue to grow; potentially, by January 31—putting Wisconsin herd size back over 3.5 million.

In response, USDA acknowledges that a pandemic was in place from approximately from March 2020 to May 2023, which caused unforeseen industry-wide supply chain issues. The pandemic not only impacted the state of Wisconsin but has had a significant impact on a large portion of the U.S. and the U.S. farming and cattle industry. Thus, to only consider the impact of the pandemic on one state and not the entire cattle industry nationwide would create an inequity. Accordingly, USDA takes the position that as an industry the impact is widespread and thus the numbers as presented for cattle inventories as of January 1 in 2020, 2021, and 2022, are the fairest and most accurate representation of the current industry numbers.

Another commenter argued that the drought negatively impacted herd numbers in the state because it changed Wisconsin's place in the cattle production cycle.

USDA acknowledges that for the reapportionment that took place on August 12, 2014 (79 FR 46961) for appointments that were seated in 2015, at that time the drought that had taken place in Texas was taken into consideration. Texas was slated to lose two board seats due to cattle inventory decease related to a three-year loss of cattle inventory due to severe drought. Due to the turnaround in environmental and economic conditions along with reports indicating that cattle were moving back into Texas from other states and the total herd inventory would be back up prior to reapportionment taking place, the

USDA issued only a loss of one seat rather than two as was outlined in the proposed rule.

However, it is important to note that in the 2015 reapportionment the environmental factors, in that case the drought, significantly impacted one state in particular, Texas and lasted several years spanning from 2011 to 2013, with 2011 being one of the worst droughts in the State's history. In contrast, under the current circumstances, a large portion of the United States was impacted by drought over the past 3 years which affected the entire cattle inventory. According to the USDA, Economic Research Service (ERS), the Western States experienced extreme or exceptional drought and, in some cases, severe drought conditions the past few years, with the most severe conditions being reported in Nebraska, Kansas, Oklahoma, Texas, New Mexico, and Oregon. Based on this data, it is clear that the current drought conditions have not only impacted the state of Wisconsin but has had a significant impact on a large portion of the U.S. and the U.S. farming and cattle industry. Thus, to only consider the impact of the drought on one state and not the entire cattle industry nationwide would create an inequity. Accordingly, USDA takes the position that as an industry the impact is widespread and thus the numbers as presented for cattle inventories as of January 1 in 2020, 2021, and 2022, are the fairest and most accurate representation of the current industry numbers.

One comment opposed Montana losing a seat similarly arguing that the drought impacted the number of herds in the state. They claimed, prior to the drought, herd numbers had been consistent since the 1980's. The drought caused a dip in 2021 and 2022; however, 2023 spring moisture has been promising for pastures. Further, according to the commentor, there is indication that Montana producers are starting to rebuild their herd and it is possible that Montana will be above 2.5 million again before the final rule goes into effect.

Again, USDA acknowledges that a large portion of the United States was impacted by drought over the past 3 years which impacted cattle inventory and again points out that in the previous reapportionment the environmental factors, in that case the drought, significantly impacted one state in particular, Texas and lasted several years spanning from 2011 to 2013, with 2011 being one of the worst droughts in the State's history. Once more, based on data provided by the USDA ERS, it is clear that the current drought conditions have not only impacted the state of Montana but has had a significant impact on a large portion of the U.S. and the U.S. farming and cattle industry and thus, to only consider the impact of the drought on one state and not the entire cattle industry nationwide would create an inequity. Accordingly, USDA takes the position that as an industry the impact is widespread and thus the numbers as presented for cattle inventories as of January 1 in 2020, 2021, and 2022, are the fairest and most accurate representation of the current industry numbers.

Lastly, although it is important to acknowledge these events play a role in the cattle inventory numbers, it is also important to note that the Order is silent on how Board seats would be impacted by natural events. The Order does specify the formula for determining the number of Board seats and USDA uses a 3-year average to attain a representative number within a State. Any change would need to be applied to the entirety of the assessment-paying population as the Act and Order govern all cattle producers and importers and all geographical units.

Cattle Inventory Margin of Error and Survey Response Rate

Eight of the nine comments stated opposition to Wisconsin losing a seat due to the margin of error associated with the statistical methodology used for determining cattle inventory numbers per state for the 3-year period reviewed. As mentioned in one of the comments, Wisconsin was 33,000 head short of maintaining their fourth seat on the Board. The average coefficient of variation for Wisconsin's total cattle inventory in 2020, 2021, and 2022 cattle inventory reports is 3.4 percent (+34,000 head). Since the coefficient of variation is greater than the amount by which the inventory is under the 3.5 million threshold, then Wisconsin should be allowed to retain their fourth seat. According to the January 1, 2023, cattle inventory numbers published, the State of Wisconsin was at 3.4 million. However, it was reported by the Wisconsin Ag Statistician that only 60 percent of surveys were returned, which questions whether the 3.4 million head is an accurate reflection of current cattle inventory.

In response, the Order is silent on whether other factors such as cattle inventory margin of error and survey response rate should be taken into consideration when determining the total cattle inventory. Section 1260.141(e)(1) of the Order states that each geographic unit or State that includes a total cattle inventory equal to or greater than 500,000 head of cattle shall be entitled to one representative on the Board. Section 1260.141(e)(4) specifically states that each unit is entitled to an additional Board member for each additional 1 million head of cattle within the unit.

USDA acknowledges the Board's recommendation as provided by § 1260.141(d) which states that the Board may recommend to the Secretary a modification in the number of cattle per unit necessary for representation on the Board. However, § 1260.141(d) applies only to a recommended change based on cattle inventory [1] and not the other factors used in the Board's current recommendation for this rule.

Further, the point estimates published by NASS are the official USDA estimates of inventory. In preparing these estimates, NASS takes into account all available and relevant data and makes the necessary adjustments based on factors such as response rate. NASS publishes the measures of uncertainty to provide transparency and context around the estimates, however making further adjustments for these purposes would introduce inconsistencies to the process and departure from the official USDA inventory estimates.

Thus, to consider other factors such as the margin of error and the survey response rate to the reapportionment of the Board, regulatory changes which require notice-and-comment rulemaking, would be necessary to make those clarifications to the Order. Any change contemplated by additional rulemaking would need to be applied to the entirety of the assessment-paying population as the Act and Order govern all cattle producers and importers and all geographical units.

Diversity

One commenter mentioned that Wisconsin is a State that includes beef and dairy producers, and allowing Wisconsin to maintain their fourth seat will ensure the Board has a strong and diverse representation from all sectors. One additional commentor opposed to Montana losing a seat because the State is home to 12 tribal nations that are already underrepresented on the Board.

It is USDA's policy concerning nominations to the Board that the Board's membership should be open to all individuals without regard based on race, color, religion, national origin, age, sex, sexual orientation, disability, marital or familial status, political

[1] Sections 1260.141.(c) and (e) use cattle inventories in calculating reapportionment numbers.

beliefs, parental status, receipt of public assistance, or protected genetic information. Board membership should also reflect the diversity of the industries in experience of members, methods of production and distribution, marketing strategies, and other distinguishing factors that will bring different perspectives and ideas to the tables. Emphasis should also be placed on the knowledge, skills, and abilities of the Board to serve and represent the diverse interests of assessment paying producers.

Thus, the number of members on the Board should not dictate the level of diversity on the Board.

Regulatory Flexibility Act

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), AMS has considered the economic effect of this action on small entities and has determined that this rule will not have a significant economic impact on a substantial number of small entities. The purpose of RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly burdened.

In 2022, the Small Business Administration (SBA) (13 CFR part 121.201) published a final rule (84 FR 64013) that updated its size standards based on income or employee numbers for various small business falling under the North American Industry Classification System (NAICS). Within that rule, the SBA threshold for ''Beef Cattle Ranching and Farming'' (NAICS code 112111) operations to qualify small businesses was raised from annual sales of $1 million or less to annual sales of $2.5 million or less.

According to the NASS 2017 Census of Agriculture, the number of U.S. operations with beef cattle totaled 729,046 and with cattle of any type totaled 882,692.[2] The same Census of Agriculture data shows that roughly 4 percent of operations with cattle, or 31,476 operations, have annual sales receipts of $1,000,000 or more, the small business standard prior to the 2022 revision.[3] No further breakout in the Census of Agriculture data is made to account for the new, higher SBA standard. However, the vast majority of cattle producers, 96 percent, would be considered small businesses under the new SBA standards. It should be noted that producers are only indirectly impacted by the rule.

Cattle, beef, and veal importers are also impacted by the rule. Based on data available on membership in the Meat Import Council of America, AMS estimates that approximately 190 firms import beef or beef products. AMS is not aware of any data that reports the number of beef-importing entities that meet the SBA definition of small businesses.

In addition to cattle producers, affected entities under this rule change include meat and meat-product merchant wholesalers (wholesalers), classified under NAICS code 424470, and meat processors from carcass (processors), classified under NAICS code 311612. The SBA thresholds for both these businesses to qualify as small are that they have fewer than 1,000 employees. The most current data from the Census of Manufacturing states that all 2,376 wholesalers were small businesses (in 2017) [4] and that all 1,423 processors were small business (in 2020).[5]

Recent import trade data was also considered for understanding the overall dynamics of this industry segment. The Foreign Agricultural Service reports monthly trade data for traded agricultural products by product type. Based on analysis of that trade data and consumption data collected in the USDA's World Agricultural Demand and Supply Estimates, over the 2017 to 2022 period, cattle imports ranged between 1.8 percent and 2.3 percent of the total cattle inventory and that beef imports ranged from 9.8 percent to 10.7 percent of total supply. Veal imports during that time were negligible as a share of domestic production.

The rule imposes no new burden on the industry, as it only adjusts representation on the Board to reflect changes in domestic cattle inventory, as well as in cattle and beef imports. Additionally, the Order § 1260.141 does not take into consideration the margin of error when analysis is conducted. Therefore, the Secretary is applying the Order guidance without using the NASS margin of error to adjust Board membership from 101 to 99.

AMS is committed to complying with the E-Government Act of 2002 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 rule.

List of Subjects in 7 CFR Part 1260

Administrative practice and procedure, Advertising, Agricultural research, Imports, Marketing agreements, Meat and meat products, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Agricultural Marketing Service amends 7 CFR part 1260 as follows:

PART 1260—BEEF PROMOTION AND RESEARCH

■ 1. The authority citation for 7 CFR part 1260 continues to read as follows:

Authority: 7 U.S.C. 2901–2911 and 7 U.S.C. 7401.

■ 2. Revise § 1260.141 paragraph (a) and the table immediately following to read as follows:

§ 1260.141 Membership of Board.

(a) Beginning with the 2023 Board nominations and the associated appointments effective early in the year 2024, the United States shall be divided into 38 geographical units and 1 unit representing importers, for a total of 39 units. The number of Board members from each unit shall be as follows:

TABLE 1 TO PARAGRAPH (a)—CATTLE AND CALVES [1]

State/unit	(1,000 head)	Directors
1. Alabama	1,285	1
2. Arizona	967	1
3. Arkansas	1,733	2
4. Colorado	2,700	3
5. Florida	1,670	2

[2] *https://www.nass.usda.gov/AgCensus/index.php.*

[3] *https://quickstats.nass.usda.gov/results/758A0A38-2BF4-39CE-90EF-A581BFEA3E81.*

[4] *https://data.census.gov/profile/424470__Meat_and_meat_product_merchant_wholesalers?g=0100000US&n=424470.*

[5] *https://data.census.gov/profile/311612_-Meat_and_meat_product_merchant_wholesalers?g=0100000US&n=311612.*

TABLE 1 TO PARAGRAPH (a)—CATTLE AND CALVES [1]—Continued

State/unit	(1,000 head)	Directors
6. Georgia	1,077	1
7. Idaho	2,507	3
8. Illinois	1,047	1
9. Indiana	833	1
10. Iowa	3,800	4
11. Kansas	6,483	6
12. Kentucky	2,073	2
13. Louisiana	777	1
14. Michigan	1,137	1
15. Minnesota	2,203	2
16. Mississippi	917	1
17. Missouri	4,217	4
18. Montana	2,383	2
19. Nebraska	6,800	7
20. New Mexico	1,373	1
21. New York	1,433	1
22. North Carolina	798	1
23. North Dakota	1,893	2
24. Ohio	1,283	1
25. Oklahoma	5,217	5
26. Oregon	1,260	1
27. Pennsylvania	1,430	1
28. South Dakota	3,900	4
29. Tennessee	1,783	2
30. Texas	12,900	13
31. Utah	803	1
32. Virginia	1,410	1
33. Wisconsin	3,467	3
34. Wyoming	1,290	1
35. Northwest Unit:		
Alaska	17	.....
Hawaii	142	.....
Washington	1,157	.....
Total	1,316	
36. Northeast Unit:		
Connecticut	48	.....
Delaware	13	.....
Maine	77	.....
Maryland	174	.....
Massachusetts	36	.....
New Hampshire	32	.....
New Jersey	26	.....
Rhode Island	4	.....
Vermont	248	.....
Total	658	1
37. Mid-Atlantic Unit:		
South Carolina	327	.....
West Virginia	380	.....
Total	707	1
38. Southwest Unit:		
California	5,167	.....
Nevada	465	.....
Total	5,632	6
39. Importers Unit [2]	7,466	7

[1] 2020, 2021, and 2022 average of January 1 cattle inventory data.
[2] 2019, 2020, and 2021 average of annual import data.

§ 1260.315 [Amended]

■ 3. Amend § 1260.315 by:
■ a. Removing paragraph (q); and
■ b. Redesignating paragraphs (r) through (rr) as paragraphs (q) through (qq), respectively.

Melissa Bailey,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2023–24395 Filed 11–3–23; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–1410; Project Identifier MCAI–2022–01517–E; Amendment 39–22575; AD 2023–21–03]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce Deutschland Ltd & Co KG Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2013–26–10 for certain Rolls-Royce Deutschland Ltd & Co KG (RRD) Model RB211–524G2–19, RB211–524G3–19, RB211–524H–36, and RB211–524H2–19 engines. AD 2013–26–10 required a one-time reduction in the cyclic life of certain high-pressure compressor (HPC) rotor stage 1 and stage 2 disks, and removal of disks that exceed the reduced cycle life. Since the FAA issued AD 2013–26–10, the manufacturer has revised the engine time limits manual (TLM), introducing new and more restrictive instructions. This AD is prompted by the manufacturer revising the engine time limits manual, introducing new and more restrictive instructions. This AD requires revisions to the airworthiness limitations section (ALS) of the operator's existing approved engine maintenance or inspection program, as applicable, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 11, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 11, 2023.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–1410; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

• For service information identified in this final rule, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* website: *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.* It is also available at *regulations.gov* under Docket No. FAA–2023–1410.

• You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

FOR FURTHER INFORMATION CONTACT: Sungmo Cho, Aviation Safety Engineer, FAA, 2200 South 216th Street, Des Moines, WA 98198; phone: (781) 238–7241; email: *sungmo.d.cho@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2013–26–10, Amendment 39–17719 (79 FR 1315, January 8, 2014), (AD 2013–26–10). AD 2013–26–10 applied to certain RRD Model RB211–524G2–19, RB211–524G3–19, RB211–524H–36, and RB211–524H2–19 engines. AD 2013–26–10 required a one-time reduction in the cyclic life of certain HPC rotor stage 1 and stage 2 disks, and removal of disks that exceed the reduced cycle life. The FAA issued AD 2013–26–10 to prevent the failure of certain life-limited parts, which could result in uncontained engine damage and damage to the airplane.

The NPRM published in the **Federal Register** on July 11, 2023 (88 FR 44075). The NPRM was prompted by AD 2022–0232, dated November 28, 2022 (EASA AD 2022–0232) (referred to after this as the MCAI), issued by EASA which is the Technical Agent for the Member States of the European Union. The MCAI states that the ALS for RB211–524G/H engines, which is approved by EASA, is defined and published in TLM T–211(524)–7RR, and that these airworthiness limitations have been identified as mandatory for continued airworthiness. The MCAI also states that since the original issue of TLM T–211(524)–7RR, updated thresholds and intervals were introduced for newly designed parts. EASA AD 2013–0246 was issued to require implementation of the reduced cyclic life limit and replacement of HPC stage 1 and 2 disks before exceeding their life limit. The MCAI also states that the manufacturer published a revised engine TLM since EASA AD 2013–0246 was issued, introducing new and more restrictive instructions. The ALS defined in the revised engine TLM also adds RRD Model RB211–524G2–T–19, RB211–524G3–T–19, RB211–524H–T–36, and RB211–524H2–T–19 engines to the list of affected engines.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2023–1410.

In the NPRM, the FAA proposed to require revising the existing approved engine maintenance or inspection program, as applicable, to incorporate new and more restrictive airworthiness limitations, which are specified in EASA AD 2022–0232 described previously, except for any differences identified as exceptions in the regulatory text of this AD and as discussed under ''Differences Between this AD and the MCAI.''

Discussion of Final Airworthiness Directive

Comments

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

Conclusion

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered the comment received, and determined that air safety requires adopting the AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, this AD is adopted as proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

The FAA reviewed EASA AD 2022–0232, which specifies instructions for

accomplishing the actions specified in the applicable TLM, including performing maintenance tasks, replacing life-limited parts, and revising the existing approved maintenance or inspection program, as applicable, by incorporating the limitations, tasks, and associated thresholds and intervals described in the TLM.

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

Differences Between This AD and the MCAI

Where paragraph (3) of EASA AD 2022–0232 specifies revising the approved Aircraft Maintenance Programme within 12 months after the effective date of EASA AD 2022–0232, this AD requires revising the ALS of the existing approved engine maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

Costs of Compliance

The FAA estimates that this AD affects 22 engines installed on airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Revise the ALS of the existing approved engine maintenance or inspection program.	1 work-hour × $85 per hour = $85	$0	$85	$1,870

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive 2013–26–10, Amendment 39–17719 (79 FR 1315, January 8, 2014); and

■ b. Adding the following new airworthiness directive:

2023–21–03 Rolls-Royce Deutschland Ltd & Co KG: Amendment 39–22575; Docket No. FAA–2023–1410; Project Identifier MCAI–2022–01517–E.

(a) Effective Date

This airworthiness directive (AD) is effective December 11, 2023.

(b) Affected ADs

This AD replaces AD 2013–26–10, Amendment 39–17719 (79 FR 1315, January 8, 2014).

(c) Applicability

This AD applies to Rolls-Royce Deutschland Ltd & Co KG (RRD) Model RB211–524G2–19, RB211–524G2–T–19, RB211–524G3–19, RB211–524G3–T–19, RB211–524H–36, RB211–524H–T–36, RB211–524H2–19, and RB211–524H2–T–19 engines.

(d) Subject

Joint Aircraft System Component (JASC) Code 7230, Turbine Engine Compressor Section.

(e) Unsafe Condition

This AD was prompted by the manufacturer revising the engine time limits manual, introducing new and more restrictive instructions. The FAA is issuing this AD to prevent failure of certain life-limited parts. The unsafe condition, if not addressed, could result in uncontained engine damage and damage to the airplane.

(f) Compliance

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

(g) Required Actions

Except as specified in paragraph (h) of this AD: Perform all required actions within the compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2022–0232, dated November 28, 2022 (EASA AD 2022–0232).

(h) Exceptions to EASA AD 2022–0232

(1) Where EASA AD 2022–0232 defines the AMP as the ''approved Aircraft Maintenance Programme which contains the tasks on the basis of which the scheduled maintenance is conducted to ensure the continuing airworthiness of each operated engine,'' replace that text with the ''Aircraft Maintenance Program which contains the tasks of which the operator or the owner ensures the continuing airworthiness of each operated airplane.''

(2) Where EASA AD 2022–0232 refers to its effective date, this AD requires using the effective date of this AD.

(3) This AD does not require compliance with paragraph (1) of EASA AD 2022–0232.

(4) This AD does not require compliance with paragraph (2) of EASA AD 2022–0232.

(5) Where paragraph (3) of EASA AD 2022–0232 specifies revising the approved Aircraft Maintenance Programme within 12 months after the effective date of EASA AD 2022–0232, this AD requires revising the airworthiness limitations section (ALS) of the

existing approved engine maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(6) This AD does not require compliance with paragraph (4) of EASA AD 2022–0232.

(7) This AD does not require compliance with paragraph (5) of EASA AD 2022–0232.

(8) This AD does not adopt the Remarks paragraph of EASA AD 2022–0232.

(i) Provisions for Alternative Actions and Intervals

After performing the actions required by paragraph (g) of this AD, no alternative actions and associated thresholds and intervals, including life limits, are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2022–0232.

(j) Alternative Methods of Compliance (AMOCs)

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

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

(k) Additional Information

For more information about this AD, contact Sungmo Cho, Aviation Safety Engineer, FAA, 2200 South 216th Street, Des Moines, WA 98198; phone: (781) 238–7241; email: *sungmo.d.cho@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2022–0232, dated November 28, 2022.

(ii) [Reserved]

(3) For EASA AD 2022–0232, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu*; website: *easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

(4) You may view this service information at FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this service information that is incorporated by reference 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.*

Issued on October 18, 2023.

Ross Landes,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2023–24383 Filed 11–3–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–1412; Project Identifier MCAI–2022–01588–E; Amendment 39–22562; AD 2023–20–03]

RIN 2120–AA64

Airworthiness Directives; Austro Engine GmbH Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Austro Engine GmbH Model E4 and E4P engines. This AD is prompted by reports of piston failures and the determination that certain batches of pistons were manufactured with a dimensional deviation in the piston pin bore and piston diameter. This AD requires repetitive engine oil analysis for aluminum content outside the acceptable limits and, if necessary, replacement of the pistons, piston rings, con-rods assembly, and crankcase or, as an alternative, replacement of the engine core. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 11, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 11, 2023.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No.FAA–2023–1412; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For service information identified in this final rule, contact Austro Engine GmbH, Rudolf-Diesel-Strasse 11, A–2700 Weiner Neustadt, Austria; phone: +43 2622 23000; website: *austroengine.at.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *regulations.gov* under Docket No. FAA–2023–1412.

FOR FURTHER INFORMATION CONTACT: Barbara Caufield, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (781) 238–7146; email: *barbara.caufield@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Austro Engine GmbH Model E4 and E4P engines. The NPRM published in the **Federal Register** on July 14, 2023 (88 FR 45118). The NPRM was prompted by European Union Aviation Safety Agency (EASA) AD 2022–0240R1, dated December 15, 2022 (referred to after this as the MCAI), issued by EASA, which is the Technical Agent for the Member States of the European Union. The MCAI states that a manufacturer investigation into reports of piston failures determined that certain batches of pistons were manufactured with a dimensional deviation in the piston pin bore and in the piston diameter, which could cause piston failure, with consequent loss of oil, loss of engine power, and reduced control of the airplane. To address the unsafe condition, EASA issued EASA AD 2022–0240, dated December 6, 2022 (EASA AD 2022–0240), to specify repetitive oil analyses and replacement of the pistons, piston rings, con-rods assembly, and crankcase, or as an alternative, replacement of the engine core. EASA AD 2022–0240 also prohibited release to service of an airplane until receipt of the results for each oil analysis.

Since EASA AD 2022–0240 was issued, the manufacturer determined that aluminum levels outside of the acceptable limits would be found during the first oil analysis, and are unlikely to be found during subsequent oil analyses. As a result, EASA revised

EASA AD 2022–0240 and issued the MCAI to allow release to service of airplanes for a limited number of flight hours immediately after the second and subsequent oil samples are taken for analyses.

In the NPRM, the FAA proposed to require initial and repetitive engine oil analysis for aluminum content outside the acceptable limits and, if necessary, replacement of the pistons, piston rings, con-rods assembly, and crankcase, or as an alternative, replacement of the engine core. The FAA is issuing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at regulations.gov under Docket No. FAA–2023–1412.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the NPRM or on the determination of the costs.

Conclusion

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, this AD is adopted as proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Austro Engine GmbH Mandatory Service Bulletin No. MSB–E4–039/1, Revision 1, dated April 24, 2023, which specifies procedures for oil analysis and replacement of the pistons, piston rings, con-rods assembly, crankcase, and engine core.

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

Costs of Compliance

The FAA estimates that this AD affects 357 engines installed on airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Oil Analysis	.25 work-hours × $85 per hour = $21.25	$0	$21.25	$7,586.25

The FAA estimates the following costs to do any necessary replacements that would be required based on the results of the inspection. The agency has no way of determining the number of aircraft that might need these replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace engine core	50 work-hours × $85 per hour = $4,250	$15,524	$19,774
Replace pistons, piston rings, and con-rods assembly	60 work-hours × 85 per hour = 5,100	2,216	7,316
Replace pistons, piston rings, con-rods assembly, and crankcase.	70 work-hours × 85 per hour = 5,950	4,141	10,091

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2023–20–03 Austro Engine GmbH: Amendment 39–22562; Docket No. FAA–2023–1412; Project Identifier MCAI–2022–01588–E.

(a) Effective Date

This airworthiness directive (AD) is effective December 11, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Austro Engine GmbH Model E4 and E4P engines with a serial number listed in Tables 1, 2, 3, and 4 of Austro Engine GmbH Mandatory Service Bulletin No. MSB–E4–039/1, Revision 1, dated April 24, 2023 (MSB–E4–039/1).

(d) Subject

Joint Aircraft System Component (JASC) Codes 8530, Reciprocating Engine Cylinder Section; 8550, Reciprocating Engine Oil System.

(e) Unsafe Condition

This AD was prompted by reports of piston failures and the determination that certain batches of pistons were manufactured with a dimensional deviation in the piston pin bore and piston diameter. The FAA is issuing this AD to prevent piston failure. The unsafe condition, if not addressed, could result in loss of oil, loss of engine power, and reduced control of the airplane.

(f) Compliance

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

(g) Required Actions

(1) For all affected engines, within the applicable compliance times specified in Table 1 to paragraph (g)(1) of this AD, perform an oil analysis in accordance with paragraph 2., Technical Details, Engine Oil Analysis of MSB–E4–039/1, and do not return the engine to service until the results of the oil analysis have been determined.

TABLE 1 TO PARAGRAPH (g)(1)—OIL ANALYSIS FOR ALL AFFECTED ENGINES

Engine group	Compliance time	Interval
Group 1 and Group 3	Within 15 flight hours (FHs) from the effective date of this AD.	Before exceeding 50 FHs since last oil analysis.
Group 2 and Group 4	Within 25 FHs from the effective date of this AD.	Before exceeding 100 FHs since last oil analysis.

(2) Thereafter, repeat the oil analysis required by paragraph (g)(1) of this AD before exceeding the applicable interval specified in Table 1 to paragraph (g)(1) of this AD.

(3) Following each repetitive oil analysis, the engine may be returned to service for no more than the applicable interval specified in Table 1 to paragraph (g)(1) of this AD, until receipt of the oil analysis result.

(4) If the result of any oil analysis required by paragraph (g)(1) of this AD indicates the aluminum content of the oil is greater than the limit specified in paragraph 2., Technical Details, Engine Oil Analysis, Table 5—Oil check analysis—Aluminum PPM allowable of MSB–E4–039/1, before further flight, replace the pistons, piston rings, con-rods assembly, and crankcase, or replace the engine core in accordance with paragraph 2., Technical Details, Engine core replacement; or Pistons, piston rings, crankcase and con-rod assy replacement; as applicable, of MSB–E4–039/1.

(5) For Group 3 and Group 4 engines, within the applicable compliance times specified in Table 2 to paragraph (g)(5) of this AD, replace the pistons, piston rings, and con-rods assembly, or replace the engine core in accordance with paragraph 2., Technical Details, Engine core replacement; or Pistons, piston rings and con-rod assy replacement, as applicable, of MSB–E4–039/1.

TABLE 2 TO PARAGRAPH (g)(5)—REPLACEMENT FOR GROUPS 3 AND 4 ENGINES

Engine group	Compliance time
Group 3	Before exceeding 900 FHs since new, or within 15 FHs after the effective date of this AD, whichever occurs later.
Group 4	Before exceeding 1,000 FHs since new, or within 25 FHs after the effective date of this AD, whichever occurs later.

Note 1 to paragraph (g)(5): FHs since new indicated in Table 2 to paragraph (g)(5) of this AD are FHs accumulated by the engine since first installation on an airplane or since last overhaul as of the effective date of this AD.

(h) Terminating Action

(1) Replacement of the pistons, piston rings, con-rods assembly, and crankcase, or replacement of the engine core, as specified in paragraph (g)(4) of this AD, constitutes terminating action for the repetitive oil analysis required by paragraph (g)(2) of this AD.

(2) Replacement of the pistons, piston rings, and con-rods assembly, or replacement of the engine core, as specified in paragraph (g)(5) of this AD, constitutes terminating action for the repetitive oil analysis required by paragraph (g)(2) of this AD.

(i) Definitions

(1) For the purpose of this AD, Group 1 engines are engines having a serial number (S/N) listed in Table 1 of MSB–E4–039/1.

(2) For the purpose of this AD, Group 2 engines are engines having an S/N listed in Table 2 of MSB–E4–039/1.

(3) For the purpose of this AD, Group 3 engines are engines having an S/N listed in Table 3 of MSB–E4–039/1.

(4) For the purpose of this AD, Group 4 engines are engines having an S/N listed in Table 4 of MSB–E4–039/1.

(j) Credit for Previous Actions

You may take credit for the actions required by paragraph (g)(1), (4), or (5) of this AD, if you performed those actions before the effective date of this AD using Austro Engine Mandatory Service Bulletin MSB–E4–039/0, dated October 24, 2022.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (l)(2) of this AD and email to: *ANE-AD-AMOC@faa.gov.*

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

(l) Additional Information

(1) Refer to European Union Aviation Safety Agency (EASA) AD 2022–0240R1, dated December 15, 2022, for related information. This EASA AD may be found in the AD docket at regulations.gov under Docket No. FAA–2023–1412.

(2) For more information about this AD, contact Barbara Caufield, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (781) 238–7146; email: *barbara.caufield@faa.gov.*

(m) Material Incorporated by Reference

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

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

(i) Austro Engine GmbH Mandatory Service Bulletin No. MSB–E4–039/1, Revision 1, dated April 24, 2023.

(ii) [Reserved]

(3) For service information identified in this AD, contact Austro Engine GmbH, Rudolf-Diesel-Strasse 11, A–2700 Weiner Neustadt, Austria; phone: +43 2622 23000; website: austroengine.at.

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

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

Issued on October 20, 2023.

Ross Landes,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2023–24385 Filed 11–3–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–1642; Project Identifier MCAI–2023–00183–T; Amendment 39–22574; AD 2023–21–02]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2022–18–14, which applied to certain Airbus SAS Model A330–200 series, A330–200 Freighter series, A330–300 series, A330–800 series, and A330–900 series airplanes. AD 2022–18–14 required revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. This AD continues to require the actions in AD 2022–18–14, and also requires revising the existing maintenance or inspection program, as applicable to incorporate additional new or more restrictive airworthiness limitations; as specified in two European Union Aviation Safety Agency (EASA) ADs, which are incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 11, 2023.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of December 11, 2023.

The Director of the Federal Register approved the incorporation by reference of certain other publication listed in this AD as of October 20, 2022 (87 FR 56566, September 15, 2022).

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–1642; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For material incorporated by reference in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *regulations.gov* under Docket No. FAA–2023–1642.

FOR FURTHER INFORMATION CONTACT: Tim Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3667; email *timothy.p.dowling@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2022–18–14, Amendment 39–22165 (87 FR 56566, September 15, 2022) (AD 2022–18–14). AD 2022–18–14 applied to certain Airbus SAS Model A330–201, –202, –203, –223, and –243 airplanes; Model A330–223F and –243F airplanes; Model A330–301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes; Model A330–841 airplanes; and Model A330–941 airplanes. AD 2022–18–14 required revising the existing maintenance or inspection program, as applicable, to incorporate additional new or more restrictive airworthiness limitations. The FAA issued AD 2022–18–14 to address fatigue cracking, accidental damage, and corrosion in principal structural elements; such fatigue cracking, accidental damage, and corrosion could result in reduced structural integrity of the airplane.

The NPRM published in the **Federal Register** on July 28, 2023 (88 FR 48760). The NPRM was prompted by AD 2022–0187, dated September 13, 2022, issued by EASA, which is the Technical Agent for the Member States of the European Union (EASA AD 2022–0187). EASA AD 2022–0187 states that new or more restrictive airworthiness limitations have been developed.

The NPRM was also prompted by EASA AD 2023–0015, dated January 19, 2023 (EASA AD 2023–0015). EASA AD 2023–0015 states that new or more restrictive airworthiness limitations have been developed. EASA AD 2023–0015 also states that it requires certain tasks also required by EASA AD 2022–0187, and invalidates (terminates) the tasks that are also required by EASA AD 2022–0187. Therefore, for this AD, where EASA AD 2023–0015 affects the same airworthiness limitations as those in EASA AD 2022–0187, the airworthiness limitations referenced in EASA AD 2023–0015 prevail.

In the NPRM, the FAA proposed to continue to require the actions in AD 2022–18–14, and to require revising the existing maintenance or inspection program, as applicable, to incorporate additional new or more restrictive airworthiness limitations, as specified in EASA ADs 2022–0187 and 2023–0015. The FAA is issuing this AD to

address fatigue cracking, accidental damage, and corrosion in principal structural elements; such fatigue cracking, accidental damage, and corrosion could result in reduced structural integrity of the airplane.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2023–1642.

Discussion of Final Airworthiness Directive

Comments

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

Additional Changes Made to This AD

The FAA revised paragraph (l) of this AD to specify that no alternative actions (*e.g.,* inspections) and intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2022–0187 or of EASA AD 2023–0015. In the NPRM, the FAA inadvertently specified that the alternatives actions and intervals had to be approved as specified in the ''Ref. Publications'' section of EASA AD 2022–0187 and of EASA AD 2023–0015.

Conclusion

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

Related Service Information Under 1 CFR Part 51

EASA AD 2022–0187 and EASA AD 2023–0015 specify new or more restrictive airworthiness limitations for airplane structures. These documents are distinct since they apply to different airplane configurations.

This AD also requires EASA AD 2021–0261, dated November 22, 2021, which the Director of the Federal Register approved for incorporation by reference as of October 20, 2022 (87 FR 56566, September 15, 2022).

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

Costs of Compliance

The FAA estimates that this AD affects 120 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

The FAA estimates the total cost per operator for the retained actions from AD 2022–18–14 to be $7,650 (90 work-hours × $85 per work-hour).

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

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2022–18–14, Amendment 39–22165 (87 FR 56566, September 15, 2022); and

■ b. Adding the following new AD:

2023–21–02 Airbus SAS: Amendment 39–22574; Docket No. FAA–2023–1642; Project Identifier MCAI–2023–00183–T.

(a) Effective Date

This airworthiness directive (AD) is effective December 11, 2023.

(b) Affected ADs

This AD replaces AD 2022–18–14, Amendment 39–22165 (87 FR 56566, September 15, 2022) (AD 2022–18–14).

(c) Applicability

This AD applies to Airbus SAS airplanes, identified in paragraphs (c)(1) through (5) of this AD, certificated in any category, with an original airworthiness certificate or original export certificate of airworthiness issued on or before November 18, 2022.

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

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

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

(4) Model A330–841 airplanes.

(5) Model A330–941 airplanes.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address fatigue cracking, accidental damage, and corrosion in principal structural elements. The unsafe

condition, if not addressed, could result in reduced structural integrity of the airplane.

(f) Compliance

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

(g) Retained Revision of the Existing Maintenance or Inspection Program, With No Changes

This paragraph restates the requirements of paragraph (i) of AD 2022–18–14, with no changes. For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before November 2, 2021, except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2021–0261, dated November 22, 2021 (EASA AD 2021–0261). Accomplishing the revision of the existing maintenance or inspection program required by paragraph (j) of this AD terminates the requirements of this paragraph.

(h) Retained Exceptions to EASA AD 2021–0261, With No Changes

This paragraph restates the exceptions specified in paragraph (j) of AD 2022–18–14, with no changes.

(1) Where EASA AD 2021–0261 refers to its effective date, this AD requires using October 20, 2022 (the effective date of AD 2022–18–14).

(2) The requirements specified in paragraphs (1) and (2) of EASA AD 2021–0261 do not apply to this AD.

(3) Paragraph (3) of EASA AD 2021–0261 specifies revising ''the AMP'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after October 20, 2022 (the effective date of AD 2022–18–14).

(4) The initial compliance time for doing the tasks specified in paragraph (3) of EASA 2021–0261 is at the applicable ''associated thresholds'' as incorporated by the requirements of paragraph (3) of EASA AD 2021–0261, or within 90 days after October 20, 2022 (the effective date of AD 2022–18–14), whichever occurs later.

(5) This AD does not require incorporating Section 4, ''Damage Tolerant-Airworthiness Limitations Items-Tasks Beyond MPPT,'' of ''the ALS'' specified in EASA AD 2021–0261.

(6) The provisions specified in paragraphs (4) and (5) of EASA AD 2021–0261 do not apply to this AD.

(7) The ''Remarks'' section of EASA AD 2021–0261 does not apply to this AD.

(i) Retained Restrictions on Alternative Actions and Intervals, With a New Exception

This paragraph restates the requirements of AD 2022–18–14, with a new exception. Except as required by paragraph (j) of this AD, after the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) and intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2021–0261.

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

Except as specified in paragraph (k) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2022–0187, dated September 13, 2022 (EASA AD 2022–0187); and EASA AD 2023–0015, dated January 19, 2023 (EASA AD 2023–0015); as applicable. Where EASA AD 2023–0015 affects the same airworthiness limitations as those in EASA AD 2022–0187, the airworthiness limitations referenced in EASA AD 2023–0015 prevail.

(k) New Exceptions to EASA AD 2022–0187 and to EASA AD 2023–0015

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

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

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

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

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

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

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

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

(l) New Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (j) of this AD, no alternative actions (*e.g.,* inspections) and intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2022–0187 or of EASA AD 2023–0015.

(m) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the International Validation Branch, send it to the attention of the person identified in paragraph (n) 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) The AMOC specified in letter AIR–676–19–120, dated March 5, 2019, approved previously for AD 2018–24–04, Amendment 39–19508 (83 FR 60756, November 27, 2018), is approved as an AMOC for the corresponding provisions of EASA AD 2022–0187 and EASA AD 2023–0015 that are required by paragraph (j) of this AD for Model A330–200 and A330–300 series airplanes modified from a passenger to freighter configuration under the provisions of FAA Supplemental Type Certificate ST04038NY.

(iii) The AMOC specified in letter AIR–731A–20–179, dated May 11, 2020, approved previously for AD 2019–23–02, Amendment 39–19795 (84 FR 64725, November 25, 2019), is approved as an AMOC for the corresponding provisions of EASA AD 2022–0187 and of EASA AD 2023–0015 that are required by paragraph (j) of this AD for Model A330–200 and A330–300 series airplanes modified from a passenger to freighter configuration under the provisions of FAA Supplemental Type Certificate ST04038NY.

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

(n) Additional Information

For more information about this AD, contact Tim Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 206–231–3667; email: *timothy.p.dowling@faa.gov.*

(o) Material Incorporated by Reference

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

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

(3) The following service information was approved for IBR on December 11, 2023.

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

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

(4) The following service information was approved for IBR on October 20, 2022 (87 FR 56566, September 15, 2022).

(i) European Union Aviation Safety Agency (EASA) AD 2021–0261, dated November 22, 2021.

(ii) [Reserved]

(5) For EASA AD 2021–0261, EASA AD 2022–0187, and EASA AD 2023–0015, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find these EASA ADs on the EASA website at *ad.easa.europa.eu.*

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

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

Issued on October 11, 2023.

Victor Wicklund,

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

[FR Doc. 2023–24406 Filed 11–3–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–1494; Project Identifier MCAI–2023–00382–T; Amendment 39–22573; AD 2023–21–01]

RIN 2120–AA64

Airworthiness Directives; Dassault Aviation Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2020–01–13, which applied to all Dassault Aviation Model MYSTERE–FALCON 200 airplanes. AD 2020–01–13 required revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. This AD continues to require the actions in AD 2020–01–13 and require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations; as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 11, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 11, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of March 5, 2020 (85 FR 5313, January 30, 2020).

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–1494; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For EASA ADs incorporated by reference in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*
- For Dassault Aviation service information incorporated by reference in this AD, contact Dassault Falcon Jet Corporation, Teterboro Airport, P.O. Box 2000, South Hackensack, NJ 07606; telephone 201–440–6700; website *dassaultfalcon.com.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2023–1494.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone 206–231–3226; email: *tom.rodriguez@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2020–01–13, Amendment 39–19819 (85 FR 5313, January 30, 2020) (AD 2020–01–13). AD 2020–01–13 applied to all Dassault Aviation Model MYSTERE–FALCON 200 airplanes. AD 2020–01–13 required revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. The FAA issued AD 2020–01–13 to address fatigue cracking, damage, and corrosion in principal structural elements; such fatigue cracking, damage, and corrosion could result in reduced structural integrity of the airplane.

The NPRM published in the **Federal Register** on July 19, 2023 (88 FR 46112). The NPRM was prompted by EASA AD 2023–0045, dated March 2, 2023; corrected March 3, 2023, issued by EASA, which is the Technical Agent for the Member States of the European Union (EASA AD 2023–0045) (also referred to as the MCAI). The MCAI states that new or more restrictive airworthiness limitations have been developed.

In the NPRM, the FAA proposed to continue to require the actions in AD 2020–01–13 and require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. The FAA is issuing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2023–1494.

Discussion of Final Airworthiness Directive

Comments

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

Conclusion

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

Related Service Information Under 1 CFR Part 51

The FAA reviewed EASA AD 2023–0045. This service information specifies

new or more restrictive airworthiness limitations for airplane structures and safe life limits.

This AD also requires Chapter 5–40–00, Airworthiness Limitations, Revision 18, dated January 15, 2019, of the Dassault Falcon 200 Maintenance Manual, which the Director of the Federal Register approved for incorporation by reference as of March 5, 2020 (85 FR 5313, January 30, 2020).

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

Costs of Compliance

The FAA estimates that this AD affects 9 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

The FAA estimates the total cost per operator for the retained actions from AD 2020–01–13 to be $7,650 (90 work-hours × $85 per work-hour).

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

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2020–01–13, Amendment 39–19819 (85 FR 5313, January 30, 2020); and

■ b. Adding the following new AD:

2023–21–01 Dassault Aviation: Amendment 39–22573; Docket No. FAA–2023–1494; Project Identifier MCAI–2023–00382–T.

(a) Effective Date

This airworthiness directive (AD) is effective December 11, 2023.

(b) Affected ADs

(1) This AD replaces AD 2020–01–13, Amendment 39–19819 (85 FR 5313, January 30, 2020) (AD 2020–01–13).

(2) This AD affects AD 2010–26–05, Amendment 39–16544 (75 FR 79952, December 21, 2010) (AD 2010–26–05).

(c) Applicability

This AD applies to all Dassault Aviation Model MYSTERE–FALCON 200 airplanes, certificated in any category.

(d) Subject

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

(e) Reason

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address fatigue cracking, damage, and corrosion in principal structural elements; such fatigue cracking, damage, and corrosion could result in reduced structural integrity of the airplane.

(f) Compliance

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

(g) Retained Revision of the Existing Maintenance or Inspection Program, With No Changes

This paragraph restates the requirements of paragraph (i) of AD 2020–01–13, with no changes. Within 90 days after March 5, 2020 (the effective date of AD 2020–01–13), revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in Chapter 5–40–00, Airworthiness Limitations, Revision 18, dated January 15, 2019, of the Dassault Falcon 200 Maintenance Manual. The initial compliance time for doing the tasks is at the applicable time specified in Chapter 5–40–00, Airworthiness Limitations, Revision 18, dated January 15, 2019, of the Dassault Falcon 200 Maintenance Manual; or within 90 days after March 5, 2020; whichever occurs later. Accomplishing the revision of the existing maintenance or inspection program required by paragraph (i) of this AD terminates the requirements of this paragraph.

(h) Retained Restrictions on Alternative Actions or Intervals, With a New Exception

This paragraph restates the requirements of paragraph (j) of AD 2020–01–13, with a new exception. Except as required by paragraph (i) of this AD, after the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions or intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (m)(1) of this AD.

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

Except as specified in paragraph (j) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2023–0045, dated March 2, 2023; corrected March 3, 2023 (EASA AD 2023–0045). Accomplishing the revision of the existing maintenance or inspection program required by this paragraph terminates the requirements of paragraph (g) of this AD.

(j) Exceptions to EASA AD 2023–0045

(1) This AD does not adopt the requirements specified in paragraphs (1) and (2) of EASA AD 2023–0045.

(2) Paragraph (3) of EASA AD 2023–0045 specifies revising ''the approved AMP'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2023–0045 is at the applicable ''limitations'' as incorporated by the requirements of paragraph (3) of EASA AD 2023–0045, or within 90 days after the effective date of this AD, whichever occurs later.

(4) This AD does not adopt the provisions specified in paragraphs (4) and (5) of EASA AD 2023–0045.

(5) This AD does not adopt the ''Remarks'' section of EASA AD 2023–0045.

(k) New Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (i) of this AD, no alternative actions (*e.g.,* inspections) and intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2023–0045.

(l) Terminating Action for AD 2010–26–05

Accomplishing the actions required by paragraph (g) or (i) of this AD terminates the requirements of paragraph (g)(1) of AD 2010–26–05, for Dassault Aviation Model MYSTERE–FALCON 200 airplanes only.

(m) Additional AD Provisions

The following provisions also apply to this AD:

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

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

(n) Additional Information

For more information about this AD, contact Tom Rodriguez, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone 206–231–3226; email: *tom.rodriguez@faa.gov.*

(o) Material Incorporated by Reference

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

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

(3) The following service information was approved for IBR on December 11, 2023.

(i) European Union Aviation Safety Agency (EASA) AD 2023–0045, dated March 2, 2023; corrected March 3, 2023.

(ii) [Reserved].

(4) The following service information was approved for IBR on March 5, 2020 (85 FR 5313, January 30, 2020).

(i) Chapter 5–40–00, Airworthiness Limitations, Revision 18, dated January 15, 2019, of the Dassault Falcon 200 Maintenance Manual.

(ii) [Reserved]

(5) For EASA AD 2023–0045, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email: *ADs@easa.europa.eu;* website: *easa.europa.eu.* You may find this EASA AD on the EASA website: *ad.easa.europa.eu.*

(6) For Dassault Aviation service information incorporated by reference in this AD, contact Dassault Falcon Jet Corporation, Teterboro Airport, P.O. Box 2000, South Hackensack, NJ 07606; telephone 201–440–6700; website *dassaultfalcon.com.*

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

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

Issued on October 30, 2023.

Victor Wicklund,

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

[FR Doc. 2023–24403 Filed 11–3–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–1708; Project Identifier MCAI–2023–00554–A; Amendment 39–22576; AD 2023–21–04]

RIN 2120–AA64

Airworthiness Directives; Embraer S.A. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Embraer S.A. (Embraer) Model EMB–505 airplanes. This AD was prompted by occurrences of an uncommanded change in the setting of the barometric pressure in both primary flight displays (PFDs). This AD requires installing a new version of the airplane avionics system software, as specified in an Agência Nacional de Aviação Civil (ANAC) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 11, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 11, 2023.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–1708; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For service information identified in this final rule, contact ANAC, Continuing Airworthiness Technical Branch (GTAC), Rua Doutor Orlando Feirabend Filho, 230—Centro Empresarial Aquarius—Torre B—Andares 14 a 18, Parque Residencial Aquarius, CEP 12.246–190—São José dos Campos—SP, Brazil; phone: 55 (12) 3203–6600; email: *pac@anac.gov.br;* website: *anac.gov.br/en/.* You may find this material on the ANAC website at *sistemas.anac.gov.br/certificacao/DA/DAE.asp.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available in the AD docket at *regulations.gov* under Docket No. FAA–2023–1708.

FOR FURTHER INFORMATION CONTACT: Jim Rutherford, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (816) 329–4165; email: *jim.rutherford@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Embraer Model EMB–505 airplanes. The NPRM published in the **Federal Register** on August 14, 2023 (88 FR 54941). The NPRM was prompted by AD 2023–04–01, effective April 4, 2023, issued by ANAC, which is the aviation authority for Brazil (ANAC AD 2023–04–01) (also referred to as the MCAI), to correct an unsafe condition for Embraer Model EMB–505 airplanes equipped with the Garmin G3000 avionics system. The MCAI states that there have been occurrences of uncommanded change in the setting of the barometric pressure in both PFDs resulting in erroneous altitude information. Erroneous altitude information on both PFDs could result in altitude mismanagement or spatial disorientation of the flight crew.

In the NPRM, the FAA proposed to require installing a new version of the airplane avionics system software, as specified in ANAC AD 2023–04–01. The FAA is issuing this AD to address the uncommanded change in the setting of the barometric pressure in both PFDs, which could consequently lead to a deviation from the intended altitude and loss of control of the airplane, risk of air collision due to inadequate air traffic separation, or risk of controlled flight into terrain.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2023–1708.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the NPRM or on the determination of the costs.

Conclusion

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, this AD is adopted as proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

ANAC AD 2023–04–01 specifies procedures for installing Garmin G3000 avionics system software updates.

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

Differences Between This AD and the MCAI

ANAC AD 2023–04–01 requires installing the software update in accordance with the service information specified in ANAC AD 2023–04–01, and this AD does not require using that service information to install the software update.

Paragraph (c) of ANAC AD 2023–04–01 provides credit for performing previous actions using previous revisions of the service information specified in ANAC AD 2023–04–01. Paragraph (d) of ANAC AD 2023–04–01 provides procedures for obtaining an alternative method of compliance. Paragraph (e) of ANAC AD 2023–04–01 requires using the service information specified in ANAC AD 2023–04–01, or future revisions approved by ANAC, to do the software update. This AD does not require compliance with paragraphs (c) through (e) of ANAC AD 2023–04–01.

Costs of Compliance

The FAA estimates that this AD affects 183 airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Install software	8 work-hours × $85 per hour = $680	$50	$730	$133,590

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, all of the costs associated with the software update may be covered under warranty.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2023–21–04 Embraer S.A.: Amendment 39–22576; Docket No. FAA–2023–1708; Project Identifier MCAI–2023–00554–A.

(a) Effective Date

This airworthiness directive (AD) is effective December 11, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Embraer S.A. Model EMB–505 airplanes, as identified in paragraph (a) of Agência Nacional de Aviação Civil (ANAC) AD 2023–04–01, effective April 4, 2023 (ANAC AD 2023–04–01), certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 3100, Indicating/recording system.

(e) Unsafe Condition

This AD was prompted by occurrences of an uncommanded change in the setting of the barometric pressure in both primary flight displays (PFDs). The FAA is issuing this AD to address the uncommanded change in the setting of the barometric pressure in both PFDs. The unsafe condition, if not addressed, could result in altitude mismanagement or spatial disorientation of the flight crew, with consequent deviation from the intended altitude and loss of control of the airplane, risk of air collision due to inadequate air traffic separation, or risk of controlled flight into terrain.

(f) Compliance

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

(g) Required Actions

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, ANAC AD 2023–04–01.

(h) Exceptions to ANAC AD 2023–04–01

(1) Where ANAC AD 2023–04–01 refers to its effective date, this AD requires using the effective date of this AD.

(2) This AD does not adopt paragraphs (c), (d), and (e) of ANAC AD 2023–04–01.

(i) No Reporting Required

Although the service information referenced in ANAC AD 2023–04–01 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs)

The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, mail it to the address identified in paragraph (k) of this AD or email to: *9-AVS-AIR-730-AMOC@faa.gov.* If mailing information, also submit information by email. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local Flight Standards District Office/certificate holding district office.

(k) Additional Information

For more information about this AD, contact Jim Rutherford, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (816) 329–4165; email: *jim.rutherford@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) Agência Nacional de Aviação Civil (ANAC) AD 2023–04–01, effective April 4, 2023.

(ii) [Reserved]

(3) For ANAC AD 2023–04–01, contact ANAC, Continuing Airworthiness Technical Branch (GTAC), Rua Doutor Orlando Feirabend Filho, 230—Centro Empresarial Aquarius—Torre B—Andares 14 a 18, Parque Residencial Aquarius, CEP 12.246–190—São José dos Campos—SP, Brazil; phone: 55 (12) 3203–6600; email: *pac@anac.gov.br;* website: *anac.gov.br/en/.* You may find this material on the ANAC website at *sistemas.anac.gov.br/certificacao/DA/DAE.asp.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110.

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

Issued on October 26, 2023.

Caitlin Locke,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2023–24393 Filed 11–3–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–1717; Project Identifier MCAI–2023–00728–A; Amendment 39–22578; AD 2023–21–06]

RIN 2120–AA64

Airworthiness Directives; Embraer S.A. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Embraer S.A. (Embraer) Model EMB–505 airplanes. This AD was prompted by analysis of certain monuments (the right-hand refreshment center and left-hand forward cabinet) that identified the need for installing structural reinforcements and replacing certain floor support rivets. This AD requires installing structural reinforcements on certain monuments and replacing certain floor support rivets, as specified in an Agência Nacional de Aviação Civil (ANAC) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 11, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 11, 2023.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–1717; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

• For the service information identified in this final rule, contact ANAC, Continuing Airworthiness Technical Branch (GTAC), Rua Doutor Orlando Feirabend Filho, 230—Centro Empresarial Aquarius—Torre B –Andares 14 a 18, Parque Residencial Aquarius, CEP 12.246–190—São José dos Campos—SP, Brazil; phone: 55 (12) 3203–6600; email: *pac@anac.gov.br;*

website: *anac.gov.br/en/*. You may find this material on the ANAC website at *sistemas.anac.gov.br/certificacao/DA/DAE.asp*.

• You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available in the AD docket at *regulations.gov* under Docket No. FAA–2023–1717.

FOR FURTHER INFORMATION CONTACT: Jim Rutherford, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (816) 329–4165; email: *jim.rutherford@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain serial-numbered Embraer Model EMB–505 airplanes. The NPRM published in the **Federal Register** on August 24, 2023 (88 FR 57907). The NPRM was prompted by AD 2023–05–03, effective June 2, 2023, issued by ANAC, which is the aviation authority for Brazil (ANAC AD 2023–04–01) (also referred to as the MCAI), to correct an unsafe condition for certain serial-numbered Embraer Model EMB–505 airplanes. The MCAI states that analysis identified certain monuments (the right-hand refreshment center and left-hand forward cabinet) that might not withstand the loads expected for specific emergency landing conditions, which may cause the detachment of mass items and result in injuries to the airplane occupants. To address this unsafe condition, the MCAI specifies installing structural reinforcements on certain monuments and replacing applicable floor support rivets.

In the NPRM, the FAA proposed to require installing structural reinforcements on certain monuments and replacing certain floor support rivets, as specified in ANAC AD 2023–04–01. The FAA is issuing this AD to address the unsafe condition.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2023–1717.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the NPRM or on the determination of the costs.

Conclusion

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. This AD is adopted as proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

ANAC AD 2023–05–03 specifies procedures for installing structural reinforcements on certain monuments and replacing applicable fasteners on the floor support.

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

Differences Between This AD and the MCAI

The service information specified in ANAC AD 2023–05–03 allows the use of alternative or similar parts in place of the ones specified in the kits, provided these alternative or similar parts are approved by Embraer, but this AD requires approval from either the Manager, International Validation Branch, FAA; ANAC; or ANAC's authorized Designee.

Costs of Compliance

The FAA estimates that this AD affects 208 airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Airplane groups 1 and 2—install structural reinforcements.	21.50 work-hours × $85 per hour = $1,827.50.	$1,600	$3,427.50	$239,925 (70 airplanes).
Airplane groups 3, 4, 5, and 10—install structural reinforcements and replace floor fasteners.	13.50 work-hours × $85 per hour = $1,147.50.	$600	$1,747.50	$214,942.50 (123 airplanes).
Airplane groups 6 and 8—install structural reinforcements and replace floor fasteners.	25.50 work-hours × $85 per hour = $2,167.50.	$2,000	$4,167.50	$37,507.50 (9 airplanes).
Airplane group 7—install structural reinforcements.	19.50 work-hours × $85 per hour = $1,657.50.	$1,600	$3,257.50	$16,287.50 (5 airplanes).
Airplane group 9—install structural reinforcements.	13.50 work-hours × $85 per hour = $1,147.50.	$1,600	$2,747.50	$2,747.50 (1 airplane).

The FAA estimates the following costs for operators that did the actions in the original version of Embraer Service Bulletin SB505–25–0046, dated March 31, 2021. The agency has no way of determining the number of airplanes that might need these actions:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Inspect floor fasteners	8.50 work-hours × $85 per hour = $722.50	$50	$772.50
Replace floor fasteners	1 work-hour × $85 per hour = $85	$50	$135

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2023–21–06 Embraer S.A.: Amendment 39–22578; Docket No. FAA–2023–1717; Project Identifier MCAI–2023–00728–A.

(a) Effective Date

This airworthiness directive (AD) is effective December 11, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Embraer S.A. Model EMB–505 airplanes, as identified in Agência Nacional de Aviação Civil (ANAC) AD 2023–05–03, effective June 2, 2023 (ANAC AD 2023–05–03), certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 2500, Cabin Equipment/Furnishings.

(e) Unsafe Condition

This AD was prompted by analysis of certain monuments (the right-hand refreshment center and left-hand forward cabinet) that identified the need for installing structural reinforcements and replacing applicable floor support rivets. The FAA is issuing this AD to address the unsafe condition. The unsafe condition, if not addressed, could result in a monument not withstanding the loads expected for specific emergency landing conditions, which may cause the detachment of mass items and result in injuries to the airplane occupants.

(f) Compliance

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

(g) Required Actions

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, ANAC AD 2023–05–03.

(h) Exceptions to ANAC AD 2023–05–03

(1) Where ANAC AD 2023–05–03 refers to its effective date, this AD requires using the effective date of this AD.

(2) The service information referenced in ANAC AD 2023–05–03 allows the use of alternative or similar parts in place of the ones specified in the kits, provided that these alternative or similar parts are approved by Embraer. This AD requires approval from either the Manager, International Validation Branch, FAA; ANAC; or ANAC's authorized Designee. If approved by the ANAC Designee, the approval must include the Designee's authorized signature.

(3) Where the service information referenced in ANAC AD 2023–05–03 specifies discarding parts, this AD requires removing those parts from service.

(4) This AD does not adopt paragraph (d) of ANAC AD 2023–05–03.

(i) No Reporting Requirement

Although the service information referenced in ANAC AD 2023–05–03 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs)

The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, mail it to the address identified in paragraph (k) of this AD or email to: *9-AVS-AIR-730-AMOC@faa.gov.* If mailing information, also submit information by email. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local Flight Standards District Office/certificate holding district office.

(k) Additional Information

For more information about this AD, contact Jim Rutherford, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (816) 329–4165; email: *jim.rutherford@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) Agência Nacional de Aviação Civil (ANAC) AD 2023–05–03, effective June 2, 2023.

(ii) [Reserved]

(3) For ANAC AD 2023–05–03, contact ANAC, Continuing Airworthiness Technical Branch (GTAC), Rua Doutor Orlando Feirabend Filho, 230—Centro Empresarial Aquarius—Torre B—Andares 14 a 18, Parque Residencial Aquarius, CEP 12.246–190—São José dos Campos—SP, Brazil; phone: 55 (12) 3203–6600; email: *pac@anac.gov.br;* website: *anac.gov.br/en/.* You may find this material on the ANAC website at *sistemas.anac.gov.br/certificacao/DA/DAE.asp.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110.

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

Issued on October 26, 2023.

Caitlin Locke,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2023–24387 Filed 11–3–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1314; Project Identifier AD–2021–00811–E; Amendment 39–22579; AD 2023–21–07]

RIN 2120–AA64

Airworthiness Directives; General Electric Company Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2018–03–13 for certain General Electric Company (GE) Model CT7–5A2, CT7–5A3, CT7–7A, CT7–7A1, CT7–9B, CT7–9B1, CT7–9B2, CT7–9C, and CT7–9C3 engines. AD 2018–03–13 required initial and repetitive visual inspections and fluorescent penetrant inspections (FPIs) of the main propeller shaft. This AD was prompted by an in-flight failure of a main propeller shaft on a GE Model CT7–9B engine, resulting in the loss of the propeller. This AD requires initial and repetitive visual inspections, FPIs, and ultrasonic inspections (USIs) of the main propeller shaft. Depending on the results of these inspections, this AD requires replacement of the main propeller shaft. As an optional terminating action to these inspections, this AD requires revising the airworthiness limitations section (ALS) of the existing maintenance manual (MM) and the operator's existing approved maintenance program or inspection program, as applicable, to incorporate incorporating the tasks and reduced inspection thresholds for the main propeller shaft. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 11, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 11, 2023.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2022–1314; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For GE service information identified in this final rule, contact General Electric Company, 1 Neumann Way, Cincinnati, OH 45215; phone: (513) 552–3272; email: *aviation.fleetsupport@ae.ge.com;* website: *ge.com.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *regulations.gov* under Docket No. FAA–2022–1314.

FOR FURTHER INFORMATION CONTACT: Sungmo Cho, Aviation Safety Engineer, FAA, 2200 South 216th Street, Des Moines, WA 98198; phone: (781) 238–7241; email: *Sungmo.D.Cho@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a supplemental notice of proposed rulemaking (SNPRM) to amend 14 CFR part 39 to supersede AD 2018–03–13, Amendment 39–19186 (83 FR 6125, February 13, 2018) (AD 2018–03–13). AD 2018–03–13 applied to certain GE Model CT7–5A2, CT7–5A3, CT7–7A, CT7–7A1, CT7–9B, CT7–9B1, CT7–9B2, CT7–9C and CT7–9C3 engines. The SNPRM published in the **Federal Register** on July 11, 2023 (88 FR 44068). The SNPRM was prompted by a comment from GE Aerospace on the notice of proposed rulemaking (NPRM). GE Aerospace stated that certain engine models were included in incorrect Figures within the Required Actions paragraph of the NPRM, which would attribute inaccurate inspection thresholds to those engine models. Therefore, the FAA issued the SNPRM with a revision to Figures 1 and 2 to include the correct engine models. The FAA also updated the affected engine models listed in paragraphs (g)(1) and (g)(2) of the SNPRM to correspond with the corrected engine models referenced in Figures 1 and 2.

In the SNPRM, the FAA proposed to require initial and repetitive visual inspections, FPIs, and USIs of the main propeller shaft. Depending on the results of these inspections, the SNPRM proposed to require replacing the main propeller shaft. As an optional terminating action to these inspections, the SNPRM proposed to require revising the ALS of the existing MM and the operator's existing approved maintenance program or inspection program, as applicable, to incorporate the tasks and reduced inspection thresholds for the main propeller shaft. The FAA is issuing this AD to address the unsafe condition on these products.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from one commenter, GE Aerospace. The following presents the comment received on the SNPRM and the FAA's response to that comment.

Request To Remove Typographical Error From SNPRM

GE noted that there is a typological [typographical] error in the ''Proposed AD Requirements in This SNPRM'' paragraph of the SNPRM in which the words ''at least'' are repeated in succession.

The FAA agrees, however, the ''Proposed AD Requirements in This SNPRM'' paragraph is not included in this Final Rule. The FAA did not change this AD as a result of this comment.

Conclusion

The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting the AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes and any other changes described previously, this AD is adopted as proposed in the SNPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

The FAA reviewed GE Service Bulletin (SB) CT7–TP 72–0541 R01, dated November 18, 2021 (GE SB CT7–TP 72–0541). This service information specifies procedures for performing initial and repetitive visual inspections, FPIs, and USIs of the main propeller shaft.

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

Costs of Compliance

The FAA estimates that this AD affects 176 engines installed on airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Visually inspect, FPI, and USI the main propeller shaft.	2 work-hours × $85 per hour = $170	$0	$170	$29,920

The FAA estimates the following costs to perform the optional terminating action or to do any necessary replacement that would be required based on the results of the inspections. The agency has no way of determining the number of operators that will perform the optional terminating action or engines that might need this replacement:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace the main propeller shaft	8 work-hours × $85 per hour = $680	$48,360	$49,040
Revise the ALS of the MM	1 work-hour × $85 per hour = $85	0	85

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive 2018–03–13, Amendment 39–19186 (83 FR 6125, February 13, 2018); and

■ b. Adding the following new airworthiness directive:

2023–21–07 General Electric Company: Amendment 39–22579; Docket No. FAA–2022–1314; Project Identifier AD–2021–00811–E.

(a) Effective Date

This airworthiness directive (AD) is effective December 11, 2023.

(b) Affected ADs

This AD replaces AD 2018–03–13, Amendment 39–19186 (83 FR 6125, February 13, 2018).

(c) Applicability

This AD applies to General Electric Company (GE) Model CT7–5A2, CT7–5A3, CT7–7A, CT7–7A1, CT7–9B, CT7–9B1, CT7–9B2, CT7–9C, and CT7–9C3 engines.

(d) Subject

Joint Aircraft System Component (JASC) Code 7210, Turbine Engine Reduction Gear.

(e) Unsafe Condition

This AD was prompted by an in-flight failure of a main propeller shaft on a GE Model CT7–9B model engine, resulting in the loss of the propeller. The FAA is issuing this AD to prevent failure of the main propeller shaft. The unsafe condition, if not addressed, could cause in-flight loss of the propeller, loss of engine thrust control, and damage to the airplane.

(f) Compliance

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

(g) Required Actions

(1) For affected CT7–5A2, CT7–5A3, CT7–9B, CT7–9B1, and CT7–9B2 model engines, using the compliance times specified in Figure 1 to paragraph (g)(1) of this AD, perform initial and repetitive visual inspections, fluorescent penetrant inspections (FPIs), and ultrasonic inspections (USIs) of the main propeller shaft.

BILLING CODE 4910–13–P

Figure 1 to Paragraph (g)(1) – Compliance Times for CT7-5A2, CT7-5A3, CT7-9B, CT7-9B1, and CT7-9B2 Model Engines

Inspection Type	Initial inspection of the main propeller shaft	Repeat inspection interval of main propeller shaft
Cleaning and visual inspection	During first propeller removal after the effective date of this AD	During every propeller removal
FPI	Before exceeding 20,000 cycles since new (CSN) or within 2,100 flight hours (FHs) after the effective date of this AD, whichever occurs later	During every propeller removal or within 2,100 FHs from performance of the previous FPI, whichever occurs later
USI	Before exceeding 20,000 CSN or within 1,600 FHs after the effective date of this AD, whichever occurs later	Before exceeding 5,000 FHs from performance of the previous USI

(2) For affected CT7–7A, CT7–7A1, CT7–9C, and CT7–9C3 model engines, using the compliance times specified in Figure 2 to paragraph (g)(2) of this AD, perform initial and repetitive visual inspections, FPIs, and USIs of the main propeller shaft.

Figure 2 to Paragraph (g)(2) – Compliance Times for CT7-7A, CT7-7A1, CT7-9C, and CT7-9C3 Model Engines

Inspection Type	Initial inspection of the main propeller shaft	Repeat inspection interval of main propeller shaft
Cleaning and visual inspection	During the first propeller removal after the effective date of this AD	During every propeller removal
FPI	Before exceeding 20,000 CSN or within 2,400 FHs after the effective date of this AD, whichever occurs later	During every propeller removal or within 2,400 FHs from performance of the previous FPI, whichever occurs later
USI	Before exceeding 20,000 CSN or within 1,600 FHs after the effective date of this AD, whichever occurs later	Before exceeding 4,800 FHs from performance of the previous USI

(3) Perform the visual inspections, FPIs, and USIs required by paragraphs (g)(1) and (2) of this AD as follows:

(i) Prior to performance of the inspections, clean the main propeller shaft flange using the Accomplishment Instructions, paragraph 3.B., of GE Service Bulletin (SB) CT7–TP 72–0541 R01, dated November 18, 2021 (GE SB CT7–TP 72–0541).

(ii) Visually inspect the main propeller shaft for wear, corrosion, and cracking using the Accomplishment Instructions, paragraph 3.C.(1), of GE SB CT7–TP 72–0541.

(iii) Spot-FPI the area on the main propeller shaft flange face using the Accomplishment Instructions, paragraph 3.C.(2)(a), of GE SB CT7–TP 72–0541.

(iv) USI the two dowel pin holes of the main propeller shaft using the Accomplishment Instructions, paragraph 3.C.(3)(a), of GE SB CT7–TP 72–0541.

(4) If a crack or rejectable indication is found during the initial and repetitive visual inspections, FPIs, or USIs required by paragraphs (g)(1) through (3) of this AD, before further flight, remove the main propeller shaft from service and replace it with a part eligible for installation.

(5) For all affected engines, if the main propeller shaft CSN is unknown, use the propeller gearbox (PGB) CSN. If the PGB CSN is unknown, assume the inspection threshold is exceeded.

(h) Optional Terminating Action

Accomplishing the actions in paragraphs (h)(1) through (4) of this AD, as applicable by engine model, constitutes terminating action for the inspections required by paragraphs (g)(1) through (3) of this AD.

(1) For affected CT7–5A2, CT7–5A3, CT7–7A, and CT7–7A1 model engines, revise the airworthiness limitations section (ALS) of the existing maintenance manual (MM) and the operator's existing approved maintenance program or inspection program, as applicable, by incorporating the information in Figure 3 to paragraph (h)(1) of this AD.

Figure 3 to Paragraph (h)(1) - CT7-5/-7 Inspection Threshold and Interval

Inspection / Maintenance	Initial Inspection Threshold (cycles since new (CSN))	Repetitive Inspection Interval	Inspection / Maintenance Requirements	Reference
*** **FOR CT7-5**				
Visual inspection of the main propeller shaft	--	At every propeller removal	VI	72-10-00, INSPECTION - PROPELLER GEARBOX INSPECTION paragraph 5.A.
Fluorescent penetrant inspection (FPI) of the main propeller shaft	20000 CSN (*)	At every propeller removal or 2100 FH, whichever is greater	FPI	72-10-00. Special Procedure 005
Ultrasonic inspection (UTI) of the main propeller shaft	20000 CSN (*)	5000 FH	UTI	72-10-00. Special Procedure 005
*** **FOR CT7-7**				
Visual inspection of the main propeller shaft	--	At every propeller removal	VI	72-10-00, INSPECTION - PROPELLER GEARBOX INSPECTION paragraph 5.A.
Fluorescent penetrant inspection (FPI) of the main propeller shaft	20000 CSN (*)	At every propeller removal or 2400 FH, whichever is greater	FPI	72-10-00. Special Procedure 005
Ultrasonic inspection (UTI) of the main propeller shaft	20000 CSN (*)	4800 FH	UTI	72-10-00. Special Procedure 005

NOTE: (*) If the main propeller shaft accumulated time/cycle is unknown, inspection must be done based on the propeller gearbox (PGB) accumulated time/cycle. If the PGB accumulated time/cycle is unknown, threshold must be assumed exceeded.

(2) For affected CT7–9B, CT7–9B1, CT7–9B2, CT7–9C, and CT7–9C3 model engines, revise the ALS of the existing MM and the operator's existing approved maintenance program or inspection program, as applicable, by incorporating the information in Figure 4 to paragraph (h)(2) of this AD.

Figure 4 to Paragraph (h)(2) - CT7-9 Inspection Threshold and Interval

Inspection / Maintenance	Initial Inspection Threshold (cycles since new (CSN))	Repetitive Inspection Interval	Inspection / Maintenance Requirements	Reference
*** **FOR CT7-9B**				
Visual inspection of the main propeller shaft	--	At every propeller removal	VI	72-10-00, INSPECTION - PROPELLER GEARBOX INSPECTION paragraph 5.A.
Fluorescent penetrant inspection (FPI) of the main propeller shaft	20000 CSN (*)	At every propeller removal or 2100 FH, whichever is greater	FPI	72-10-00. Special Procedure 005
Ultrasonic inspection (UTI) of the main propeller shaft	20000 CSN (*)	5000 FH	UTI	72-10-00. Special Procedure 005
*** **FOR CT7-9C/9C3**				
Visual inspection of the main propeller shaft	--	At every propeller removal	VI	72-10-00, INSPECTION - PROPELLER GEARBOX INSPECTION paragraph 5.A.
Fluorescent penetrant inspection (FPI) of the main propeller shaft	20000 CSN (*)	At every propeller removal or 2400 FH, whichever is greater	FPI	72-10-00. Special Procedure 005
Ultrasonic inspection (UTI) of the main propeller shaft	20000 CSN (*)	4800 FH	UTI	72-10-00. Special Procedure 005

NOTE: (*) If the main propeller shaft accumulated time/cycle is unknown, inspection must be done based on the propeller gearbox (PGB) accumulated time/cycle. If the PGB accumulated time/cycle is unknown, threshold must be assumed exceeded.

(3) Thereafter, except as provided in paragraph (k) of this AD, no alternative inspection times or intervals may be approved for this main propeller shaft.

(4) The optional terminating actions in paragraphs (h)(1) and (2) of this AD may be performed by the owner/operator (pilot) holding at least a private pilot certificate and must be entered into the aircraft records showing compliance with this AD in accordance with 14 CFR 43.9(a) and 91.417(a)(2)(v). The record must be maintained as required by 14 CFR 91.417, 121.380, or 135.439.

(i) Definition

For the purpose of this AD, a ''part eligible for installation'' is a main propeller shaft that has been inspected in accordance with paragraphs (g)(1) or (2), and (3) of this AD, and there was no crack or rejectable indication.

(j) Credit for Previous Actions

You may take credit for the initial visual inspection, FPI, and USI required by paragraphs (g)(1) through (3) of this AD if you performed these initial inspections before the effective date of this AD in accordance with GE SB CT7–TP 72–0541 R00, dated September 9, 2021.

(k) Alternative Methods of Compliance (AMOCs)

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

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

(l) Additional Information

For more information about this AD, contact Sungmo Cho, Aviation Safety Engineer, FAA, 2200 South 216th Street, Des Moines, WA 98198; phone: (781) 238–7241; email: *Sungmo.D.Cho@faa.gov.*

(m) Material Incorporated by Reference

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

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

(i) General Electric Company (GE) Service Bulletin CT7–TP 72–0541 R01, dated November 18, 2021.

(ii) [Reserved]

(3) For GE service information identified in this AD, contact General Electric Company, 1 Neumann Way, Cincinnati, OH 45215; phone: (513) 552–3272; email: *aviation.fleetsupport@ae.ge.com;* website: ge.com.

(4) You may view this service information at FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

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

Issued on October 20, 2023.

Ross Landes,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2023–24386 Filed 11–3–23; 8:45 am]

BILLING CODE 4910–13–C

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2023–0916; Airspace Docket No. 22–AAL–85]

RIN 2120–AA66

Revocation of Alaskan Very High Frequency Omnidirectional Range (VOR) Federal Airway V–318; Level Island, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action revokes Alaskan VOR Federal Airway V–318 in the vicinity of Level Island, AK. The FAA is taking this action due to the airway's lack of use.

DATES: Effective date 0901 UTC, January 25, 2024. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: A copy of the Notice of Proposed Rulemaking (NPRM), all comments received, this final rule, and all background material may be viewed online at *www.regulations.gov* using the FAA Docket number. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year.

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

FOR FURTHER INFORMATION CONTACT: Steven Roff, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System (NAS).

History

The FAA published an NPRM for Docket No. FAA 2023–0916 in the **Federal Register** (88 FR 23597; April 18, 2023), proposing to revoke Alaskan VOR Federal Airway V–318. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. No comments were received.

Incorporation by Reference

Alaskan VOR Federal Airways are published in paragraph 6010 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the current version of that order, FAA Order JO 7400.11H, dated August 11, 2023, and effective September 15, 2023. These updates will be published in the next update to FAA Order JO 7400.11. That order is publicly available as listed in the **ADDRESSES** section of this document.

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

The Rule

This action amends 14 CFR part 71 by revoking Alaskan VOR Federal Airway V–318 in its entirety.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action of revoking Federal Airway V–318 and replacing it with existing route T–269 in the vicinity of Level Island, AK qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050,1F, Environmental Impacts: Policies and Procedures, paragraph 5–6–5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D and E Airspace Areas; Air Traffic Service Routes; and Reporting Points); and paragraph 5–6.5.k., which categorically excludes from further environmental review the publication of existing air traffic control procedures that do not essentially change existing tracks, create new tracks, change altitude, or change concentration of aircraft on these tracks. As such, this action is not expected to result in in any potentially significant

environmental impacts. In accordance with FAA Order 1050.1f, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant prepared of the environmental impact statement.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

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

Paragraph 6010(b) Alaskan VOR Federal Airways

* * * * *

V–318 [Remove]

* * * * *

Issued in Washington, DC, on September 25, 2023.

Karen L. Chiodini,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2023–24353 Filed 11–3–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 95

[Docket No. 31516; Amdt. No. 575]

IFR Altitudes; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule

SUMMARY: This amendment adopts miscellaneous amendments to the required IFR (instrument flight rules) altitudes and changeover points for certain Federal airways, jet routes, or direct routes for which a minimum or maximum en route authorized IFR altitude is prescribed. This regulatory action is needed because of changes occurring in the National Airspace System. These changes are designed to provide for the safe and efficient use of the navigable airspace under instrument conditions in the affected areas.

DATES: Effective 0901 UTC, November 30, 2023.

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., STB Annex, Bldg 26, Room 217, Oklahoma City, OK 73099. Telephone: (405) 954–1139.

SUPPLEMENTARY INFORMATION: This amendment to part 95 of the Federal Aviation Regulations (14 CFR part 95) amends, suspends, or revokes IFR altitudes governing the operation of all aircraft in flight over a specified route or any portion of that route, as well as the changeover points (COPs) for Federal airways, jet routes, or direct routes as prescribed in part 95.

The Rule

The specified IFR altitudes, when used in conjunction with the prescribed changeover points for those routes, ensure navigation aid coverage that is adequate for safe flight operations and free of frequency interference. The reasons and circumstances that create the need for this amendment involve matters of flight safety and operational efficiency in the National Airspace System, are related to published aeronautical charts that are essential to the user, and provide for the safe and efficient use of the navigable airspace. In addition, those various reasons or circumstances require making this amendment effective before the next scheduled charting and publication date of the flight information to assure its timely availability to the user. The effective date of this amendment reflects those considerations. In view of the close and immediate relationship between these regulatory changes and safety in air commerce, I find that notice and public procedure before adopting this amendment are impracticable and contrary to the public interest and that good cause exists for making the amendment effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 95

Airspace, Navigation (air).

Issued in Washington, DC on, October 27, 2023.

Thomas J Nichols,

Manager, Aviation Safety, Flight Standards Service, Standards Section, Flight Procedures & Airspace Group, Flight Technologies and Procedures Division.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, part 95 of the Federal Aviation Regulations (14 CFR part 95) is amended as follows effective at 0901 UTC, November 30, 2023.

PART 95—IFR Altitudes

■ 1. The authority citation for part 95 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113 and 14 CFR 11.49(b)(2)

■ 2. Part 95 is amended to read as follows:

REVISIONS TO IFR ALTITUDES & CHANGEOVER POINT

[Amendment 575 Effective Date November 30, 2023]

From	To	MEA	MAA
§ 95.3000 Low Altitude RNAV Routes			
§ 95.3223 RNAV Route T223			
Is Amended by Adding			
ZIKNI, AK WP	ROGOC, AK FIX	4000	17500
ROGOC, AK FIX	CEKBA, AK FIX	4400	17500
CEKBA, AK FIX	*DILLINGHAM, AK VOR/DME	4000	17500
*2400—MCA DILLINGHAM, AK VOR/DME, W BND			
Is Amended To Delete			
CAPE NEWENHAM, AK NDB/DME	DILLINGHAM, AK VOR/DME	4400	17500
Is Amended To Read in Part			
DILLINGHAM, AK VOR/DME	ZUNOS, AK FIX	2200	17500
ZUNOS, AK FIX	FAGIN, AK FIX	5000	17500
§ 95.3242 RNAV Route T242			
Is Amended by Adding			
BARROW, AK VOR/DME	WUPUV, AK WP	*1900	17500
*1900—MOCA			
WUPUV, AK WP	LACIL, AK WP	*5900	17500
*3000—MOCA			
LACIL, AK WP	KUTDE, AK WP	9500	17500
KUTDE, AK WP	TADUE, AK WP	5900	17500
TADUE, AK WP	*JOKAP, AK WP	**4000	17500
*10700—MCA JOKAP, AK WP, SE BND			
**3400—MOCA			
JOKAP, AK WP	*WEGNO, AK WP	15300	17500
*12200—MCA WEGNO, AK WP, NW BND			
WEGNO, AK WP	*HUMUB, AK WP	4600	17500
*3100—MCA HUMUB, AK WP, NW BND			
HUMUB, AK WP	TALKEETNA, AK VOR/DME	*3000	17500
Is Amended To Delete			
*TALKEETNA, AK VOR/DME	JOKAP, AK WP	**16000	17500
*12100—MCA TALKEETNA, AK VOR/DME, N BND			
**15300—MOCA			
*JOKAP, AK WP	KUTDE, AK WP	6000	17500
*11500—MCA JOKAP, AK WP, S BND			
KUTDE, AK WP	LACIL, AK WP	*15000	17500
*9400—MOCA			
LACIL, AK WP	BARROW, AK VOR/DME	*8000	17500
*1800—MOCA			
§ 95.3356 RNAV Route T356 Is Amended To Read in Part			
REESY, PA WP	FOLEZ, PA WP	2400	17500
§ 95.3447 RNAV Route T447 Is Added To Read			
SMYRNA, DE VORTAC	CHAZR, DE WP	1800	17500
CHAZR, DE WP	APEER, MD WP	2000	17500
APEER, MD WP	REESY, PA WP	2000	17500
REESY, PA WP	FOLEZ, PA WP	2400	17500
FOLEZ, PA WP	HOSKR, PA WP	2400	17500
HOSKR, PA WP	POTTSTOWN, PA VORTAC	2400	17500
POTTSTOWN, PA VORTAC	HIKES, PA FIX	2800	17500
HIKES, PA FIX	EAST TEXAS, PA VOR/DME	2900	17500
EAST TEXAS, PA VOR/DME	DIANO, PA FIX	*4200	17500
*3700—MOCA			
DIANO, PA FIX	WILLIAMSPORT, PA VOR/DME	4400	17500
WILLIAMSPORT, PA VOR/DME	DLMAR, PA WP	4800	17500
§ 95.3449 RNAV Route T449 Is Added To Read			
KITHE, PA FIX	GEERI, PA FIX	2700	17500
GEERI, PA FIX	LANCASTER, PA VOR/DME	*2400	17500
*1900—MOCA			
LANCASTER, PA VOR/DME	KERYN, PA FIX	3000	17500
KERYN, PA FIX	JUPAS, PA FIX	3400	17500
JUPAS, PA FIX	CHLSE, PA FIX	3300	17500
CHLSE, PA FIX	MARRC, PA FIX	3700	17500

REVISIONS TO IFR ALTITUDES & CHANGEOVER POINT—Continued

[Amendment 575 Effective Date November 30, 2023]

From	To	MEA	MAA
MARRC, PA FIX	MEGSS, PA FIX	3700	17500
MEGSS, PA FIX	*MEATS, PA FIX	3700	17500
*4100—MCA MEATS, PA FIX, N BND			
MEATS, PA FIX	*OYUCA, PA FIX	4900	17500
*4200—MCA OYUCA, PA FIX, S BND			
OYUCA, PA FIX	BINGHAMTON, NY VOR/DME	3700	17500
§ 95.3460	**RNAV Route T460 Is Added To Read**		
PHILIPSBURG, PA VORTAC	WILLIAMSPORT, PA VOR/DME	4900	17500
WILLIAMSPORT, PA VOR/DME	NOSEE, PA FIX	4700	17500
NOSEE, PA FIX	*HANCOCK, NY VOR/DME	4100	17500
*4600—MCA HANCOCK, NY VOR/DME, E BND			
HANCOCK, NY VOR/DME	RIMBA, NY FIX	5800	17500
RIMBA, NY FIX	*SAGES, NY FIX	6400	17500
*6300—MCA SAGES, NY FIX, W BND			
SAGES, NY FIX	SASHA, MA FIX	6100	17500
SASHA, MA FIX	TOMES, MA FIX	*4100	17500
*3500—MOCA			
TOMES, MA FIX	BARNES, MA VORTAC	3400	17500
BARNES, MA VORTAC	GLYDE, MA FIX	3000	17500
§ 95.3469	**RNAV Route T469 Is Added To Read**		
TASEY, TX WP	RICH MOUNTAIN, OK VORTAC	4300	17500
§ 95.3472	**RNAV Route T472 Is Added To Read**		
TASEY, TX WP	HOT SPRINGS, AR VOR/DME	3000	17500
§ 95.3479	**RNAV Route T479 Is Added To Read**		
DNVIL, VA WP	ENTUK, VA FIX	2800	17500
ENTUK, VA FIX	PIGGS, VA FIX	3500	17500
PIGGS, VA FIX	*DEWET, VA FIX	3600	17500
*4300—MCA DEWET, VA FIX, NW BND			
DEWET, VA FIX	DBRAH, VA WP	5300	17500
DBRAH, VA WP	NATTS, WV FIX	6000	17500
NATTS, WV FIX	VELLI, WV FIX	7000	17500
VELLI, WV FIX	AHCIN, WV FIX	6900	17500
AHCIN, WV FIX	ELKINS, WV VORTAC	*5900	17500
*5300—MOCA			
§ 95.4000 High Altitude RNAV Route			
§ 95.4445 RNAV Route Q445 Is Amended To Delete			
PAACK, NC WP	JAMIE, VA FIX	*18000	45000
*18000–GNSS MEA			
*DME/DME/IRU MEA			
JAMIE, VA FIX	CONFR, MD WP	*18000	45000
*18000–GNSS MEA			
*DME/DME/IRU MEA			
CONFR, MD WP	RADDS, DE FIX	*18000	45000
*18000–GNSS MEA			
*DME/DME/IRU MEA			
RADDS, DE FIX	WNSTN, NJ WP	*18000	45000
*18000–GNSS MEA			
*DME/DME/IRU MEA			
WNSTN, NJ WP	AVALO, NJ FIX	*18000	45000
*18000–GNSS MEA			
*DME/DME/IRU MEA			
AVALO, NJ FIX	BRIGS, NJ FIX	*18000	45000
*18000–GNSS MEA			
*DME/DME/IRU MEA			
BRIGS, NJ FIX	SHAUP, OA WP	*18000	45000
*18000–GNSS MEA			
*DME/DME/IRU MEA			

From	To	MEA
§ 95.6001 Victor Route—U.S.		
§ 95.6010 VOR Federal Airway V10 Is Amended To Delete		
YOUNGSTOWN, OH VORTAC	VOLAN, PA FIX	*5000
*3000—MOCA		
*3000—GNSS MEA		
VOLAN, PA FIX	TALLS, PA WP	*5000
*3200—MOCA		
*3300—GNSS MEA		
TALLS, PA WP	*REVLOC, PA VOR/DME.	
	SE BND	4200
	NW BND	5000
*5000—MCA REVLOC, PA VOR/DME, SE BND		
REVLOC, PA VOR/DME	JUNEY, PA FIX	*5000
		MAA—12000
*5000—GNSS MEA		
JUNEY, PA FIX	LANCASTER, PA VOR/DME	*5000
*3600—MOCA		
§ 95.6020 VOR Federal Airway V20 Is Amended To Read in Part		
MONROEVILLE, AL VORTAC	MONTGOMERY, AL VORTAC	2300
§ 95.6075 VOR Federal Airway V75 Is Amended To Read in Part		
BELLAIRE, OH VOR/DME	ATWOO, OH FIX	*6000
*3100—MOCA		
§ 95.6097 VOR Federal Airway V97 Is Amended To Read in Part		
LA BELLE, FL VORTAC	ROGAN, FL FIX.	
	SE BND	*2000
	NW BND	*5000
*2000—GNSS MEA		
§ 95.6103 VOR Federal Airway V103 Is Amended To Read in Part		
CLARKSBURG, WV VOR/DME	BELLAIRE, OH VOR/DME	*3400
*CLARKSBURG R–335 UNUSABLE, USE BELLAIR R–158		
BELLAIRE, OH VOR/DME	ATWOO, OH FIX	*6000
*3100—MOCA		
ATWOO, OH FIX	AKRON, OH VOR/DME	3100
§ 95.6123 VOR Federal Airway V123 Is Amended To Read in Part		
ALBANY, NY VORTAC	CAMBRIDGE, NY VOR/DME	*4000
*ALBANY R–067 UNUSABLE, USE CAMBRIDGE R–248		
§ 95.6137 VOR Federal Airway V137 Is Amended To Read in Part		
IMPERIAL, CA VORTAC	BRAWL, CA FIX	*3700
*2300—MOCA		
§ 95.6210 VOR Federal Airway V210 Is Amended To Delete		
REVLOC, PA VOR/DME	BLINK, PA FIX	4500
BLINK, PA FIX	HARRISBURG, PA VORTAC	4000
§ 95.6314 VOR Federal Airway V314 Is Amended To Delete		
U.S. CANADIAN BORDER	PATTA, ME WP	*6000
*3900—MOCA		
PATTA, ME WP	MILLINOCKET, ME VOR/DME	*6000
*3900—MOCA		
§ 95.6388 VOR Federal Airway V388		
Is Amended by Adding		
SEAL BEACH, CA VORTAC	AHEIM, CA FIX	*3000
*2200—MOCA		
AHEIM, CA FIX	DOWDD, CA FIX	4000
DOWDD, CA FIX	PARADISE, CA VORTAC	4400
Is Amended To Read in Part		
PARADISE, CA VORTAC	ACINS, CA FIX.	

From	To	MEA
*5300—MOCA	W BND E BND	*5300 *7000
§ 95.6395 VOR Federal Airway V395 Is Amended To Read in Part		
NOGALES, AZ VOR/DME *8000—MOCA	U.S. MEXICAN BORDER	*10000
§ 95.6456 VOR Federal Airway V456 Is Amended To Delete		
MANKATO, MN VOR/DME *2400—MOCA	FLYING CLOUD, MN VOR/DME	*2900
§ 95.6469 VOR Federal Airway V469 Is Amended To Delete		
JOHNSTOWN, PA VOR/DME	ST THOMAS, PA TACAN	5000
ST THOMAS, PA TACAN *4000—MOCA	BADDI, PA FIX	*5000
BADDI, PA FIX	HARRISBURG, PA VORTAC	4000
§ 95.6474 VOR Federal Airway V474 Is Amended To Delete		
ST THOMAS, PA TACAN *4000—MOCA	NOENO, PA FIX	*5000
NOENO, PA FIX *3400—MOCA *3400—GNSS MEA	DELRO, PA FIX	*5000
DELRO, PA FIX *10000—MCA MODENA, PA VORTAC, W BND **4000—GNSS MEA	*MODENA, PA VORTAC	**10000
§ 95.6479 VOR Federal Airway V479 Is Amended To Read in Part		
MENGE, NJ FIX	YARDLEY, PA VOR/DME. N BND S BND	 2000 4000
§ 95.6501 VOR Federal Airway V501		
Is Amended by Adding		
HAGERSTOWN, MD VOR	GGRIF, PA FIX	4100
GGRIF, PA FIX	PHILIPSBURG, PA VORTAC	4900
Is Amended To Delete		
HAGERSTOWN, MD VOR	ST THOMAS, PA TACAN	4000
ST THOMAS, PA TACAN *4000—MOCA	PHILIPSBURG, PA VORTAC	*4500
§ 95.6402 Hawaii VOR Federal Airway V2 Is Amended To Read in Part		
LANAI, HI VORTAC	KEIKI, HI FIX	5000
§ 95.6421 Hawaii VOR Federal Airway V21 Is Amended To Read in Part		
LANAI, HI VORTAC	KEIKI, HI FIX	5000

Airway Segment	Changeover Points		
From	To	Distance	From
§ 95.8003 VOR Federal Airways Changeover Points V501 Is Amended To Delete Changeover Point			
ST THOMAS, PA VORTAC	PHILIPSBURG, PA VORTAC	22	ST THOMAS.
§ 95.8005 JET Route Changeover Points J523 Is Amended To Modify Changeover Point			
BRYCE CANYON, UT VORTAC	ELY, NV VOR/DME	134	BRYCE CANYON.

[FR Doc. 2023–24424 Filed 11–3–23; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 744

[Docket No. 231101–0257]

RIN 0694–AJ44

Entity List Additions

AGENCY: Bureau of Industry and Security, Department of Commerce.

ACTION: Final rule.

SUMMARY: In this rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) by adding 13 entities to the Entity List under the destinations of Russia (12), and Uzbekistan (1). These entities have been determined by the U.S. Government to be acting contrary to the national security or foreign policy interests of the United States.

DATES: This rule is effective November 2, 2023.

FOR FURTHER INFORMATION CONTACT: Chair, End-User Review Committee, Office of the Assistant Secretary for Export Administration, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482–5991, Email: *ERC@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Entity List (supplement no. 4 to part 744 of the EAR (15 CFR parts 730–774)) identifies entities for which there is reasonable cause to believe, based on specific and articulable facts, that the entities have been involved, are involved, or pose a significant risk of being or becoming involved in activities contrary to the national security or foreign policy interests of the United States, pursuant to § 744.11(b). The EAR impose additional license requirements on, and limit the availability of, most license exceptions for exports, reexports, and transfers (in-country) when a listed entity is a party to the transaction. The license review policy for each listed entity is identified in the ''License Review Policy'' column on the Entity List, and the impact on the availability of license exceptions is described in the relevant **Federal Register** document that added the entity to the Entity List. The Bureau of Industry and Security (BIS) places entities on the Entity List pursuant to parts 744 (Control Policy: End-User and End-Use Based) and 746 (Embargoes and Other Special Controls) of the EAR.

The End-User Review Committee (ERC), composed of representatives of the Departments of Commerce (Chair), State, Defense, Energy and, where appropriate, the Treasury, makes all decisions regarding additions to, removals from, or other modifications to the Entity List. The ERC makes all decisions to add an entry to the Entity List by majority vote and makes all decisions to remove or modify an entry by unanimous vote.

Entity List Decisions

Additions to the Entity List

The ERC determined to add Aeroscan Limited Liability Company; Alfakomponent; BIC-Inform LLC; Hartis DV LLC; ID Solution LLC; OOO OMP; Orelmetallpolimer LLC; Spel LLC; Spetstehnotreyd LLC; STC Orion LLC; Technical Center Windeq LLC; and ZALA Aero Group, all under the destination of Russia; and Mvizion LLC, under the destination of Uzbekistan, to the Entity List. These entities are added for supporting Russia's military through the procurement, development, and proliferation of Russian unmanned aerial vehicles (UAVs). This activity is contrary to the national security and foreign policy interests of the United States under § 744.11(b) and these entities qualify as military end users under §§ 744.21(e), 744.21(g), and 746.8(b) of the EAR. These entities are receiving a footnote 3 designation because the ERC has determined that they are Russian or Belarusian 'military end users' pursuant to § 744.21. A footnote 3 designation subjects these entities to the Russia/Belarus-Military End User Foreign Direct Product (FDP) rule, detailed in § 734.9(g). The entities are added with a license requirement for all items subject to the EAR and a license review policy of denial for all items subject to the EAR apart from food and medicine designated as EAR99, which will be reviewed on a case-by-case basis.

For the reasons described above, this final rule adds the following 13 entities, including aliases where appropriate, to the Entity List:

Russia

- Aeroscan Limited Liability Company;
- Alfakomponent;
- BIC-Inform LLC;
- Hartis DV LLC;
- ID Solution LLC;
- OOO OMP;
- Orelmetallpolimer LLC;
- Spel LLC;
- Spetstehnotreyd LLC;
- STC Orion LLC;
- Technical Center Windeq LLC; *and*
- ZALA Aero Group.

Uzbekistan

- Mvizion LLC.

Savings Clause

For the changes being made in this final rule, shipments of items removed from eligibility for a License Exception or export, reexport, or transfer (in-country) without a license (NLR) as a result of this regulatory action that were en route aboard a carrier to a port of export, reexport, or transfer (in-country), on November 2, 2023, pursuant to actual orders for export, reexport, or transfer (in-country) to or within a foreign destination, may proceed to that destination under the previous eligibility for a License Exception or export, reexport, or transfer (in-country) without a license (NLR) before December 4, 2023. Any such items not actually exported, reexported or transferred (in-country) before midnight, on November 2, 2023, require a license in accordance with this final rule.

Export Control Reform Act of 2018

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA) (50 U.S.C. 4801–4852). ECRA provides the legal basis for BIS's principal authorities and serves as the authority under which BIS issues this rule.

Rulemaking Requirements

1. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to or be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves an information collection approved by OMB under control number 0694–0088, Simplified Network Application Processing System. BIS does not anticipate a change to the burden hours associated with this collection as a result of this rule. Information regarding the collection, including all supporting materials, can be accessed at *https://www.reginfo.gov/public/do/PRAMain.*

3. This rule does not contain policies with federalism implications as that term is defined in Executive Order 13132.

4. Pursuant to section 1762 of the Export Control Reform Act of 2018, this action is exempt from the Administrative Procedure Act (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation, and delay in effective date.

5. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* are not applicable. Accordingly, no regulatory flexibility analysis is required, and none has been prepared.

List of Subjects in 15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

Accordingly, part 744 of the Export Administration Regulations (15 CFR parts 730–774) is amended as follows:

PART 744—END-USE AND END-USER CONTROLS

■ 1. The authority citation for part 744 is revised to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 3201 *et seq.;* 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of November 8, 2022, 87 FR 68015, 3 CFR, 2022 Comp., p. 563; Notice of September 7, 2023, 88 FR 62439 (September 11, 2023).

■ 2. Supplement no. 4 is amended:

■ a. Under RUSSIA by adding, in alphabetical order, entries for ''Aeroscan Limited Liability Company;'' ''Alfakomponent;'' ''BIC-Inform LLC;'' ''Hartis DV LLC;'' ''ID Solution LLC;'' ''OOO OMP;'' ''Orelmetallpolimer LLC;'' ''Spel LLC;'' ''Spetstehnotreyd LLC;'' ''STC Orion LLC;'' ''Technical Center Windeq LLC;'' ''ZALA Aero Group;'' *and*

■ b. Under UZBEKISTAN by adding, in alphabetical order, an entry for ''Mvizion LLC'' to read as follows:

Supplement No. 4 to Part 744—Entity List

* * * * *

Country	Entity	License requirement	License review policy	**Federal Register** citation
*	* * *	*	* *	*
RUSSIA	* *	*	* *	*
	Aeroscan Limited Liability Company, a.k.a., the following two aliases: —Aeroscan; *and* —OOO Aeroskan. 3 Perunovsky Pereulok, Building 2, Moscow, 127055, Russia; *and* 2a Avtozavodskaya Street, Izhevsk, Udmurt Republic, Russia; *and* 2 Moskovskaya, Street, Buzuluk, Orenburgskaya Oblast, 461042, Russia; *and* 3 Per. Perunovski, Street 2, Floor 2, Pomeshch. 11, Munitsipalny Okrug Marina Roshcha, Moscow, 127055, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of denial for all items subject to the EAR apart from food and medicine designated as EAR99, which will be reviewed on a case-by-case basis. See §§ 746.8(b) and 744.21(e).	88 FR [INSERT FR PAGE NUMBER] 11/6/2023.
	* *	*	* *	*
	Alfakomponent, a.k.a., the following one alias: —OOO Alfakomponent. 140 Leninski Prospect, Litera E, Office 407A, Saint Petersburg, 198216, Russia.	For all items subject to the EAR (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of denial for all items subject to the EAR apart from food and medicine designated as EAR99, which will be reviewed on a case-by-case basis. See §§ 746.8(b) and 744.21(e).	88 FR [INSERT FR PAGE NUMBER] 11/6/2023.
	* *	*	* *	*
	BIC-Inform LLC, a.k.a., the following two aliases: —OOO BIC-Inform; *and* —OOO BIK-Inform. 9 Bumazhnaya Street, K. 1, Litera A, Rooms 201–209, Saint Petersburg, 190020, Russia.	For all items subject to the EAR (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of denial for all items subject to the EAR apart from food and medicine designated as EAR99, which will be reviewed on a case-by-case basis. See §§ 746.8(b) and 744.21(e).	88 FR [INSERT FR PAGE NUMBER] 11/6/2023.
	* *	*	* *	*
	Hartis DV LLC, a.k.a., the following two aliases: —Trade House Alkopanel Limited Liability Company; *and* —OOO Khartis DV. 35 Svobody Street, Building 5, Floor 1, Kom. 4, Moscow, 125362, Russia.	For all items subject to the EAR (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of denial for all items subject to the EAR apart from food and medicine designated as EAR99, which will be reviewed on a case-by-case basis. See §§ 746.8(b) and 744.21(e).	88 FR [INSERT FR PAGE NUMBER] 11/6/2023.
	* *	*	* *	*
	ID Solution LLC, a.k.a., the following one alias: —OOO Aidi Solyushn. Annino Plaza Business Center, 60B Dorozhnaya Street, Room 421, Moscow, 117405, Russia; *and* 2 Donbasskaya Street, Vidnoe, Moscow Oblast, 142700, Russia.	For all items subject to the EAR (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of denial for all items subject to the EAR apart from food and medicine designated as EAR99, which will be reviewed on a case-by-case basis. See §§ 746.8(b) and 744.21(e).	88 FR [INSERT FR PAGE NUMBER] 11/6/2023.
	* *	*	* *	*

Country	Entity	License requirement	License review policy	**Federal Register** citation
	OOO OMP, 31/1 Stanislavskogo Street, Floor 1, Office 2, Novosibirsk, Novosibirskaya Oblast, 630097, Russia.	For all items subject to the EAR (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of denial for all items subject to the EAR apart from food and medicine designated as EAR99, which will be reviewed on a case-by-case basis. See §§ 746.8(b) and 744.21(e).	88 FR [INSERT FR PAGE NUMBER] 11/6/2023.
	* *	*	* *	*
	Orelmetallpolimer LLC, a.k.a., the following two aliases: —OMP LLC, *and* —OOO Orelmetallpolimer. 1 Yu Avtomagistral Street, Mtsensk, Orovskaya Oblast, 303032, Russia; *and* 45 Olkhovskaya Street, Building 3, Floor 1, Room 1/10, Munitsipalny Okrug Krasnoselski, Moscow, 105066, Russia; *and* 19B Novosushchevskaya Street, Moscow, 127055, Russia; *and* 24/8 Vatutina Street, Office 204, Dzerzhinsk, Nizhny Novgorod Oblast, 606019, Russia.	For all items subject to the EAR (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of denial for all items subject to the EAR apart from food and medicine designated as EAR99, which will be reviewed on a case-by-case basis. See §§ 746.8(b) and 744.21(e).	88 FR [INSERT FR PAGE NUMBER] 11/6/2023.
	* *	*	* *	*
	Spel LLC, 12 Gavanskaya Street, Building 2, Litera B, Room 1–N, Saint Petersburg, 199106, Russia; *and* 39 Morskaya Embankment, Building 2A, Room 9–N, St. Petersburg, 199155, Russia.	For all items subject to the EAR (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of denial for all items subject to the EAR apart from food and medicine designated as EAR99, which will be reviewed on a case-by-case basis. See §§ 746.8(b) and 744.21(e).	88 FR [INSERT FR PAGE NUMBER] 11/6/2023.
	* *	*	* *	*
	Spetstehnotreyd LLC, a.k.a., the following one alias: —OOO Spetstekhnotreid. 11 Mekhanizatorski Per., Office 105, Izhevsk, Udmurt Republic, 426028, Russia.	For all items subject to the EAR (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of denial for all items subject to the EAR apart from food and medicine designated as EAR99, which will be reviewed on a case-by-case basis. See §§ 746.8(b) and 744.21(e).	88 FR [INSERT FR PAGE NUMBER] 11/6/2023.
	* *	*	* *	*
	STC Orion LLC, a.k.a., the following three aliases: —OOO NTTS Orion; —OOO Nauchno-Tekhnicheski Tsentr Orion; *and* —Limited Liability Company Scientific and Technical Center Orion. 7A Gostinichnaya, Pomeshch. 1/1, Office 1/V–08, Munitipalny Okrug Marfino, Moscow, 127106, Russia; *and* 3 Perunovskiy Per., Annex 2, Moscow, 127055, Russia.	For all items subject to the EAR (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of denial for all items subject to the EAR apart from food and medicine designated as EAR99, which will be reviewed on a case-by-case basis. See §§ 746.8(b) and 744.21(e).	88 FR [INSERT FR PAGE NUMBER] 11/6/2023.
	* *	*	* *	*
	Technical Center Windeq LLC, a.k.a., the following two aliases: —OOO Tekhnicheski Tsentr Vindek; *and* —TC Windeq. 1B/3 Pokrovskaya Street, Office 69, G.O. Podolsk, Moscow Oblast, 142116, Russia; *and* 1 Domodedovskoye Avenue, Building 3, Podolskiy District, Moscow Oblast, 142116, Russia.	For all items subject to the EAR (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of denial for all items subject to the EAR apart from food and medicine designated as EAR99, which will be reviewed on a case-by-case basis. See §§ 746.8(b) and 744.21(e).	88 FR [INSERT FR PAGE NUMBER] 11/6/2023.
	* *	*	* *	*
	ZALA Aero Group, a.k.a., the following fourteen aliases: —A-Level Aerosystems; —CST; —CST LLC; —CST Limited; —CST, OOO; —TsST Limited Liability Company; —TsST LLC; —TsST Limited; —TsST, OOO;	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR.	Policy of denial for all items subject to the EAR apart from food and medicine designated as EAR99, which will be reviewed on a case-by-case basis. See §§ 746.8(b) and 744.21(e).	88 FR [INSERT FR PAGE NUMBER] 11/6/2023.

Country	Entity	License requirement	License review policy	Federal Register citation
	—ZALA; —ZALA AERO; —ZALA AERO GROUP—Bespilotniye Sistemy; —ZALA AERO GROUP—Unmanned Systems; *and* —ZALA Aero Group Limited Liability Company. 118 40 Let Pobedy Street, Izhevsk, Udmurt Republic, 426072, Russia; *and* 3 Perunovsky Per., Building 2, Floor 3, Room 21, Moscow, 127055, Russia.			
UZBEKISTAN	Mvizion LLC, 8 Katartal Street, 7th Block, Chilanzarskiy District, Tashkent, 100113, Uzbekistan; *and* 313 Gaydar Alieev Kuchasi, Tashkent, Uzbekistan.	For all items subject to the EAR (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of denial for all items subject to the EAR apart from food and medicine designated as EAR99, which will be reviewed on a case-by-case basis. See §§ 746.8(b) and 744.21(e).	88 FR [INSERT FR PAGE NUMBER] 11/6/2023.

[3] For this entity, ''items subject to the EAR'' includes foreign-produced items that are subject to the EAR under § 734.9(g) of the EAR. See §§ 746.8 and 744.21 of the EAR for related license requirements, license review policy, and restrictions on license exceptions.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2023–24508 Filed 11–2–23; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2023–0850]

RIN 1625–AA00

Safety Zone; Ohio River Mile Markers 2.5–3, Brunot Island, PA

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

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is proposing to establish a temporary safety zone for the Ohio River several days in November and December 2023, and January 2024, at mile marker 2.5 to mile marker 3 from 8 a.m. through 6 p.m. each day. This action is necessary to provide for the safety of life on the navigable waters during a helicopter operation to install aerial transverse wirelines. This rule prohibits persons and vessels from being in the safety zone unless authorized by the Captain of the Port Pittsburgh (COTP) or a designated representative.

DATES: This rule is effective from 8 a.m. on November 3, 2023, through 6 p.m. on January 22, 2024. This rule will be enforced from 8 a.m. through 6 p.m. daily on November 3 through November 6, November 11, November 12, December 2, December 3, 2023, and January 8 through January 22, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2023–0850 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 LTJG Eyobe Mills, Marine Safety Unit Pittsburgh, U.S. Coast Guard, at telephone 412–221–0807, email *Eyobe.D.Mills@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 and contrary to the public interest. This safety zone must be established by November 3, 2023, to provide for the safety of life on the navigable waters during a helicopter operation, and we lack sufficient time to provide a reasonable comment period and then consider those comments before issuing this rule. Vessels inside of the safety zone have the potential of getting hit by debris from the helicopter.

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 and contrary to the public interest because action is needed by November 3, 2023, to ensure the safety of the of life on the navigable waters during a helicopter operation.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Pittsburgh (COTP) has determined that potential hazards associated with a helicopter operation on November 3 through November 6, November 11 through November 12, December 2 through December 3, 2023, and January 8 through January 22, 2024, will be a safety concern for anyone on the Ohio River from mile markers 2.5 to mile marker 3 from 8 a.m. to 6 p.m. The purpose of this rule is to ensure safety of the participant, vessels, and the

navigable waters in the safety zone before, during, and after the scheduled event.

IV. Discussion of the Rule

This rule establishes a temporary safety zone that will be enforced each day from 8 a.m. until 6 p.m. on November 3 through November 6, November 11 through November 12, December 2 through December 3, 2023, and January 8 through January 22, 2024. The safety zone will cover all navigable waters on the Ohio River from mile markers 2.5 to mile marker 3. The duration of the zone is intended to protect personnel, vessels, and the marine environment in the navigable waters during an installation of aerial transverse wirelines using a helicopter.

No vessel or person is permitted to enter the safety zone without obtaining permission from the COTP or a designated representative of the COTP. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard (USCG) assigned to units under the operational control of the COTP. To seek permission to enter, contact the COTP or a designated representative via VHF–FM channel 16, or through Marine Safety Unit Pittsburgh at 412–221–0807. Persons and vessels permitted to enter the safety zone must comply with all lawful orders or directions issued by the COTP or designated representative. The COTP or a designated representative will inform the public of the effective period for the safety zone as well as any changes in the dates and times of enforcement through Local Notice to Mariners (LNMs), Broadcast Notices to Mariners (BNMs), and/or Marine Safety Information Bulletins (MSIBs), as appropriate.

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 size, location, and duration of the temporary safety zone. This safety zone only impacts a 0.5-mile stretch on the Ohio River for 10 hours each day from November 3 through November 6, November 11 through November 12, December 2 through December 3, 2023, and January 8 through January 22, 2024. Moreover, the Coast Guard will issue Local Notice to Mariners and Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone and the rule allows vessels to seek permission from the COTP to transit 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 temporary safety zone lasting 10 hours each day from November 3 through November 6, November 11 through November 12, December 2 through December 3, 2023, and January 8 through January 22, 2024, on the Ohio

River. 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

Marine Safety, Navigation (water), Reporting, and recordkeeping requirements, Waterways.

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T08–0850 to read as follows:

§ 165.T08–0850 Safety Zone; Ohio River, Brunot Island, PA.

(a) *Location.* The following area is a temporary safety zone on the Ohio River from mile marker 2.5 to mile marker 3.

(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 Pittsburgh (COTP) in the enforcement of the safety zone. Designated representative includes safety boat provided by the event organizers.

(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 C'TP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative on Channel 16 or at 412–670–7288. To seek permission, concerned traffic may reach contact the event organizers on channel 13 or at (860) 573–6646. 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) *Enforcement period.* This section will be enforced each day from 8 a.m. through 6 p.m. from November 3 through November 6, November 11 through November 12, December 2 through December 3, 2023, and January 8 through January 22, 2024. The temporary safety zone will be enforced during the 10 hour helicopter operation.

Justin R. Jolley,

Commander, U.S. Coast Guard, Acting, Captain of the Port, MSU Pittsburgh.

[FR Doc. 2023–24388 Filed 11–3–23; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number: USCG–2023–0135]

RIN 1625–AA00

Safety Zone; Atlantic Ocean, Key West, FL

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a safety zone to be enforced in the event of hurricanes, tropical storms, and other disasters in the Florida Keys, FL. This action is necessary to ensure the safety of the waters of the Key West Captain of the Port (COTP) zone. This regulation establishes actions to be completed by parties operating on and around the navigable waterways of the Key West COTP zone. This may include the owners and operators, and those in management and control positions of regulated facilities, waterfront facilities, and vessels, prior to landfall of hurricanes, tropical storms, and other disasters threatening the Florida Keys.

DATES: This rule is effective without actual notice November 6, 2023. For the purposes of enforcement, actual notice will be used from November 1, 2023, until November 6, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2023–0135 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 notification of enforcement, call or email Hailye Wilson, Sector Key West Waterways Management Department, Coast Guard; telephone 305–292–8768; email: *hailye.m.wilson@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

COTP Captain of the Port
CFR Code of Federal Regulations
CWA Clean Water Act
DHS Department of Homeland Security
FR Federal Register
MTSA Maritime Transportation Security Act
NPRM Notice of proposed rulemaking
OPA90 The Oil Pollution Act of 1990
PWSA Ports and Waterways Safety Act
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Florida Keys has the potential to be affected by hurricanes, tropical storms, and other disasters on a yearly basis, especially between the months of June and November. The Key West COTP is establishing a safety zone to provide for the safety of life during such storms and events. In response, on May 2, 2023, the Coast Guard published a notice of proposed rulemaking (NPRM).[1] There, we stated why we issued the NPRM and invited comments on our proposed regulatory action related to safety zone. During the comment period that ended June 1, 2023, we received two comments.

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 and contrary to public interest because immediate action is needed to respond to the potential safety hazards associated with the rapid formation of a tropical storm or hurricane that would pose an imminent threat to vessels, persons, structures, and shore areas.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The purpose of this rule is to protect the general maritime public, to include vessel owners, vessel operators, and those in management and control positions related to facilities and waterways regulated by the Coast Guard, along with those in management and control positions related to any land

[1] 88 FR 27421.

or shore area immediately adjacent to those waterways in the COTP Key West zone, in the event of a hurricane, tropical storm, and other natural disasters.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received two comments on our NPRM published May 2, 2023. The first commenter positively endorsed the Coast Guard's establishment of this safety zone. They further recommended that small entities and individuals who choose to reside in Florida assume all the liability, risk and responsibilities associated with hurricanes. They also recommended that tax-payer-funds not be expended to combat the effects of climate change. The Coast Guard acknowledges these comments and determined no recommended changes are needed in response to these suggestions. Additionally, this commenter recommended the fossil fuel industry, and their shareholders bear the cost associated with climate change. With regards to this suggestion, the suggestion is outside the scope of this rulemaking, which pertains to the establishment of a safety zone to be subject to enforcement in the event of a hurricane, tropical storm, and other disaster in the Florida Keys, FL.

The second commenter raised several issues regarding the lack of clarity in the proposed regulatory text and questioned whether the rule is necessary. The rule is necessary to protect the general maritime public in the COTP Key West zone, in the event of extreme weather or other natural disasters. While the regulations in 33 CFR part 160, subpart B, ''Control of Vessel and Facility Operations'' grants the COTP the broad authority to direct the operations of vessels on the navigable waters, and waterfront facilities, land structures or shore areas immediately adjacent to the navigable waters, this rule is intended to specifically streamline the COTP's actions and processes for specific scenarios that may occur in the event of extreme weather or other natural disasters.

This rule is intended to inform the general maritime public, to include vessel owners and operators, regulated facilities, and waterfront facilities of the Coast Guard's expectations in the event of a hurricane, tropical storm, or other disaster, thereby expediting the enforcement of the safety zone, and providing more advanced notice of the Coast Guard's expectations in the event of a hurricane, tropical storm, or other natural disaster. The rule is also intended to provide vessel owners and operators, along with the owners and operators of regulated facilities and waterfront facilities with a deeper understanding of how the Coast Guard intends to handle extreme weather-related events so they can plan accordingly.

To address the commenter's concerns regarding the regarding the lack of clarity in the proposed regulatory text, the Coast Guard is making the following changes in the final rule regulatory text in § 165.707.

The Coast Guard is adding three definitions for ''regulated facilities,'' ''waterfront facilities,'' and ''authorized law enforcement agencies'' in paragraph (a). The Coast Guard has the authority to regulate facilities and land structure or shore area immediately adjacent to navigable waters under certain, specific statutory and regulatory frameworks. We are adding a definition for ''regulated facilities'' to clarify the regulated facilities covered by this rule are those regulated under the Ports and Waterways Safety Act,[2] Maritime Transportation and Security Act,[3] Clean Water Act,[4] and the Oil Pollution Act of 1990.[5] These statutes give the Coast Guard the authority and jurisdiction to take certain actions on certain regulated facilities that have a maritime nexus. We are adding a definition for ''waterfront facilities'' to the regulatory text which will include any land structure or shore area immediately adjacent to the navigable waters of the Key West COTP zone. We also added a definition for ''authorized law enforcement agencies'' to clarify that Federal, State, and local law enforcement agencies that have received specific authorization from or are operating in concert with the Coast Guard are authorized to conduct operations related to the safety, security, and stability of the Key West COTP zone.

Additionally, the commenter raised concerns related to enforceability and notice requirements. The Coast Guard understands that its regulations are not enforceable on the public without proper notice. While the publication of this final rule document in the **Federal Register** constitutes constructive notice of the requirements within the regulations. However, there will be circumstances where individuals are notified by the Coast Guard of an impending extreme weather situation causing the need for the safety zone to be made subject to enforcement. In those types of circumstances, the Coast Guard will provide affected individuals with actual notice of the safety zone prior to its enforcement or assessment of any fines or penalties. In addition to changes made to the regulatory text in this final rule in response to comment, we are making the following changes to the regulatory text.

In paragraph (a), we are adding ''regulated facilities, and ''waterfront facilities'' to clarify that regulated facilities and waterfront facilities as defined in paragraphs (b)(6) and (b)(7) respectively are covered by this safety zone when port conditions are met in accordance with the requirements in paragraph (c)(1) *Port Condition WHISKEY* and (c)(2) *Port Condition X–RAY.* Additionally, in paragraph (a), we are deleting ''during specified conditions'' because the location of the safety zone is intended to be constant. When the safety zone is subject to enforcement it will be determinate of conditions set forth in paragraphs (c)(1) through (c)(5) of the regulatory text. In paragraph (c)(1), we are deleting ''port facilities'' and adding in its place, ''regulated facilities and waterfront facilities'' for consistency as definitions for these terms have been added in paragraphs (a)(6) and (a)(7). In the event Port Condition WHISKEY is set, all vessels, regulated facilities, and waterfront facilities within the Key West COTP zone would have to comply with the applicable regulations in (c)(1). Additionally, in paragraph (c)(1), we removed the sentence, ''Vessels wishing to remain in port are required to submit an application to the COTP prior to setting Port Condition X–Ray.'' In its place, we are adding the sentence, ''Oceangoing vessels greater than 300 gross tons (GT) intending to remain in the port during Port Condition Whiskey must contact the Key West COTP prior to the setting of port condition X–Ray.'' We are taking this action to prevent vessel owners and operators from having to generate additional documentation.

In paragraph (c)(2), we are deleting ''port facilities'' and adding in its place, ''regulated facilities and waterfront facilities'' for consistency as definitions for these terms have been added in paragraphs (a)(6) and (a)(7). In the event Port Condition X–RAY is set, all vessels, regulated facilities, and waterfront facilities within the Key West COTP zone would have to comply with the applicable regulations in paragraph (c)(2). Additionally, in paragraph (c)(2), we are deleting the sentence, ''The COTP may require additional precautions to ensure the safety of the ports and waterways'' because it is

[2] 46 U.S.C. 70001 *et seq.*

[3] 46 U.S.C. 70101 *et seq.*

[4] 33 U.S.C. 1251 *et seq.*

[5] 33 U.S.C. 2701 *et seq.*

overly vague and may cause undue confusion for owners and operators of vessels and regulated facilities.

In paragraph (c)(3), we clarified we are only limiting cargo operations at ''regulated facilities.'' We also removed some the language that went into specifics of cargo operations. Removing the language made the regulatory text more succinct, as the initial language contained unnecessary redundancies. We also clarified that only facilities regulated under the MTSA will be required to operate in accordance with their security plan.

In paragraph (c)(4), we are removing the words ''are suspended'' and replacing it with, ''must cease all cargo operations'' because the phrase ''are suspended'' may be confusing in this context. By using the phrase ''must cease all cargo operations'' we are making it clear to the regulated parties that cargo operations must stop when Port ZULU is set.

In paragraph (c)(6), we are revising the text to clarify that the Coast Guard Sector Key West will notify the maritime community, ''to the furthest extent practicable'' of the periods which the safety zone in paragraph (a) will be subject to enforcement via Broadcast Notice to Mariners or by on-scene designated representatives.

We are deleting paragraph (c)(7) because it is duplicative of what is contained in paragraph (c)(6). The information previously described in (c)(8) was thereby moved to (c)(7).

Lastly, we are making non-substantive editorial changes and revising terminology for consistency throughout the final rule regulatory text.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the necessity to protect life and port infrastructure during a hurricanes, tropical storms, and other disasters. The absence of a safe harbor in the Florida Keys precludes large vessels from accessing adequate facilities to weather a substantial storm or natural disaster within the Key West COTP zone. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the safety zone, and the rule would allow vessels to seek permission to remain in port.

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 received 00 comments from the Small Business Administration on this rulemaking. 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 that would prohibit entry in certain waters of the Key West COTP for

the duration needed to ensure safe transit of vessels and industry post-hurricane, post-storm, and post-emergency. 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, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.707 to read as follows:

§ 165.707 Safety Zone; Hurricanes, Tropical Storms and Other Disasters in Florida Keys.

(a) *Regulated Areas.* All navigable waters, regulated facilities, and waterfront facilities within the Key West Captain of the Port (COTP) zone, Key West, Florida (as described in 33 CFR 3.35–40).

(b) *Definitions.* As used in this section:

Authorized Law Enforcement Agencies means Federal, State, and local law enforcement agencies that have received specific authorization from or are operating in concert with the Coast Guard to conduct operations related to the safety, security and stability of the Key West COTP zone.

Designated Representative means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, State, and local officers designated by or assisting the COTP in the enforcement of the regulated areas.

Port Condition WHISKEY means a condition set by the COTP when weather advisories indicate sustained gale force winds (39–54 mph/34–47 knots) from a tropical or hurricane force storm are predicted to make landfall at the port within 72 hours.

Port Condition X–RAY means a condition set by the COTP when weather advisories indicate sustained gale force winds (39–54 mph/34–47 knots) from a tropical or hurricane force storm are predicted to make landfall at the port within 48 hours.

Port Condition YANKEE means a condition set by the COTP when weather advisories indicate that sustained gale force winds (39–54 mph/34–47 knots) from a tropical or hurricane force storm are predicted to make landfall at the port within 24 hours.

Port Condition ZULU means a condition set by the COTP when weather advisories indicate that sustained gale force winds (39–54 mph/34–47 knots) from a tropical or hurricane force storm are predicted to make landfall at the port within 12 hours.

Regulated Facilities means shoreside facilities regulated by the Coast Guard under the Ports and Waterways Safety Act,[6] Maritime Transportation and Security Act,[7] Clean Water Act,[8] and the Oil Pollution Act of 1990,[9] and regulations in 33 CFR parts 105, 154, 156, and 158.

Waterfront Facilities means any land structure or shore area immediately adjacent to the navigable waters of the Key West COTP zone.

(c) *Regulations*—(1) *Port Condition WHISKEY.* All vessels, regulated facilities, and waterfront facilities within the Key West COTP zone must exercise due diligence in preparation for potential storm impacts. All regulated facilities and waterfront facilities must begin removing all debris and securing potential flying hazards. Oceangoing vessels greater than 300 gross tons (GT) must make plans to depart no later than the setting of Port Condition Yankee unless authorized by the COTP. Oceangoing vessels greater than 300 GT intending to remain in port must contact the COTP prior to the setting port condition X–Ray.

(2) *Port Condition X–RAY.* All vessels, regulated facilities, and waterfront facilities within the Key West COTP zone must ensure that potential flying debris is removed or secured. Hazardous materials/pollution hazards must be secured in a safe manner and away from waterfront areas. Vessels greater than 300 GT without an approval to remain in port must depart prior to the setting of Port Condition YANKEE. Vessels with the COTP's permission to remain in port must implement their pre-approved mooring arrangement. Regulated facilities must prepare to terminate all cargo operations.

(3) *Port Condition YANKEE.* Affected ports are closed to inbound vessel traffic. All oceangoing vessels greater than 300 GT must have departed designated ports within the Key West COTP zone. Regulated facilities must terminate all cargo operations, not associated with storm preparations, unless specifically authorized by the COTP. All MTSA regulated facilities must continue to operate in accordance with their approved Facility Security Plans and comply with the requirements of the MTSA.

(4) *Port Condition ZULU.* The port is closed to all vessel traffic except as specifically authorized by the COTP. Regulated facilities must cease all cargo operations, including bunkering and lightering. Waivers may be granted except for when Cargo of Particular Hazard or Certain Dangerous Cargo are involved.

(5) *Emergency Restrictions for Other Disasters.* Any natural or other disasters that are anticipated to affect the Key West COTP zone will result in the prohibition of regulated facility operations and vessel traffic transiting or remaining in the affected port.

(6*) Safety Zones Notice.* Coast Guard Sector Key West will notify the maritime community, to the furthest extent practicable, of the periods during which the safety zone described in paragraph (a) will be subject to enforcement via Broadcast Notice to Mariners or by on-scene designated representatives.

(7) *Exception.* This regulation does not apply to authorized law enforcement agencies operating within the regulated area.

Jason D. Ingram,

Captain, U.S. Coast Guard, Captain of the Port, Sector Key West.

[FR Doc. 2023–24471 Filed 11–3–23; 8:45 am]

BILLING CODE 9110–04–P

[6] 46 U.S.C. 70001 *et seq.*

[7] 46 U.S.C. 70101 *et seq.*

[8] 33 U.S.C. 1251 *et seq.*

[9] 33 U.S.C. 2701 *et seq.*

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2023–0056; FRL–11369–02–R4]

Air Plan Approval; FL; Miscellaneous SIP Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a Florida State Implementation Plan (SIP) revision, submitted by the State of Florida through the Florida Department of Environmental Protection (FDEP) on April 1, 2022. The SIP revision revises multiple stationary source rules in Florida's SIP with substantive and minor changes throughout. EPA is approving these changes pursuant to the Clean Air Act (CAA or Act).

DATES: This rule is effective December 6, 2023.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2023–0056. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information may not be publicly available, *i.e.,* 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 either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Josue Ortiz Borrero, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. Mr. Ortiz can be reached via phone number (404) 562–8085 or via electronic mail at *ortizborrero.josue@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

EPA is approving certain changes to the Florida SIP that were submitted by FDEP on April 1, 2022. Specifically, EPA is approving changes to Rules 62–296.414, Florida Administrative Code (F.A.C.), *Concrete Batching Plants;* 62–296.415, F.A.C., *Soil Thermal Treatment Facilities;* 62–296.418, F.A.C., *Bulk Gasoline Plants;* 62–296.500, F.A.C., *Reasonably Available Control Technology (RACT)—Volatile Organic Compounds (VOC) and Nitrogen Oxides (NO_X) Emitting Facilities;* 62–296.501, F.A.C., *Can Coating;* 62–296.502, F.A.C., *Coil Coating;* 62–296.503, F.A.C., *Paper Coating;* 62–296.504, F.A.C., *Fabric and Vinyl Coating;* 62–296.505, F.A.C., *Metal Furniture Coating;* 62–296.506, F.A.C., *Surface Coating of Large Appliances;* 62–296.507, F.A.C., *Magnet Wire Coating;* 62–296.508, F.A.C., *Petroleum Liquid Storage;* 62–296.510, F.A.C., *Bulk Gasoline Terminals;* 62–296.511, F.A.C., *Solvent Metal Cleaning;* 62–296.512, F.A.C., *Cutback Asphalt;* 62–296.513, F.A.C., *Surface Coating of Miscellaneous Metal Parts and Products;* 62–296.514, F.A.C., *Surface Coating of Flat Wood Paneling;* 62–296.515, F.A.C., *Graphic Arts Systems;* and 62–296.516, F.A.C., *Petroleum Liquid Storage Tanks with External Floating Roofs.*[1] These changes are for multiple stationary source emission standards rules in Florida's SIP with substantive and minor changes throughout.

Through a notice of proposed rulemaking (NPRM), published on September 11, 2023, (88 FR 62303), EPA proposed to approve the April 1, 2022, submission. The details of Florida's submission, which amend various stationary source emission standards, as well as EPA's rationale for approving the changes, are described in the September 11, 2023, NPRM. Comments on the September 11, 2023, NPRM were due on or before October 11, 2023. EPA did not receive any adverse comments on the September 11, 2023, NPRM.

II. Incorporation by Reference

In this document, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, and as discussed in Section I of this preamble, EPA is finalizing the incorporation by reference of Rules 62–296.414, F.A.C., *Concrete Batching Plants;* 62–296.415, F.A.C., *Soil Thermal Treatment Facilities;* 62–296.511, F.A.C., *Solvent Metal Cleaning,* each state effective November 5, 2020; 62–296.418, F.A.C., *Bulk Gasoline Plants;* 62–296.500, F.A.C., *Reasonably Available Control Technology (RACT)—Volatile Organic Compounds (VOC) and Nitrogen Oxides (NO_X) Emitting Facilities;* 62–296.512, F.A.C., *Cutback Asphalt,* each state effective August 14, 2019; and 62–296.501, F.A.C., *Can Coating;* 62–296.502, F.A.C., *Coil Coating;* 62–296.503, F.A.C., *Paper Coating;* 62–296.504, F.A.C., *Fabric and Vinyl Coating;* 62–296.505, F.A.C., *Metal Furniture Coating;* 62–296.506, F.A.C., *Surface Coating of Large Appliances;* 62–296.507, F.A.C., *Magnet Wire Coating;* 62–296.508, F.A.C., *Petroleum Liquid Storage;* 62–296.510, F.A.C., *Bulk Gasoline Terminals;* 62–296.513, F.A.C., *Surface Coating of Miscellaneous Metal Parts and Products;* 62–296.514, F.A.C., *Surface Coating of Flat Wood Paneling;* 62–296.515, F.A.C., *Graphic Arts Systems;* and 62–296.516, F.A.C., *Petroleum Liquid Storage Tanks with External Floating Roofs,* all state effective on July 10, 2014. EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 4 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[2]

III. Final Action

EPA is finalizing the approval of the April 1, 2022, Florida SIP revision to incorporate various changes to Rules 62–296.414, F.A.C., *Concrete Batching Plants;* 62–296.415, F.A.C., *Soil Thermal Treatment Facilities;* 62–296.418, F.A.C., *Bulk Gasoline Plants;* 62–296.500, F.A.C., *Reasonably Available Control Technology (RACT)—Volatile Organic Compounds (VOC) and Nitrogen Oxides (NO_X) Emitting Facilities;* 62–296.501, F.A.C., *Can Coating;* 62–296.502, F.A.C., *Coil Coating;* 62–296.503, F.A.C., *Paper Coating;* 62–296.504, F.A.C., *Fabric and Vinyl Coating;* 62–296.505, F.A.C., *Metal Furniture Coating;* 62–296.506, F.A.C., *Surface Coating of Large*

[1] The April 1, 2022, submittal transmits several changes to other Florida SIP-approved rules. These changes are not addressed in this action and will be considered by EPA in separate rulemakings.

[2] *See* 62 FR 27968 (May 22, 1997).

Appliances; 62–296.507, F.A.C., *Magnet Wire Coating;* 62–296.508, F.A.C., *Petroleum Liquid Storage;* 62–296.510, F.A.C., *Bulk Gasoline Terminals;* 62–296.511, F.A.C., *Solvent Metal Cleaning;* 62–296.512, F.A.C., *Cutback Asphalt;* 62–296.513, F.A.C., *Surface Coating of Miscellaneous Metal Parts and Products;* 62–296.514, F.A.C., *Surface Coating of Flat Wood Paneling;* 62–296.515, F.A.C., *Graphic Arts Systems;* and 62–296.516, F.A.C., *Petroleum Liquid Storage Tanks with External Floating Roofs,* from the Florida SIP. EPA is approving these changes because they will not interfere with the attainment or maintenance of the NAAQS or any other applicable requirement of the CAA.

IV. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 14094 (88 FR 21879, April 11, 2023);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on Tribal Governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, February 16, 1994) directs Federal agencies to identify and address ''disproportionately high and adverse human health or environmental effects'' of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. EPA defines environmental justice (EJ) as ''the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.'' EPA further defines the term fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.''

FDEP did not evaluate EJ considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. EPA did not perform an EJ analysis and did not consider EJ in this action. Due to the nature of the action being taken here, this action is expected to have a neutral to positive impact on the air quality of the affected area. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goal of E.O. 12898 of achieving EJ for people of color, low-income populations, and Indigenous peoples.

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 5, 2024. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: October 24, 2023.

Jeaneanne Gettle,

Acting Regional Administrator, Region 4.

For the reasons stated in the preamble, the EPA amends 40 CFR part 52 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart K—Florida

■ 2. In § 52.520(c), amend the table by revising the entries for ''62–296.414,'' ''62–296.415,'' ''62–62–296.418,'' ''62–296.500,'' ''62–296.501,'' ''62–296.502,'' ''62–296.503,'' ''62–296.504,'' ''62–296.505,'' ''62–296.506,'' ''62–296.507,'' ''62–296.508,'' ''62–296.510,'' ''62–296.511,'' ''62–296.512,'' ''62–296.513,'' ''62–296.514,'' ''62–296.515,'' and ''62–296.516.''

The revisions read as follows:

§ 52.520 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED FLORIDA LAWS AND REGULATIONS

State citation (section)	Title/subject	State effective date	EPA approval date	Explanation
*	*	*	*	*
Chapter 62–296 Stationary Sources—Emission Standards				
62–296.414	Concrete Batching Plants	11/5/2020	11/6/2023, [Insert citation of publication].	
62–296.415	Soil Thermal Treatment Facilities	11/5/2020	11/6/2023, [Insert citation of publication].	
62–296.418	Bulk Gasoline Plants	8/14/2019	11/6/2023, [Insert citation of publication].	
*	*	*	*	*
62–296.500	Reasonably Available Control Technology (RACT)—Volatile Organic Compounds (VOC) and Nitrogen Oxides (NO_X) Emitting Facilities.	8/14/2019	11/6/2023, [Insert citation of publication].	
62–296.501	Can Coating	7/10/2014	11/6/2023, [Insert citation of publication].	
62–296.502	Coil Coating	7/10/2014	11/6/2023, [Insert citation of publication].	
62–296.503	Paper Coating	7/10/2014	11/6/2023, [Insert citation of publication].	
62–296.504	Fabric and Vinyl Coating	7/10/2014	11/6/2023, [Insert citation of publication].	
62–296.505	Metal Furniture Coating	7/10/2014	11/6/2023, [Insert citation of publication].	
62–296.506	Surface Coating of Large Appliances	7/10/2014	11/6/2023, [Insert citation of publication].	
62–296.507	Magnet Wire Coating	7/10/2014	11/6/2023, [Insert citation of publication].	
62–296.508	Petroleum Liquid Storage	7/10/2014	11/6/2023, [Insert citation of publication].	
62–296.510	Bulk Gasoline Terminals	7/10/2014	11/6/2023, [Insert citation of publication].	
62–296.511	Solvent Metal Cleaning	11/5/2020	11/6/2023, [Insert citation of publication].	
62–296.512	Cutback Asphalt	8/14/2019	11/6/2023, [Insert citation of publication].	
62–296.513	Surface Coating of Miscellaneous Metal Parts and Products.	7/10/2014	11/6/2023, [Insert citation of publication].	
62–296.514	Surface Coating of Flat Wood Paneling.	7/10/2014	11/6/2023, [Insert citation of publication].	
62–296.515	Graphic Arts Systems	7/10/2014	11/6/2023, [Insert citation of publication].	
62–296.516	Petroleum Liquid Storage Tanks with External Floating Roofs.	7/10/2014	11/6/2023, [Insert citation of publication].	
*	*	*	*	*

* * * * *

[FR Doc. 2023–23833 Filed 11–3–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2022–0681; FRL–10386–02–R9]

Approval of Air Quality Implementation Plans; Vehicle Miles Traveled Emissions Offset Demonstrations for the 2015 Ozone Standards; California

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve revisions to the California state implementation plan (SIP) concerning vehicle miles traveled (VMT) offset demonstrations for the Los Angeles–South Coast Air Basin (South Coast), Riverside County (Coachella Valley), Los Angeles–San Bernadino Counties (West Mojave Desert), and San Joaquin Valley nonattainment areas (NAAs) for the 2015 ozone national ambient air quality standards (2015 ozone NAAQS). The EPA is taking action to approve these revisions because they demonstrate that California has added or implemented specific enforceable transportation control strategies and transportation control measures to offset

the growth in emissions from growth in VMT and vehicle trips. We are taking final action to approve these revisions under the Clean Air Act (CAA or ''the Act''), which establishes VMT offset demonstration requirements for ozone nonattainment areas classified as ''Severe'' or ''Extreme.''

DATES: This action will be effective on December 6, 2023.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2022–0681. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information or other information whose disclosure is restricted by stature. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information. If you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Michael Dorantes, Geographic Strategies and Modeling Section (AIR–2–2), EPA Region IX, (415) 972–3934, *dorantes.michael@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' refer to the EPA.

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I. Summary of Proposed Action
II. Public Comments and EPA Responses
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IV. Statutory and Executive Order Reviews

I. Summary of Proposed Action

On December 20, 2022, the EPA proposed to approve a revision to the California SIP concerning VMT emissions offset demonstrations required for the Coachella Valley and West Mojave Desert Severe ozone NAAs and for the South Coast and San Joaquin Valley Extreme ozone NAAs.[1] Section 182(d)(1)(A) of the Act and 40 CFR 51.1302 require a state to submit, for each ozone nonattainment area classified as Severe or above, a SIP revision that ''identifies or adopts specific enforceable transportation control strategies and transportation control measures to offset any growth in emissions from growth in vehicle miles traveled or number of vehicle trips in such area.'' Herein, we refer to this SIP requirement as the ''VMT emissions offset requirement.'' In addition, we refer to the SIP revision intended to demonstrate compliance with the VMT emissions offset requirement as the ''VMT emissions offset demonstration.'' In *Association of Irritated Residents* v. *EPA,* the Ninth Circuit ruled that additional transportation control measures are required whenever vehicle emissions are projected to be higher than they would have been had VMT not increased, even when aggregate vehicle emissions are decreasing.[2] In August 2012, the EPA issued a memorandum titled ''Implementing Clean Air Act Section 182(d)(1)(A): Transportation Control Measures and Transportation Control Strategies to Offset Growth in Emissions Due to Growth in Vehicle Miles Travelled'' (''August 2012 Guidance'').[3] The August 2012 Guidance discusses the meaning of ''transportation control strategies'' and ''transportation control measures'' and recommends that both be included in the calculations made for the purpose of determining the degree to which any hypothetical growth in emissions due to growth in VMT should be offset. The proposed rulemaking for this action outlines the August 2012 Guidance in further detail and how states may demonstrate that their VMT emissions offset demonstrations can satisfactorily conform with Court's ruling in *Association of Irritated Residents.*

The California Air Resources Board (CARB) provided two separate submittals as VMT emissions offset demonstrations for California's Severe and Extreme ozone NAAs. On July 27, 2020, CARB submitted a staff report to the EPA titled ''70 ppb Ozone SIP Submittal'' (''July 2020 submittal'').[4] In part, the July 2020 submittal contains the VMT offset demonstrations for the South Coast, Coachella Valley, and San Joaquin Valley ozone NAAs.[5] Additionally, on December 28, 2020, CARB submitted to the EPA a staff report titled ''West Mojave Desert VMT Offset Demonstration'' (''December 2020 submittal'') for the West Mojave Desert ozone NAA.[6]

In our proposal, we evaluated the portions of the July 2020 submittal that address the South Coast, Coachella Valley, and San Joaquin Valley VMT offset demonstrations and the December 2020 submittal of the West Mojave Desert VMT offset demonstration against the statutory and regulatory requirements of CAA section 182(d)(1)(A) and 40 CFR 51.1302, and detailed our consideration of relevant Agency guidance and court rulings. The full evaluation and discussion of our review of the State's submittals can be found in our proposal. Therein we proposed approval of the submittals as revisions to the California SIP on the basis that they met the VMT emissions offset requirements of CAA section 182(d)(1)(A) and 40 CFR 51.1302 for the 2015 ozone NAAQS.

II. Public Comments and EPA Responses

The 30-day public comment period for the notice of proposed rulemaking closed on January 19, 2023. We did not receive any public comments.

III. Final Action

For the reasons discussed in our proposed rule and summarized in this document, we are finalizing our approval of the following as revisions to the California SIP:

- VMT emissions offset demonstration element in the July 27, 2020 CARB submittal for the Los Angeles–South Coast Air Basin (South Coast), Riverside County (Coachella Valley), and San Joaquin Valley ozone nonattainment areas as meeting the requirements of CAA section 182(d)(1)(A) and 40 CFR 51.1302 for the 2015 ozone NAAQS.
- VMT emissions offset demonstration element in the December 28, 2020 CARB submittal for the Los Angeles–San Bernadino Counties (West Mojave Desert) ozone nonattainment area as meeting the requirements of CAA section 182(d)(1)(A) and 40 CFR 51.1302 for the 2015 ozone NAAQS.

[1] 87 FR 77774 (December 20, 2022).

[2] See *Association of Irritated Residents* v. *EPA,* 632 F.3d. 584, at 596–597 (9th Cir. 2011), reprinted as amended on January 27, 2012, 686 F.3d 668, further amended February 13, 2012 (''*Association of Irritated Residents*'').

[3] Memorandum dated August 30, 2012, Karl Simon, Director Transportation and Climate Division, Office of Transportation and Air Quality, to Carl Edland, Director, Multimedia Planning and Permitting Division, EPA Region VI, and Deborah Jordan, Director, Air Division, EPA Region IX.

[4] Letter dated July 24, 2020, from Richard W. Corey, Executive Officer, CARB, to John Busterud, Regional Administrator, EPA Region IX (submitted electronically July 27, 2020).

[5] The July 2020 submittal also addresses base year emissions inventory requirements for 18 of the 21 NAAs in California. The EPA approved the July 2020 submittal as meeting the base year emissions inventory requirements for the 18 areas addressed in the submittal on September 29, 2022, (87 FR 59015).

[6] Letter dated December 28, 2020, from Richard W. Corey, Executive Officer, CARB, to John Busterud, Regional Administrator, EPA Region IX (submitted electronically December 29, 2020).

IV. 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 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 action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 14094 (88 FR 21879, April 11, 2023);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

In addition, the SIP is not approved to 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, this rulemaking does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, Feb. 16, 1994) directs Federal agencies to identify and address ''disproportionately high and adverse human health or environmental effects'' of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. The EPA defines environmental justice (EJ) as ''the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.'' The EPA further defines the term fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.''

The State did not evaluate environmental justice considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. The EPA did not perform an EJ analysis and did not consider EJ in this action. This final action is expected to have a neutral to positive impact on the air quality of the affected area. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goal of Executive Order 12898 of achieving environmental justice for people of color, low-income populations, and Indigenous peoples.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements.

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

Dated: October 25, 2023.

Martha Guzman Aceves,

Regional Administrator, Region IX.

For the reasons stated in the preamble, the EPA amends part 52, chapter I, title 40 of the Code of Federal Regulations as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(589)(ii)(A)(*2*) and (c)(605) to read as follows:

§ 52.220 Identification of plan—in part.

* * * * *

(c) * * *

(589) * * *

(ii) * * *

(A) * * *

(*2*) California Air Resources Board ''70 ppb Ozone SIP Submittal,'' section III, ''VMT Offset Demonstration,'' adopted on June 25, 2020.

* * * * *

(605) The following materials were submitted electronically on December 29, 2020, by the Governor's designee as an attachment to a letter dated December 28, 2020.

(i) [Reserved]

(ii) *Additional materials.*

(A) California Air Resources Board.

(*1*) ''West Mojave Desert Vehicle-Miles Traveled Offset Demonstration,'' adopted on October 22, 2020.

(*2*) [Reserved]

(B) [Reserved]

[FR Doc. 2023–24001 Filed 11–3–23; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 230224–0053; RTID 0648–XD509]

Fisheries of the Exclusive Economic Zone Off Alaska; Reallocation of Pacific Cod in the Western Regulatory Area of the Gulf of Alaska

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

ACTION: Temporary rule; reallocation.

SUMMARY: NMFS is reallocating the projected unused amount of Pacific cod from catcher vessels using trawl gear and vessels using pot gear to catcher vessels using hook-and-line gear and catcher/processors using hook-and-line gear in the Western Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to allow the 2023 total allowable catch (TAC) of Pacific cod to be harvested.

DATES: Effective November 1, 2023, through 2400 hours, Alaska local time (A.l.t.), December 31, 2023.

FOR FURTHER INFORMATION CONTACT: Adam Zaleski, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR parts 600 and 679.

The 2023 Pacific cod TAC specified for catcher vessels using trawl gear in the Western Regulatory Area of the GOA is 1,956 metric tons (mt), as established by the final 2023 and 2024 harvest specifications for groundfish in the GOA (88 FR 13238, March 2, 2023).

The 2023 Pacific cod TAC specified for vessels using pot gear in the Western Regulatory Area of the GOA is 1,936 mt, as established by the final 2023 and 2024 harvest specifications for groundfish in the GOA (88 FR 13238, March 2, 2023).

The 2023 Pacific cod TAC specified for catcher vessels using hook-and-line gear in the Western Regulatory Area of the GOA is 71 mt, as established by the final 2023 and 2024 harvest specifications for groundfish in the GOA (88 FR 13238, March 2, 2023).

The 2023 Pacific cod TAC specified for catcher/processors using hook-and-line gear in the Western Regulatory Area of the GOA is 1,009 mt, as established by the final 2023 and 2024 harvest specifications for groundfish in the GOA (88 FR 13238, March 2, 2023).

The Administrator, Alaska Region, NMFS, (Regional Administrator) has determined that catcher vessels using trawl gear will not be able to harvest 430 mt of the 2023 Pacific cod TAC allocated to those vessels under § 679.20(a)(12)(i)(A)(*3*), and vessels using pot gear will not be able to harvest 220 mt of the 2023 Pacific cod TAC allocated to those vessels under § 679.20(a)(12)(i)(A)(*5*).

Therefore, in accordance with § 679.20(a)(12)(ii)(B), NMFS apportions 430 mt of Pacific cod from catcher vessels using trawl gear to the annual amount specified for catcher/processors using hook-and-line gear, and 220 mt of Pacific cod from vessels using pot gear to the annual amount specified for catcher vessels using hook-and-line gear.

The harvest specifications for 2023 Pacific cod included in the final 2023 and 2024 harvest specifications for groundfish in the Western Regulatory Area of the GOA (88 FR 13238, March 2, 2023) is revised as follows: 1,526 mt to catcher vessels using trawl gear, 1,716 mt to vessels using pot gear, 291 mt to catcher vessels using hook-and-line gear, and 1,439 mt to catcher/processors using hook-and-line gear.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 679, which was issued pursuant to section 304(b), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would allow for harvests that exceed the originally specified apportionment of the Pacific cod TAC. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of October 31, 2023.

The Assistant Administrator for Fisheries, NOAA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

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

Dated: November 1, 2023.

Jennifer M. Wallace,

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

[FR Doc. 2023–24461 Filed 11–1–23; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 88, No. 213
Monday, November 6, 2023

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

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1000

[Doc. No. 23–J–0067; AMS–DA–23–0031]

Milk in the Northeast and Other Marketing Areas; Notice of Hearing on Proposed Amendments to Marketing Agreements and Orders

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice of reconvened public hearing on proposed rulemaking.

SUMMARY: This notice announces the reconvening of the national public hearing, which began on August 23, 2023, in Carmel, Indiana, to consider and take evidence on proposals to amend the pricing formulas in the 11 Federal Milk Marketing Orders (FMMOs).

DATES: The hearing will reconvene at 1 p.m. ET on Monday, November 27, 2023.

ADDRESSES: The reconvened hearing, for the week of November 27, 2023, will be held at the 502 East Event Centre, 502 East Carmel Drive, Carmel, Indiana 46032. Telephone (317) 843–1234. If the hearing is not completed by 5 p.m. ET Friday, December 1, 2023, the hearing will reconvene at 8 a.m. ET on Monday, December 4, 2023, at the Palomino Ballroom, 481 South County Road 1200 East, Zionsville, Indiana 46077. Telephone (317) 769–4180.

FOR FURTHER INFORMATION CONTACT: Erin Taylor, Director, Order Formulation and Enforcement Division, USDA/AMS/Dairy Programs, Stop 0225—Room 2530, 1400 Independence Avenue SW, Washington, DC 20250–0225, (202) 720–7311, Email: *Erin.Taylor@usda.gov.*

Persons requiring a sign language interpreter or other special accommodations should contact *FMMOHearing@usda.gov* a minimum of five days before the start of the hearing.

SUPPLEMENTARY INFORMATION: Prior documents in this proceeding:

Notice of Hearing: Published July 24, 2023 (88 FR 47396).

Notice is hereby given that the hearing, which was recessed in Carmel, Indiana, on October 11, 2023, by the Administrative Law Judge designated to hold said hearing and preside thereof, will reconvene at 1 p.m. ET on Monday, November 27, 2023, at the 502 East Event Centre, 502 East Carmel Drive, Carmel, Indiana 46032. If the hearing is not completed by 5 p.m. ET on Friday, December 1, 2023, the hearing will reconvene at 8 a.m. ET on Monday, December 4, 2023, at the Palomino Ballroom, 481 South County Road 1200 East, Zionsville, Indiana 46077. With the exception of Monday, November 27, the hearing will be held from 8 a.m. until 5 p.m. each weekday. If not completed, the hearing will recess at 5 p.m. ET on Friday, December 8, 2023, and reconvene at a later date.

Dairy farmer virtual testimony will no longer be available. Dairy farmers may continue to testify in person at any time during the reconvened hearing. Dairy farmers testifying in person are not required to pre-submit testimony or exhibits.

List of Subjects in 7 CFR Part 1000

Milk marketing orders.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2023–24389 Filed 11–3–23; 8:45 am]

BILLING CODE P

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 50, 51, and 71

[NRC–2020–0034]

RIN 3150–AK79

Increased Enrichment of Conventional and Accident Tolerant Fuel Designs for Light-Water Reactors; Extension of Comment Period

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory basis; extension of comment period.

SUMMARY: On September 8, 2023, the U.S. Nuclear Regulatory Commission (NRC) requested comments on the regulatory basis to support a rulemaking to amend the NRC's regulations related to the use of conventional and accident tolerant light-water reactor fuel designs. The public comment period was originally scheduled to close on November 22, 2023. The NRC has decided to extend the public comment period to allow more time for members of the public to develop and submit their comments.

DATES: The due date of comments requested in the document published on September 8, 2023 (88 FR 61986) is extended. Comments should be filed no later than January 22, 2024. Comments received after this date will be considered, if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0034. Address questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; email: *Dawn.Forder@nrc.gov.* For technical questions contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Email comments to: Rulemaking.Comments@nrc.gov.* If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.
- *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.
- *Hand deliver comments to:* 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. eastern time, Federal workdays; telephone: 301–415–1677.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Philip Benavides, Office of Nuclear Materials Safety and Safeguards, telephone: 301–415–3246, email:

Philip.Benavides@nrc.gov and Carla Roque-Cruz, Office of Nuclear Reactor Regulation, telephone: 301–415–1455, email: *Carla.Roque-Cruz@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2020–0034 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0034.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The regulatory basis, ''Increased Enrichment of Conventional and Accident Tolerant Fuel Designs for Light-Water Reactors, is available in ADAMS under Accession No. ML23032A504.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time, Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal Rulemaking Website (*https://www.regulations.gov*). Please include Docket ID NRC–2020–0034 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Discussion

On September 8, 2023, the NRC requested comments on a regulatory basis titled ''Increased Enrichment of Conventional and Accident Tolerant Fuel Designs for Light-Water Reactors'' to support a rulemaking that would amend the NRC's regulations to facilitate the use of light-water reactor fuel containing uranium enriched to greater than 5.0 weight percent uranium-235 (U–235) in part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Domestic Licensing of Production and Utilization Facilities,'' 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,'' and 10 CFR part 71, ''Packaging and Transportation of Radioactive Material.'' This rulemaking would allow the NRC to prepare for the effective and efficient licensing of applications using fuels enriched to greater than 5.0 and less than 20.0 weight percent U–235 without compromising reasonable assurance of adequate protection of public health and safety, reduce the need for exemptions from existing regulations and license amendment requests, provide licensees operational flexibility and certainty in licensing of accident tolerant fuel, and support the principles of good regulation. The rule changes would apply to any light-water power reactor application submitted to the NRC under 10 CFR part 50 and part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants.''

The public comment period was originally scheduled to close on November 22, 2023. The NRC has decided to extend the public comment period on this document until January 22, 2024, to allow more time for members of the public to submit their comments.

The NRC may post materials related to this document, including public comments, on the Federal rulemaking website at *https://www.regulations.gov* under Docket ID NRC–2020–0034. In addition, the Federal rulemaking website allows members of the public to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) navigate to the docket folder (NRC–2020–0034); (2) click the ''Subscribe'' link; and (3) enter an email address and click on the ''Subscribe'' link.

Dated: October 31, 2023.

For the Nuclear Regulatory Commission.

Catherine E. Kanatas,

Acting Deputy Director, Division of Rulemaking, Environmental, and Financial Support, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2023–24396 Filed 11–3–23; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–2146; Project Identifier MCAI–2023–00646–T]

RIN 2120–AA64

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

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Airbus Canada Limited Partnership Model BD–500–1A10 and BD–500–1A11 airplanes. This proposed AD was prompted by a report of possible chafing of a power harness at fuselage frame (FR) 65. This proposed AD would require rerouting the power harness, as specified in a Transport Canada 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 December 21, 2023.

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

- *Federal eRulemaking Portal:* Go to *regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

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

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–2146; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

• For material that is identified in this NPRM, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca;* website *tc.canada.ca/en/aviation.* It is also available at *regulations.gov* under Docket No. FAA–2023–2146.

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

FOR FURTHER INFORMATION CONTACT: William Reisenauer, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7301; email: *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2023–2146; Project Identifier MCAI–2023–00646–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to William Reisenauer, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7301; email: *9-avs-nyaco-cos@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

Transport Canada, which is the aviation authority for Canada, has issued Transport Canada AD CF–2023–27, dated May 4, 2023 (Transport Canada AD CF–2023–27) (also referred to as the MCAI), to correct an unsafe condition for certain Airbus Canada Limited Partnership Model BD–500–1A10 and BD–500–1A11 airplanes. The MCAI states that during production, a possibility of chafing between a power harness and the left side window shade at fuselage FR 65 was detected. Damage to the power harness can result in an emergency equipment failure, including the partial loss of the public address system and the inability to deploy half the passenger oxygen masks when required.

The FAA is proposing this AD to address the unsafe condition on these products. You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2023–2146.

Related Service Information Under 1 CFR Part 51

Transport Canada AD CF–2023–27 specifies procedures for rerouting the power harness, which requires the modification of an insulation blanket and the installation of a standoff and a clamp on the left side stringer 11 between fuselage FR 65 and FR 67 to prevent damage to the harness.

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

FAA's Determination

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

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in Transport Canada AD CF–2023–27 described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate Transport Canada AD CF–2023–27 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with Transport Canada AD CF–2023–27 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Service information required by Transport Canada AD CF–2023–27 for compliance will be available at *regulations.gov* under Docket No. FAA–2023–2146 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 29 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
4 work-hours × $85 per hour = $340	$10	$350	$10,150

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus Canada Limited Partnership (Type Certificate Previously Held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.): Docket No. FAA–2023–2146; Project Identifier MCAI–2023–00646–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by December 21, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Canada Limited Partnership (Type Certificate previously held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.) Model BD–500–1A10 and BD–500–1A11 airplanes, certificated in any category, as identified in Transport Canada AD CF–2023–27, dated May 4, 2023 (Transport Canada AD CF–2023–27).

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by a report of possible chafing of a power harness at fuselage frame (FR) 65. The FAA is issuing this AD to address chafing of the power harness. The potential unsafe condition, if not addressed, could result in an emergency equipment failure, including the partial loss of the public address system and the inability to deploy half the passenger oxygen masks when required.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, Transport Canada AD CF–2023–27.

(h) Exceptions to Transport Canada AD CF–2023–27

(1) Where Transport Canada AD CF–2023–27 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where Transport Canada AD CF–2023–27 refers to hours air time, this AD requires using flight hours.

(i) Additional AD Provisions

The following provisions also apply to this AD:

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

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

(j) Additional Information

For more information about this AD, contact William Reisenauer, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7301; email: *9-avs-nyaco-cos@faa.gov.*

(k) Material Incorporated by Reference

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

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

(i) Transport Canada AD CF–2023–27, dated May 4, 2023.

(ii) [Reserved]

(3) For Transport Canada AD CF–2023–27, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca;* website *tc.canada.ca/en/aviation.*

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

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

Issued on October 30, 2023.

Victor Wicklund,

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

[FR Doc. 2023–24305 Filed 11–3–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–2144; Project Identifier MCAI–2023–00898–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) 2018–14–09, which applies to certain Airbus SAS Model A318 series airplanes; Model A319 series airplanes; Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. AD 2018–14–09 requires repetitive inspections for cracking of the fastener holes in certain fuselage frames, and depending on airplane configuration, provides an optional terminating action to the repetitive inspections. Since the FAA issued AD 2018–14–09, it was determined that additional actions are necessary beyond those required by AD 2018–14–09. This proposed AD would continue to require the actions in AD 2018–14–09 and would require modified compliance times, as well as further inspections and optional terminating actions for certain airplanes, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference (IBR). The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by December 21, 2023.

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

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

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–2144; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For the EASA AD identified in this NPRM, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.* It is also available at *regulations.gov* under Docket No. FAA–2023–2144.
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

FOR FURTHER INFORMATION CONTACT: Timothy Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 817–222–5102; email *timothy.p.dowling@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2023–2144; Project Identifier MCAI–2023–00898–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Timothy Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 817–222–5102; email *timothy.p.dowling@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 2018–14–09, Amendment 39–19329 (83 FR 34034, July 19, 2018) (AD 2018–14–09), for certain Airbus SAS Model A318 series airplanes; Model A319 series airplanes; Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. AD 2018–14–09 was prompted by an MCAI originated by EASA, which is the Technical Agent for the Member States of the European Union. EASA issued AD 2016–0139, dated July 14, 2016, to correct an unsafe condition.

AD 2018–14–09 requires repetitive inspections for cracking of the fastener holes in certain fuselage frames, and depending on airplane configuration, provides an optional terminating action to the repetitive inspections. The FAA

issued AD 2018–14–09 to address cracking at two upper rows of fasteners of the crossbeam splicing at frame (FR)16 and FR20, on both the left-hand (LH) and right-hand (RH) sides, which can result in reduced structural integrity of the airplane due to the failure of structural components.

Actions Since AD 2018–14–09 Was Issued

Since the FAA issued AD 2018–14–09, EASA superseded AD 2016–0139, dated July 14, 2016, and issued EASA AD 2023–0150, dated July 20, 2023 (EASA AD 2023–0150) (also referred to as the MCAI), to correct an unsafe condition for Airbus SAS A318–111, A318–112, A318–121, A318–122, A319–111, A319–112, A319–113, A319–114, A319–115, A319–131, A319–132, A319–133, A320–211, A320–212, A320–214, A320–215, A320–216, A320–231, A320–232, A320–233, A321–111, A321–112, A321–131, A321–211, A321–212, A321–213, A321–231 and A321–232 airplanes, all manufacturer serial numbers, except airplanes on which Airbus modification (mod) 161255 was embodied in production, Model A318 airplanes on which Airbus mod 39195 was embodied in production, or Airbus Service Bulletin A320–00–1219 was embodied in service; and Model A319 airplanes on which Airbus mod 28238, mod 28162, and mod 28342 were embodied in production. Model A320–215 airplanes are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this proposed AD therefore does not include those airplanes in the applicability. The MCAI states that repetitive inspections were instituted due to reports of cracks on the four holes of the crossbeam splicing at FR16 and FR20 on both LH and RH sides. Following further assessments, the need was determined for additional inspections, reduced compliance times, and an additional terminating action option.

For the reasons described above, this proposed AD retains the requirements of AD 2018–14–09 (which corresponds to EASA AD 2016–0139), introduces new compliance times for airplanes that embody Airbus mod 20416 or mod 21999, expands the inspection area for airplanes that embody neither Airbus mod 20416 nor mod 21999, and adds a terminating action option.

The FAA is proposing this AD to address cracking at two upper rows of fasteners of the crossbeam splicing at FR16 and FR20, on both the LH and RH sides, which can result in reduced structural integrity of the airplane due to the failure of structural components. You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2023–2144.

Explanation of Retained Requirements

Although this proposed AD does not explicitly restate the requirements of AD 2018–14–09, this proposed AD would retain all of the requirements of AD 2018–14–09. Those requirements are referenced in EASA AD 2023–0150, which, in turn, is referenced in paragraph (g) of this proposed AD.

Related Service Information Under 1 CFR Part 51

EASA AD 2023–0150 specifies procedures for repetitive rototest inspections for cracking of the holes in certain fuselage frames and crossbeams and applicable corrective actions (including repairing cracking and replacing fasteners); and, for certain airplanes, procedures for modifying the airplane, including cold working instructions in certain fuselage frames and crossbeams, which would terminate the inspections (optional terminating action). This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

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

Proposed AD Requirements in This NPRM

This proposed AD would retain all requirements of AD 2018–14–09. This proposed AD would require accomplishing the actions specified in EASA AD 2023–0150 described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD and except as discussed under ''Differences Between this Proposed AD and the MCAI.''

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 2023–0150 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2023–0150 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 2023–0150 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 2023–0150. Service information required by EASA AD 2023–0150 for compliance will be available at *regulations.gov* under Docket No. FAA–2023–2144 after the FAA final rule is published.

Differences Between This Proposed AD and the MCAI

Although the applicability of EASA AD 2023–0150 references Airbus Service Bulletin A320–00–1219, the FAA contacted Airbus and learned that the referenced service information has not been published. Therefore, this proposed AD does not include that service information in the applicability.

Where the service information referenced in paragraphs (8) and (9) of EASA AD 2023–0150, *i.e.,* ''Airbus SB A320–53–1295,'' refers to actions when an existing hole diameter is ''more than or equal to the minimum starting hole diameter,'' paragraph (h)(6) of this proposed AD specifies to replace those words with ''more than or equal to the maximum starting hole diameter.'' In Airbus Operators Information Telex (OIT) 15–0097, Revision 01, dated January 7, 2016, Airbus confirmed that the corrective action in Airbus Service Bulletin A320–53–1295 that refers to ''more than or equal to the minimum starting hole diameter'' should be ''more than or equal to the maximum starting hole diameter.'' As explained in the ''Request to Include Corrections to Service Information'' paragraph in AD 2018–14–09, Airbus released OIT 15–0097, Revision 01, dated January 7, 2016, to correct discrepancies in Airbus Service Bulletin A320–53–1295, which is referred to paragraphs (k) and (m) of AD 2018–14–09. The FAA added paragraph (r) to AD 2018–14–09 to address the diameter hole discrepancy.

Paragraphs (k) and (m) of AD 2018–14–09 correspond to paragraphs (8) and (9) of EASA AD 2023–0150. Paragraph (r) of AD 2018–14–09 corresponds to paragraph (h)(6) of this proposed AD.

Where rows B and C of the ''Threshold'' column in Table 1 of EASA AD 2023–0150 refer to ''54 800 FH,'' for this proposed AD, those words should be replaced with ''54 900 FH'' because the existing flight-hour interval specified in Table 1 of AD 2018–14–09 is 54,900 flight hours. Once the initial inspection is done within the ''Threshold'' compliance times in Table 1 of EASA AD 2023–0150, the new repetitive flight-hour interval will be 54,800 flight hours (flight-hour component only; the complete new interval is 27,400 flight cycles or 54,800 flight hours, whichever occurs first). The FAA has included this exception in paragraph (h)(3) of the proposed AD.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 1,680 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 2018–14–09	31 work-hours × $85 per hour = $2,635	$0	$2,635	$4,426,800

ESTIMATED COSTS FOR OPTIONAL ACTIONS

Labor cost	Parts cost	Cost per product
28 work-hours × $85 per hour = $2,380	$3,020	$5,400

The FAA estimates the following costs to do any necessary on-condition actions that would be required based on the results of any required or optional actions. The FAA has no way of determining the number of aircraft that might need this on-condition action:

ESTIMATED COSTS OF ON-CONDITION REPLACEMENTS

Labor cost	Parts cost	Cost per product
14 work-hours × $85 per hour = $1,190	$50	$1,240

The FAA has received no definitive data that would enable us to provide cost estimates for the on-condition repairs specified in this proposed AD.

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) 2018–14–09, Amendment 39–19329 (83 FR 34034, July 19, 2018); and

■ b. Adding the following new AD:

Airbus SAS: Docket No. FAA–2023–2144; Project Identifier MCAI–2023–00898–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by December 21, 2023.

(b) Affected ADs

This AD replaces AD 2018–14–09, Amendment 39–19329 (83 FR 34034, July 19, 2018) (AD 2018–14–09).

(c) Applicability

This AD applies to Airbus SAS Model A318–111, –112, –121, and –122 airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes; certificated in any category, all

manufacturer serial numbers, except the airplanes specified in paragraphs (c)(1) through (3) of this AD.

(1) Airplanes on which Airbus modification 161255 has been embodied in production.

(2) Model A319 series airplanes on which Airbus modifications 28238, 28162, and 28342 have been concurrently embodied in production.

(3) Model A318 series airplanes on which Airbus modification 39195 has been embodied in production.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by reports of early cracking on the four holes of the crossbeam splicing at certain fuselage frames (FR). The FAA is issuing this AD to address cracking at two upper rows of fasteners of the crossbeam splicing at FR16 and FR20, on both the left-hand (LH) and right-hand (RH) sides. The unsafe condition, if not addressed, could result in reduced structural integrity of the airplane due to the failure of structural components.

(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, European Union Aviation Safety Agency (EASA) AD 2023–0150, dated July 20, 2023 (EASA AD 2023–0150).

(h) Exceptions to EASA AD 2023–0150

(1) Where EASA AD 2023–0150 refers to ''28 July 2016 [the effective date of EASA AD 2016–0139],'' this AD requires using August 23, 2018 (the effective date of AD 2018–14–09).

(2) Where EASA AD 2023–0150 refers to its effective date, this AD requires using the effective date of this AD.

(3) Where rows B and C of the ''Threshold'' column in Table 1 of EASA AD 2023–0150 refer to ''54 800 FH,'' for this AD, replace those words with ''54 900 FH.''

(4) Where paragraph (5) of EASA AD 2023–0150 refers to ''valid within the EASA system,'' for this AD, replace those words with ''approved by the FAA, EASA, Airbus's EASA Design Organization Approval (DOA), or an EASA DOA (other than Airbus's EASA DOA).''

(5) Where paragraph (5) of EASA AD 2023–0150 specifies ''contact that design approval holder (DAH) for assessment and repair instructions, obtain EASA AMOC approval and accomplish those instructions accordingly, as applicable,'' for this AD, replace those words with ''modify the repair using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Airbus's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.''

(6) Where the service information referenced in paragraphs (8) and (9) of EASA AD 2023–0150 refers to actions when an existing hole diameter is ''more than or equal to the minimum starting hole diameter,'' for this AD, replace those words with ''more than or equal to the maximum starting hole diameter.''

(7) This AD does not adopt the ''Remarks'' section of EASA AD 2023–0150.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2023–0150 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Additional AD Provisions

The following provisions also apply to this AD:

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

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or 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):* Except as required by paragraphs (i) and (j)(2) of this AD, if any service information contains procedures or tests that are identified as RC, those 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.

(k) Additional Information

For more information about this AD, contact Timothy Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 817–222–5102; email *timothy.p.dowling@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2023–0150, dated July 20, 2023.

(ii) [Reserved]

(3) For EASA AD 2023–0150, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

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

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

Dated: Issued on October 30, 2023.

Victor Wicklund,

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

[FR Doc. 2023–24300 Filed 11–3–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2023–2115; Airspace Docket No. 23–ASO–40]

RIN 2120–AA66

Amendment of Class E Airspace; Natchez, MS

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class E airspace at Natchez, MS. The FAA is proposing this action as the result of an airspace review conducted due to the decommissioning of the Natchez very high frequency omnidirectional range (VOR) as part of the VOR Minimum Operating Network (MON) Program. The name and geographic coordinates of the airport would also be updated to coincide with the FAA's aeronautical database. This action will bring the airspace into compliance with FAA orders to support instrument flight rule (IFR) operations.

DATES: Comments must be received on or before December 21, 2023.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2023–2115

and Airspace Docket No. 23–ASO–40 using any of the following methods:

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

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

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

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

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

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class E airspace extending upward from 700 feet above the surface at Hardy-Anders Field/Natchez-Adams County Airport, Natchez, MS, to support IFR operations at this airport.

Comments Invited

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

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

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT post 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–14FDMS), which can be reviewed at *www.dot.gov/privacy.*

Availability of Rulemaking Documents

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

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Incorporation by Reference

Class E airspace is published in paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11H, dated August 11, 2023, and effective September 15, 2023. These updates would be published subsequently in the next update to FAA Order JO 7400.11. That order is publicly available as listed in the **ADDRESSES** section of this document.

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

The Proposal

The FAA is proposing to amend 14 CFR part 71 by modifying the Class E airspace extending upward from 700 feet above the surface to within a 6.6-mile (decreased from a 7-mile) radius of Hardy-Anders Field/Natchez-Adams County Airport, Natchez, MS; updating the name (previously Hardy-Anders Field Natchez-Adams County Airport) and geographic coordinates of airport to coincide with the FAA's aeronautical database; and removing the city associated with the airport from the header to comply with changes to FAA Order JO 7400.2P, Procedures for Handling Airspace Matters.

This action is the result of an airspace review conducted due to the decommissioning of the Natchez VOR, which provided navigation information to this airport, as part of the VOR MON Program, and to support IFR operations at this airport.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will

not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

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

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASO MS E5 Natchez, MS [Amended]

Hardy-Anders Field/Natchez-Adams County Airport, MS
(Lat. 31°36′50″ N, long. 91°17′49″ W)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of Hardy-Anders Field/Natchez-Adams County Airport.

* * * * *

Issued in Fort Worth, Texas, on November 1, 2023.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2023–24438 Filed 11–3–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2023–2118; Airspace Docket No. 23–AGL–31]

RIN 2120–AA66

Amendment of Class E Airspace; Harrison, OH

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class E airspace at Harrison, OH. The FAA is proposing this action as the result of an airspace review conducted due to the decommissioning of the Cincinnati very high frequency omnidirectional range (VOR) as part of the VOR Minimum Operating Network (MON) Program. The geographic coordinates of the airport would also be updated to coincide with the FAA's aeronautical database. This action will bring the airspace into compliance with FAA orders to support instrument flight rule (IFR) operations.

DATES: Comments must be received on or before December 21, 2023.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2023–2118 and Airspace Docket No. 23–AGL–31 using any of the following methods:

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

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

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

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

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

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class E airspace extending upward from 700 feet above the surface at Cincinnati West Airport, Harrison, OH, to support IFR operations at this airport.

Comments Invited

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

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it received on or before the closing date for comments. The FAA

will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT post 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–14FDMS), which can be reviewed at *www.dot.gov/privacy.*

Availability of Rulemaking Documents

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

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Incorporation by Reference

Class E airspace is published in paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11H, dated August 11, 2023, and effective September 15, 2023. These updates would be published subsequently in the next update to FAA Order JO 7400.11. That order is publicly available as listed in the **ADDRESSES** section of this document.

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

The Proposal

The FAA is proposing to amend 14 CFR part 71 by modifying the Class E airspace extending upward from 700 feet above the surface to within a 7.1-mile (increased from a 6.4-mile) radius of Litchfield Municipal Airport, Litchfield, MN; removing the exclusionary language as it is not required; removing the city associated with the airport in the legal description header to comply with changes to FAA Order JO 7400.2P, Procedures for Handling Airspace Matters; and updating the geographic coordinates of the airport to coincide with the FAA's aeronautical database.

This action is the result of an airspace review conducted due to the decommissioning of the Cincinnati VOR, which provided navigation information to this airport, as part of the VOR MON Program, and to support IFR operations at this airport.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

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

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AGL OH E5 Harrison, OH [Amended]

Cincinnati West Airport, OH
(Lat. 39°15′33″ N, long. 84°46′28″ W)

That airspace extending upward from 700 feet above the surface within a 7.1-mile radius of Cincinnati West Airport.

* * * * *

Issued in Fort Worth, Texas, on November 1, 2023.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2023–24435 Filed 11–3–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2023–2116; Airspace Docket No. 23–AGL–29]

RIN 2120–AA66

Amendment of Class E Airspace; Hutchinson, MN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class E airspace at Hutchinson, MN. The FAA is proposing this action as the result of an airspace review conducted due to the decommissioning of the Darwin very high frequency omnidirectional range (VOR) as part of the VOR Minimum Operating Network (MON) Program. The name of the airport would also be updated to coincide with the FAA's aeronautical database. This action will bring the airspace into compliance with FAA orders to support instrument flight rule (IFR) operations.

DATES: Comments must be received on or before December 21, 2023.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2023–2116 and Airspace Docket No. 23–AGL–29 using any of the following methods:

* *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the

online instruction for sending your comments electronically.

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

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

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

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

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class E airspace extending upward from 700 feet above the surface at Hutchinson Municipal Airport/Butler Field, Hutchinson, MN, to support IFR operations at this airport.

Comments Invited

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

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

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT post 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–14FDMS), which can be reviewed at *www.dot.gov/privacy.*

Availability of Rulemaking Documents

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

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Incorporation by Reference

Class E airspace is published in paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11H, dated August 11, 2023, and effective September 15, 2023. These updates would be published subsequently in the next update to FAA Order JO 7400.11. That order is publicly available as listed in the **ADDRESSES** section of this document.

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

The Proposal

The FAA is proposing to amend 14 CFR part 71 by modifying the Class E airspace extending upward from 700 feet above the surface to within a 6.4-mile (decreased from a 6.6-mile) radius of Hutchinson Municipal Airport/Butler Field, Hutchinson, MN; and updating the name (previously Hutchinson Municipal Airport-Butler Field) of airport to coincide with the FAA's aeronautical database.

This action is the result of an airspace review conducted due to the decommissioning of the Darwin VOR, which provided navigation information to this airport, as part of the VOR MON Program, and to support IFR operations at this airport.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and

Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

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

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AGL MN E5 Hutchinson, MN [Amended]

Hutchinson Municipal Airport/Butler Field, MN
(Lat 44°51′36″ N, long 94°22′57″ W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Hutchinson Municipal Airport/Butler Field.

* * * * *

Issued in Fort Worth, Texas, on November 1, 2023.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2023–24441 Filed 11–3–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2023–2114; Airspace Docket No. 23–AEA–17]

RIN 2120–AA66

Amendment of Class E Airspace; Bedford, PA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class E airspace at Bedford, PA. The FAA is proposing this action as the result of an airspace review conducted due to the decommissioning of the St. Thomas very high frequency omnidirectional range (VOR) as part of the VOR Minimum Operating Network (MON) Program. This action will bring the airspace into compliance with FAA orders to support instrument flight rule (IFR) operations.

DATES: Comments must be received on or before December 21, 2023.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2023–2114 and Airspace Docket No. 23–AEA–17 using any of the following methods:

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

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

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

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

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

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class E airspace extending upward from 700 feet above the surface at Bedford County Airport, Bedford, PA, to support IFR operations at this airport.

Comments Invited

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

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

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT post 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–14FDMS), which can be reviewed at *www.dot.gov/privacy*.

Availability of Rulemaking Documents

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

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Incorporation by Reference

Class E airspace is published in paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11H, dated August 11, 2023, and effective September 15, 2023. These updates would be published subsequently in the next update to FAA Order JO 7400.11. That order is publicly available as listed in the **ADDRESSES** section of this document.

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

The Proposal

The FAA is proposing to amend 14 CFR part 71 by modifying the Class E airspace extending upward from 700 feet above the surface to within an 8-mile (decreased from a 12.5-mile) radius of Bedford County Airport, Bedford, PA; and within 2 miles each side of the 128° bearing from the airport extending from the 8-mile radius to 13 miles southeast of the airport; and within 2 miles each side of the 308° bearing from the airport extending from the 8-mile radius to 14.8 miles northwest of the airport.

This action is the result of an airspace review conducted due to the decommissioning of the St. Thomas VOR, which provided navigation information to this airport, as part of the VOR MON Program, and to support IFR operations at this airport.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

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

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AEA PA E5 Bedford, PA [Amended]

Bedford County Airport, PA
(Lat. 40°05′10″ N, long. 78°30′49″ W)

That airspace extending upward from 700 feet above the surface within an 8-mile radius of Bedford County Airport; and within 2 miles each side of the 128° bearing from the airport extending from the 8-mile radius to 13 miles southeast of the airport; and within 2 miles each side of the 308° bearing from the airport extending from the 8-mile radius to 14.8 miles northwest of the airport.

* * * * *

Issued in Fort Worth, Texas, on November 1, 2023.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2023–24437 Filed 11–3–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2023–2117; Airspace Docket No. 23–AGL–30]

RIN 2120–AA66

Amendment of Class E Airspace; Litchfield, MN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class E airspace at Litchfield, MN. The FAA is proposing this action as the result of an airspace review conducted due to the decommissioning of the Darwin very high frequency omnidirectional range (VOR) as part of the VOR Minimum Operating Network (MON) Program. This action will bring the airspace into compliance with FAA orders to support instrument flight rule (IFR) operations.

DATES: Comments must be received on or before December 21, 2023.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2023–2117 and Airspace Docket No. 23–AGL–30 using any of the following methods:

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

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

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

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

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

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class E airspace extending upward from 700 feet above the surface at Litchfield Municipal Airport, Litchfield, MN, to support IFR operations at this airport.

Comments Invited

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

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

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT post 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–14FDMS), which can be reviewed at *www.dot.gov/privacy.*

Availability of Rulemaking Documents

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

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Incorporation by Reference

Class E airspace is published in paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11H, dated August 11, 2023, and effective September 15, 2023. These updates would be published subsequently in the next update to FAA Order JO 7400.11. That order is publicly available as listed in the **ADDRESSES** section of this document.

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

The Proposal

The FAA is proposing to amend 14 CFR part 71 by modifying the Class E airspace extending upward from 700 feet above the surface to within a 6.4-mile (increased from a 6.3-mile) radius of Litchfield Municipal Airport, Litchfield, MN; and removing the Darwin VORTAC and associated extension from the airspace legal description.

This action is the result of an airspace review conducted due to the decommissioning of the Darwin VOR, which provided navigation information to this airport, as part of the VOR MON Program, and to support IFR operations at this airport.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

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

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AGL MN E5 Litchfield, MN [Amended]

Litchfield Municipal Airport, MN
(Lat 45°05′50″ N, long 94°30′26″ W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Litchfield Municipal Airport.

* * * * *

Issued in Fort Worth, Texas, on November 1, 2023.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2023–24439 Filed 11–3–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2023–2113; Airspace Docket No. 23–AGL–28]

RIN 2120–AA66

Amendment of Class E Airspace; Jackson, OH

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class E airspace at Jackson, OH. The FAA is proposing this action as the result of an airspace review conducted due to the decommissioning of the York very high frequency omnidirectional range (VOR) as part of the VOR Minimum Operating Network (MON) Program. The geographic coordinates of the airport would also be updated to coincide with the FAA's aeronautical database. This action will bring the airspace into compliance with FAA orders to support instrument flight rule (IFR) operations.

DATES: Comments must be received on or before December 21, 2023.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2023–2113 and Airspace Docket No. 23–AGL–28 using any of the following methods:

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

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

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

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

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

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class E airspace extending upward from 700 feet above the surface at James A. Rhodes Airport, Jackson, OH, to support IFR operations at this airport.

Comments Invited

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

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it received 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 dely. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT post 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–14FDMS), which can be reviewed at *www.dot.gov/privacy*.

Availability of Rulemaking Documents

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

You may review the public docket containing the proposal, any comments received, and any final disposition in

person in the Dockets Office (see the **ADDRESSES** section for the address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Incorporation by Reference

Class E airspace is published in paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11H, dated August 11, 2023, and effective September 15, 2023. These updates would be published subsequently in the next update to FAA Order JO 7400.11. That order is publicly available as listed in the **ADDRESSES** section of this document.

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

The Proposal

The FAA is proposing to amend 14 CFR part 71 by modifying the Class E airspace extending upward from 700 feet above the surface to within a 6.8-mile (decreased from a 7.5-mile) radius of James A. Rhodes Airport, Jackson, OH; updating the geographic coordinates of airport to coincide with the FAA's aeronautical database; and removing the city associated with the airport from the header to comply with changes to FAA Order JO 7400.2P, Procedures for Handling Airspace Matters.

This action is the result of an airspace review conducted due to the decommissioning of the York VOR, which provided navigation information to this airport, as part of the VOR MON Program, and to support IFR operations at this airport.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

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

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AGL OH E5 Jackson, OH [Amended]

James A. Rhodes Airport, OH
(Lat. 38°58′53″ N, long. 82°34′40″ W)

That airspace extending upward from 700 feet above the surface within a 6.8-mile radius of the James A. Rhodes Airport.

* * * * *

Issued in Fort Worth, Texas, on November 1, 2023.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2023–24436 Filed 11–3–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2023–0690]

RIN 1625–AA08

Special Local Regulations; Recurring Marine Events, Sector Key West, Update

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

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to revise existing regulations by updating the table for existing events in the Seventh Coast Guard District Captain of the Port (COTP) Key West. This action is necessary to provide for the safety of life on these navigable waters in Key West, FL. Through this notice, the current list of recurring special local regulations is updated with the removal of an event that no longer takes place, the addition of two events, and revisions to existing events. When these special local regulations are enforced, certain restrictions are placed on marine traffic in specified areas. The Coast Guard invites your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before December 6, 2023.

ADDRESSES: You may submit comments identified by docket number USCG–2023–0690 using the Federal eRulemaking Portal at *https://www.regulations.gov*. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Lieutenant Hailye Wilson, Sector Key West, Waterways Management Division, Coast Guard; telephone (305) 292–8768 (ext. 768), email *Hailye.M.Wilson@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, Purpose, and Legal Basis

The Coast Guard proposes to amending and updating the annual recurring special local regulations for events in the geographic boundaries of the Seventh Coast Guard District Captain of the Port (COTP) Key West Zone that are listed in 33 CFR 100.701, paragraph (b) in Table 1 to § 100.701. The proposed rule would ensure that the public is informed of the most up to date recurring special local regulations. The current list under § 100.701, paragraph (b) in Table 1 to § 100.701 requires amendments to existing special local regulations, adds two new special local regulations expected to recur annually, and removes a special local regulation that is no longer required. The Coast Guard proposes this rulemaking under authority in 46 U.S.C. 70041.

III. Discussion of Proposed Rule

This rule proposes to make the following changes in 33 CFR 100.701 to paragraph (b) in Table 1 to § 100.701:

1. Removing the Yachting Key West Race Week special local regulation (SLR) from Line 1 since this event no longer occurs in the COTP Key West zone.
2. Moving the existing SLR in Line 2 to Line 1.
3. Moving the SLR in Line 3 to Line 2 and changing the date from the ''1st Weekend of June'' to ''One Saturday in June.'' There will also be non-substantive changes made to spelling and word usage for this SLR. In addition, a contingency will be added stating, ''Depending on the weather on the day of race, the racecourse might proceed counterclockwise to accommodate for current and wind.''
4. Inserting a new SLR in Line 3 for the Annual Swim Around Key West.
5. Inserting a new SLR in Line 4 for the Alligator Reef Lighthouse Swim/Friends of The Pool, Inc. and;
6. Moving the existing SLR in Line 4 to Line 5, and changing the event sponsor name from ''Super Boat International Productions, Inc.'' to ''Race World Offshore.''

Marine events listed in paragraph (b) of Table 1 to § 100.701 are listed as recurring over a particular time, during each month and each year. Exact dates are intentionally omitted since calendar dates for specific events change from year to year. Once dates for a marine event are known, the Coast Guard notifies the public it intends to enforce the special local regulation through various means including a notice of enforcement published in the **Federal Register**, Local Notice to Mariners, and Broadcast Notice to Mariners.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on 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 NPRM has not been designated a ''significant regulatory action,'' under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, and duration of the special local regulations. These areas are limited in size and duration, and usually do not affect high vessel traffic areas. Moreover, the Coast Guard would provide advance notice of the regulated areas to the local maritime community by Local Notice to Mariners, Broadcast Notice to Mariners via VHF–FM marine channel 16, and the rule would allow vessels to seek permission to enter the regulated area.

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 proposed rule would not have a significant economic impact on a substantial number of small entities.

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

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

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

C. Collection of Information

This proposed rule would 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 proposed rule under that order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

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

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or Tribal Government, in the aggregate, or by the private sector of

$100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed 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 made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves revising an existing recurring event to reflect a date and time change for the event. Normally such actions are categorically excluded from further review under paragraphs L61 in Table 3–1 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1, because it involves a revised special local regulation related to a marine event permit for marine parades, regattas, and other marine events. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

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

V. Public Participation and Request for Comments

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

Submitting comments. We encourage you to submit comments through the Federal Decision-Making Portal at *https://www.regulations.gov*. To do so, go to *https://www.regulations.gov,* type USCG–2023–0690 in the search box and click ''Search.'' Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using *https://www.regulations.gov,* call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions.

Viewing material in docket. To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the previous paragraph, and then select ''Supporting & Related Material'' in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the *https://www.regulations.gov* Frequently Asked Questions webpage. Also, if you click on the Dockets tab and then the proposed rule, you should see a ''Subscribe'' option for email alerts. The option will notify you when comments are posted, or a final rule is published.

We review all comments received, but we will only post comments that address the topic of the proposed rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

Personal information. We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

List of Subjects in 33 CFR Part 100

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

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR parts 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

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

Authority: 46 U.S.C. 70041; 33 CFR 1.05–1.

■ 2. In § 100.701, revise paragraph (b) of Table 1 to § 100.701 to read as follows:

§ 100.701 Special Local Regulations; Marine Events in the Seventh Coast Guard District.

* * * * *

TABLE 1 TO § 100.701

Number/date	Event	Sponsor	Location
*	*	* *	* * *
		(b) COTP Zone Key West; Special Local Regulations.	
1. Last Friday in April	Conch Republic Navy Parade and Battle.	Conch Republic Navy, LLC	Location: All waters approximately 150 yards offshore from Ocean Key Sunset Pier, Mallory Square and Pier B within the Key West Harbor in Key West, Florida.
2. One Saturday in June	Swim Around Key West	Florida Keys Community College.	Location: Beginning at Smathers Beach in Key West, Florida. The regulated area will move, west to the area offshore of Fort Zachary Taylor Historic State Park, north through Key West Harbor, east through Fleming Cut, south on Cow Key Channel and west back to origin. The center of the regulated area will at all times remain approximately 50 yards offshore of the island of Key West Florida; extend 50 yards in front of the lead safety vessel preceding the first race participants; extend 50 yards behind the safety vessel trailing the last race participants; and at all times extend 100 yards on either side of the race participants and safety vessels. Depending on the weather on the day of race, the racecourse might proceed counter-clockwise to accommodate for current and wind.

TABLE 1 TO § 100.701—Continued

Number/date	Event	Sponsor	Location
3. One Saturday in June	Annual Swim Around Key West.	Anna Fugina	Location: Beginning at Higgs Beach in Key West, Florida. The regulated area will move, west to the area offshore of Fort Zachary Taylor Historic State Park, north through Key West Harbor, east through Fleming Cut, south on Cow Key Channel and west, past Smathers Beach and back to origin. The center of the regulated area will at all times remain approximately 50 yards offshore of the island of Key West Florida; extend 50 yards in front of the lead safety vessel preceding the first race participants; extend 50 yards behind the safety vessel trailing the last race participants; and at all times extend 100 yards on either side of the race participants and safety vessels. Depending on the weather on the day of race, the racecourse might proceed counter-clockwise to accommodate for current and wind.
4. One Saturday in September.	Alligator Reef Lighthouse Swim.	Friends of The Pool, Inc	Location(s) (Primary): Beginning at a point Latitude 24°54.82′ N, longitude 080°38.03′ W, thence to latitude 24°54.36′ N, longitude 080°37.72′ W, thence to latitude 24°51.07′ N, longitude 080°37.14′ W, thence to latitude 24°54.36′ N, longitude 080°37.72′ W, thence to point of origin at latitude 24°54.82′ N, longitude 080°38.03′ W. Location(s) (Alternate) [1]: Beginning at a point Latitude 24°54.82′ N, longitude 080°38.03′ W, thence to latitude 24°53.25′ N, longitude 080°37.04′ W, thence to latitude 24°52.05′ N, longitude 080°38.85′ W, thence to latitude 24°54.36′ N, longitude 080°37.72′ W, thence to point of origin at latitude 24°54.82′ N, longitude 080°38.03′ W.
5. 2nd week (Wednesday through Sunday) in November.	Key West Offshore World Championship.	Race World Offshore	Location: In the Atlantic Ocean, off the tip of Key West, Florida, on the waters of the Key West Main Ship Channel, Key West Turning Basin, and Key West Harbor Entrance.

* * * * * * *

Jason D. Ingram,

Captain, U.S. Coast Guard, Captain of the Port Sector Key West.

[FR Doc. 2023–24470 Filed 11–3–23; 8:45 am]

BILLING CODE 9110–04–P

POSTAL SERVICE

39 CFR Part 111

Use of Foreign Return Addresses on Domestic Mailpieces

AGENCY: Postal Service™.

ACTION: Proposed rule.

SUMMARY: The Postal Service is proposing to amend *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM®) in various subsections to clarify the consequences of the use of a foreign return address on a domestic mailpiece.

DATES: Submit comments on or before December 6, 2023.

ADDRESSES: Mail or deliver written comments to the Director, Product Classification, U.S. Postal Service, 475 L'Enfant Plaza SW, Room 4446, Washington, DC 20260–5015. If sending comments by email, include the name and address of the commenter and send to *PCFederalRegister@usps.gov,* with a subject line of ''Use of Foreign Return Addresses''. Faxed comments are not accepted.

You may inspect and photocopy all written comments, by appointment only, at USPS® Headquarters Library, 475 L'Enfant Plaza SW, 11th Floor North, Washington, DC 20260. These records are available for review on Monday through Friday, 9 a.m.–4 p.m., by calling 202–268–2906.

FOR FURTHER INFORMATION CONTACT: Catherine Knox at (202) 268–5636, Treishawna Harris at (202) 268–2965, or Garry Rodriguez at (202) 268–7281.

SUPPLEMENTARY INFORMATION: All submitted comments and attachments are part of the public record and subject to disclosure. Do not enclose any material in your comments that you consider to be confidential or inappropriate for public disclosure.

Effective April 1, 2023, DMM subsection 602.1.5.4, *Using Return Addresses,* was amended by publication in Postal Bulletin 22619 (3–9–23) to eliminate an exception that allowed a domestic mailpiece to have a foreign return address in certain circumstances as a courtesy. The Postal Service is proposing to further amend subsection 602.1.5.4 and various other subsections in the DMM to clarify the procedures applicable to the undeliverable domestic mailpieces bearing a foreign return address.

The elimination of the courtesy exception allowing foreign return addresses on domestic mailpieces under certain circumstances requires amendment of the procedures that apply to undeliverable domestic mailpieces bearing a foreign return address, which are no longer authorized under DMM 602.1.5.4. Therefore, the Postal Service is proposing to revise DMM subsections 602.1.5.4, and 609.4.3, to clarify procedures applicable to undeliverable domestic mailpieces bearing a foreign return address.

The Postal Service is authorized pursuant to 39 U.S.C. 404(a)(1) to provide for the disposition of undeliverable mail. However, for the Postal Service to incur destination country delivery charges as a result of attempting to return certain undeliverable domestic mailpieces with a foreign return address is not practicable. Thus, under this proposed rule, such mailpieces would be handled by the Postal Service, in accordance with Postal Service's dead mail procedures.

In addition, if the proposed rule is adopted the Postal Service would also revise a few related sections of the International Mail Manual (IMM) including subsection 762.2, *Undeliverable Domestic Mail Bearing U.S. Postage and a Foreign Return Address.*

The Postal Service is proposing to implement this change effective January 1, 2024.

We believe the proposed revisions will provide customers with a more efficient mailing experience. Although exempt from the notice and comment requirements of the Administrative Procedure Act (5 U.S.C. 553(b), (c)) regarding proposed rulemaking by 39 U.S.C. 410(a), the Postal Service invites public comment on the following proposed revisions 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.

If the proposed rule is adopted, we will publish an appropriate amendment to 39 CFR part 111 to reflect these changes.

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

Accordingly, 39 CFR part 111 is proposed to be 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, 401–404, 414, 416, 3001–3018, 3201–3220, 3401–3406, 3621, 3622, 3626, 3629, 3631–3633, 3641, 3681–3685, and 5001.

■ 2. Revise the *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)

* * * * *

600 Basic Standards for All Mailing Services

* * * * *

602 Addressing

1.0 Elements of Addressing

* * * * *

1.5 Return Addresses

* * * * *

[*Revise the heading of 1.5.4 to read as follows:*]

1.5.4 Use of Foreign Return Addresses

[*Revise the text of 1.5.4 to read as follows:*]

When U.S. postage is applied to a domestic mailpiece, as defined under 608.2.1 and 608.2.2, only a domestic return address is authorized. An undeliverable domestic mailpiece bearing a foreign return address cannot be returned to sender and will be handled as dead mail under 507.1.9.

* * * * *

609 Filing Indemnity Claims for Loss or Damage

* * * * *

4.0 Claims

* * * * *

4.3 Nonpayable Claims

Indemnity is not paid for insured mail (including Priority Mail Express and Priority Mail), Registered Mail, COD, or Priority Mail and Priority Mail Express in these situations:

* * * * *

[Revise the text of 4.3 by adding a new item ''ag'' to read as follows:]

ag. An undeliverable, registered or insured domestic mailpiece bearing a foreign return address.

* * * * *

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2023–24447 Filed 11–3–23; 8:45 am]

BILLING CODE P

Notices

Federal Register
Vol. 88, No. 213
Monday, November 6, 2023

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture will submit the following information collection requirement(s) to OMB for review and approval under the Paperwork Reduction Act of 1995, Public Law 104–13 on or after the date of publication of this notice. Comments are requested regarding: (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 the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding these information collections are best assured of having their full effect if received by December 6, 2023. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

National Agricultural Statistics Service

Title: Agricultural Prices.

OMB Control Number: 0535–0003.

Summary of Collection: The U.S. Department of Agriculture needs estimates of prices received by farmers and prices paid by farmers for production goods and services for the following purposes:

—computing Parity Prices in accordance with requirements of the Agricultural Adjustment Act of 1938 as amended;
—estimating value of production, inventory values, and cash receipts from farming;
—determining the level for farmer-owned reserves;
—providing guidelines for Risk Management Agency price selection options;
—determining Federal disaster prices to be paid;
—input into agricultures contribution to the national income and product accounts (NIPA);
—use in agricultures contribution to national gross domestic product (GDP);
—establishing USDA's net farm income projections by the Economic Research Service; and
—determining the grazing fee on Federal lands.

General authority for these data collection activities is granted under U.S. Code Title 7, Section 2204 (a). This statute specifies that ''The Secretary of Agriculture shall procure and preserve all information concerning agriculture which he can obtain . . . by the collection of statistics . . . and shall distribute them among agriculturalists.''

Need and Use of the Information: The NASS price program computes annual U.S. weighted average prices received by farmers for wheat, barley, oats, corn, grain sorghum, rice, cotton, peanuts, pulse crops and oilseeds based on monthly marketing. Estimates of prices received are used by NASS to determine the value of agricultural production. Prices estimates are used by many Government agencies as a general measure of commodity price changes, economic analysis relating to farm income and alternative marketing policies, and for disaster and insurance payments. NASS estimates based on these surveys are used as a Principle Economic Indicator of the United States. These price estimates are also used to compute Parity Prices in accordance with requirements of the Agricultural Adjustment Act of 1938 as amended (Title III, Subtitle A, Section 301(a)).

Description of Respondents: Farms; Business or other for-profit.

Number of Respondents: 39,525.

Frequency of Responses: Reporting: Weekly; Monthly; Quarterly; Biennially; Annually.

Total Burden Hours: 25,205.

Levi S. Harrell,

Departmental Information Collection Clearance Officer.

[FR Doc. 2023–24460 Filed 11–3–23; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF AGRICULTURE

Farm Service Agency

[Docket ID: FSA–2023–0021]

Information Collection Request; Urban Agriculture Cooperative Agreement

AGENCY: Farm Service Agency, United States Department of Agriculture.

ACTION: Notice; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act, the Farm Service Agency (FSA) is requesting comments from all interested individuals and organizations on a new information collection request associated with Urban Agriculture Cooperative Agreements. The awarded cooperators are assisting FSA in providing outreach, education, resources, and technical assistance for urban agriculture producers to access USDA programs and focus on long-term food sovereignty in historically marginalized and underfunded communities.

DATES: We will consider comments that we receive by January 5, 2024.

ADDRESSES: We invite you to submit comments on this notice. You may submit comments electronically through the Federal eRulemaking Portal: Go to *http://www.regulations.gov* and search for Docket ID FSA–2023–0021. Follow the online instructions for submitting comments.

All comments received will be posted without change and will be publicly available on *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: William O. Cruz, telephone: (202) 205–4567; email: *william.cruz@usda.gov.*

SUPPLEMENTARY INFORMATION:

Description of Information Collection Request

Title: Urban Agriculture Cooperative Agreement.

OMB Control Number: 0560–0000.

Type of Request: New.

Abstract: The awarded cooperators are working to successfully implement urban agriculture outreach, training, technical assistance, and education to urban agriculture communities. With the complex nature of some of FSA's programs, FSA is focusing on additional outreach and education to producers who could benefit from additional outreach to (1) increase knowledge, awareness, and participation in FSA and USDA programs and services associated with growing food in an urban area; (2) assist farmers with expanding their farming operations, accessing land, and implementing climate-friendly practices that can mitigate their susceptibility to natural disasters in urban areas; and (3) increase representation of underserved farmers serving on Urban County Committees.

FSA is requesting comments on the project's semi-annual progress reports that the awarded cooperators are required to submit to FSA. We received OMB clearance to use the electronic submission (SF–270, SF–424 and SF–425) in the *Grants.gov.*

For the following estimated total annual burden on respondents, the formula used to calculate the total burden hour is the estimated average time per responses hours multiplied by the estimated total annual responses.

Estimate of Annual Burden: Public reporting burden for the collection of information is estimated to average 10 hours per response.

Respondents: Cooperators.

Estimated Number of Respondents: 18.

Estimated Number of Responses per Respondent: 2.

Estimated Total Annual Number of Responses: 36.

Estimated Average Time per Response: 10 hours.

Estimated Total Annual Burden Hours: 360 hours.

We are requesting comments on all aspects of the information collections to help us:

(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 collection of information including the validity of the methodology and assumptions used;

(3) Evaluate the quality, utility, and clarity of the information technology; and

(4) Minimize the burden of the information collection on those who respond through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses where provided, will be made a matter of public record. Comments will be summarized and included in the request for OMB approval of the information collection.

Zach Ducheneaux,

Administrator, Farm Service Agency.

[FR Doc. 2023–24413 Filed 11–3–23; 8:45 am]

BILLING CODE 3410–E2–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the U.S. Virgin Islands Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Notice of virtual business meetings.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the U.S. Virgin Islands Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold public meetings via Zoom. The purpose of these meetings is to discuss, plan, and vote, as needed, on matters related to the Committee's inaugural civil rights project.

DATES:

- Wednesday, November 15, 2023, from a.m.–1 p.m. Atlantic Time
- Thursday, November 30, 2023, from 12 p.m.–1:30 p.m. Atlantic Time

ADDRESSES: These meetings will be held via Zoom.

- *November 15th Meeting*
  - *Meeting Link (Audio/Visual): https://www.zoomgov.com/j/1604313189*
  - *Join by Phone (Audio Only):* 1–833–435–1820 USA Toll Free; Meeting ID: 160 431 3189#
- *November 30th Meeting*
  - *Meeting Link (Audio/Visual): https://www.zoomgov.com/j/1612643265*
  - *Join by Phone (Audio Only):* 1–833–435–1820 USA Toll Free; Meeting ID: 161 264 3265#

FOR FURTHER INFORMATION CONTACT: David Barreras, Designated Federal Officer, at *dbarreras@usccr.gov* or 1–202–656–8937.

SUPPLEMENTARY INFORMATION: These Committee meetings are available to the public through the meeting links above. Any interested member of the public may attend these meetings. An open comment period will be provided to allow members of the public to make oral statements as time allows. Pursuant to the Federal Advisory Committee Act, public minutes of the meeting will include a list of persons who are present at the meeting. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Closed captioning is available by selecting ''CC'' in the meeting platform. To request additional accommodations, please email *svillanueva@usccr.gov* at least 10 business days prior to the meeting.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the scheduled meeting. Written comments may be emailed to Sarah Villanueva at *svillanueva@usccr.gov.* Persons who desire additional information may contact the Regional Programs Coordination Unit at 1–202–656–8937.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meeting. Records of the meetings will be available via *www.facadatabase.gov* under the Commission on Civil Rights, U.S. Virgin Islands Advisory Committee Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *www.usccr.gov,* or may contact the Regional Programs Coordination Unit at *svillanueva@usccr.gov.*

Agenda

I. Welcome and Roll Call
II. Annoucements and Updates
III. Committee Discussion
IV. Next Steps
V. Public Comment

VI. Adjournment

Dated: October 31, 2023.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2023–24390 Filed 11–3–23; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Ohio Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Notice of virtual business meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Ohio Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a public meeting via Zoom. The purpose of the meeting is to discuss the outline of the draft report on the source of income discrimination in Ohio housing.

DATES: Wednesday, December 13, 2023, from 12 p.m.–1 p.m. Eastern Time.

ADDRESSES: The meeting will be held via Zoom.

Registration Link (Audio/Visual): https://www.zoomgov.com/j/1619236390

Join by Phone (Audio Only): 1–833–435–1820 USA Toll Free; Meeting ID: 161 923 6390#

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski, Designated Federal Officer, at *mwojnaroski@usccr.gov* or 1–202–618–4158.

SUPPLEMENTARY INFORMATION: This Committee meeting is available to the public through the registration link above. Any interested member of the public may attend this meeting. An open comment period will be provided to allow members of the public to make oral statements as time allows. Pursuant to the Federal Advisory Committee Act, public minutes of the meeting will include a list of persons who are present at the meeting. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Closed captioning is available by selecting ''CC'' in the meeting platform. To request additional accommodations, please email *svillanueva@usccr.gov* at least 10 business days prior to the meeting.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the scheduled meeting. Written comments may be emailed to Sarah Villanueva at *svillanueva@usccr.gov.* Persons who desire additional information may contact the Regional Programs Coordination Unit at 1–202–618–4158.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meeting. Records of the meetings will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Ohio Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Coordination Unit at *svillanueva@usccr.gov.*

Agenda

I. Welcome and Roll Call
II. Approval of Minutes
III. Announcements and Updates
IV. Committee Discussion
V. Next Steps
VI. Public Comment
VII. Adjournment

Dated: October 31, 2023.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2023–24391 Filed 11–3–23; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Hawai'i Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of a virtual briefing.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a meeting of the Hawai'i Advisory Committee to the U.S. Commission on Civil Rights will convene by ZoomGov on Monday, November 20, 2023, from 2 p.m. to 4:30 p.m. HST, to collect testimony related to the Committee's topic ''Examining Hawai'i's Child Welfare System and its Impact on Native Hawaiian Children and Families.''

DATES: The briefing will take place on Monday, November 20, 2023, from 2 p.m.–4:30 p.m. HST.

ADDRESSES:

Zoom Link to Join (Audio/Visual): https://www.zoomgov.com/meeting/register/vJIsd-2vrj8jHPPWjAz0vH_PqGvCnayAwHg.

Audio: (833) 435–1820; Meeting ID: 161 047 0496.

FOR FURTHER INFORMATION CONTACT: Kayla Fajota, Designated Federal Officer (DFO) at *kfajota@usccr.gov* or by phone at (434) 515–2395.

SUPPLEMENTARY INFORMATION: Committee meetings are available to the public through the videoconference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. Per the Federal Advisory Committee Act, public minutes of the meeting will include a list of persons who are present at the meeting. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Closed captions will be provided for individuals who are deaf, hard of hearing, or who have certain cognitive or learning impairments. To request additional accommodations, please email Angelica Trevino, Support Services Specialists, at *atrevino@usccr.gov* at least 10 business days prior to the meeting.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be emailed to Kayla Fajota at *kfajota@usccr.gov.*

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzl0AAA.*

Please click on ''Committee Meetings'' tab. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's website, *https://www.usccr.gov,* or may contact the Regional Programs Unit at

the above phone number or email address.

Agenda

I. Welcome, Opening Remarks, and Roll Call
II. Panelists Presentations
III. Committee Question and Answer
IV. Public Comment
V. Adjournment

Dated: October 31, 2023.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2023–24398 Filed 11–3–23; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Georgia Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Notice of public meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Georgia Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a public meeting via Zoom. The purpose of the meeting is to discuss the post-report activities of the Committee's recent civil rights project on civil asset forfeiture in Georgia.

DATES: Friday, December 1, 2023, from 10 a.m.–11 a.m. Eastern Time.

ADDRESSES: The meeting will be held via Zoom.

Registration Link (Audio/Visual): https://www.zoomgov.com/j/1601357294.

Join by Phone (Audio Only): 1–833–435–1820 USA Toll-Free; Meeting ID: 160 135 7294#.

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski, Designated Federal Officer (DFO), at *mwojnaroski@usccr.gov* or 1–202–618–4158.

SUPPLEMENTARY INFORMATION: This Committee meeting is available to the public through the registration link above. Any interested member of the public may attend this meeting. An open comment period will be provided to allow members of the public to make oral statements as time allows. Pursuant the Federal Advisory Committee Act, public minutes of the meeting will include a list of persons who are present at the meeting. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Closed captioning is available by selecting ''CC'' in the meeting platform. To request additional accommodations, please email *svillanueva@usccr.gov* at least 10 business days prior to the meeting.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the scheduled meeting. Written comments may be emailed to Sarah Villanueva at *svillanueva@usccr.gov.* Persons who desire additional information may contact the Regional Programs Coordination Unit at 1–434–515–0204.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meeting. Records of the meetings will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Georgia Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Coordination Unit at *svillanueva@usccr.gov.*

Agenda

I. Welcome & Roll Call
II. Approval of Minutes
III. Announcements and Updates
IV. Discussion: Post-Report Activities
V. Next Steps
VI. Public Comment
VII. Adjournment

Dated: October 31, 2023.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2023–24392 Filed 11–3–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Census Household Panel Topical 2 and Topical 3 Operations

On June 29, 2023, the Department of Commerce received clearance from the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act of 1995 to conduct the Census Household Panel recruitment and first topical operation (OMB No. 0607–1025, Exp. 6/20/26). The Census Household Panel is designed to ensure availability of frequent data collection for nationwide estimates on a variety of topics for a variety of subgroups of the population.

Content for both Topical 2 and Topical 3 will consist of a modified version of the Household Pulse Survey questionnaire. Topics covered include employment, telework, access to infant formula, health and disability, children's mental health treatment, social connection/isolation, childcare arrangements, educational enrollment, inflation and spending, food security, experience of national disasters, housing, COVID testing and symptoms, COVID vaccination uptake, and long COVID. Data will be collected in December and January to study methodological implications of having a repeated measure design. These data will also be studied in conjunction with the January fielding of the Household Pulse Survey. The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on February 6, 2023, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: U.S. Census Bureau, Department of Commerce.

Title: Census Household Panel Topical 2 and Topical 3 Operations.

OMB Control Number: 0607–1025.

Form Number(s): To be determined.

Type of Request: Request for a Revision of a currently approved collection.

Number of Respondents: 12,225 panel members.

Average Hours per Response: 4 hours per year (20 minutes for monthly collection).

Burden Hours: 43,956.

Needs and Uses: The Census Household Panel is a probability-based nationwide nationally representative survey panel designed to test the methods to collect data on a variety of

topics of interest, and for conducting experimentation on alternative question wording and methodological approaches. The goal of the Census Household Panel is to ensure availability of frequent data collection for nationwide estimates on a variety of topics and a variety of subgroups of the population, meeting standards for transparent quality reporting of the Federal Statistical Agencies and the Office of Management and Budget (OMB).

Panelists and households selected for the Panel were recruited from the Census Bureau's gold standard Master Address File. This ensures the Panel is rooted in this rigorously developed and maintained frame and available for linkage to administrative records securely maintained and curated by the Census Bureau. Invitations to complete the monthly surveys will be sent via email and SMS messages and questionnaires will be mainly internet self-response. The Panel will maintain representativeness by allowing respondents who do not use the internet to respond via computer-assisted telephone interviewing (CATI). All panelists will receive an incentive for each complete questionnaire. Periodic replenishment samples will maintain representativeness and panelists will be replaced after a period of three years.

Affected Public: Individuals or Households.

Frequency: Monthly.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13, United States Code, Sections 8(b), 141, 182 and 193.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0607–1025.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2023–24429 Filed 11–3–23; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–56–2023]

Foreign-Trade Zone 61; Application for Subzone; PR Five Vega Alta, LLC; Vega Alta, Puerto Rico

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the Department of Economic Development and Commerce, grantee of FTZ 61, requesting subzone status for the facility of PR Five Vega Alta, LLC, located in Vega Alta, Puerto Rico. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on November 1, 2023.

The proposed subzone (61.9878 acres) is located at Carr. 690, Km. 1.3, Vega Alta, Puerto Rico. No authorization for production activity has been requested at this time.

In accordance with the FTZ Board's regulations, Camille Evans of the FTZ Staff is designated examiner to review the application and make recommendations to the FTZ Board.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is December 18, 2023. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to January 2, 2024.

A copy of the application will be available for public inspection in the ''Online FTZ Information Section'' section of the FTZ Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Camille Evans at *Camille.Evans@trade.gov.*

Dated: November 1, 2023.

Elizabeth Whiteman,

Executive Secretary.

[FR Doc. 2023–24480 Filed 11–3–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–896]

Common Alloy Aluminum Sheet From India: Final Results of Countervailing Duty Administrative Review; 2020–2021

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that Hindalco Industries Limited (Hindalco), a producer/exporter of common alloy aluminum sheet (aluminum sheet) from India received countervailable subsidies during the period of review (POR), August 14, 2020, through December 31, 2021.

DATES: Applicable November 6, 2023.

FOR FURTHER INFORMATION CONTACT: Benito Ballesteros, AD/CVD Operations, Office IX, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–7425.

SUPPLEMENTARY INFORMATION:

Background

On May 4, 2023, Commerce published the *Preliminary Results* of this administrative review in the **Federal Register** and invited interested parties to comment.[1] On August 1, 2023, Commerce extended the deadline for issuing the final results until October 31, 2023.[2] For a complete description of the events that occurred since the publication of the *Preliminary Results, see* the Issues and Decision Memorandum.[3]

Scope of the Order [4]

The product covered by the *Order* is aluminum sheet.[5]

[1] *See Common Alloy Aluminum Sheet from India: Preliminary Results of Countervailing Duty Administrative Review and Partial Rescission; 2020–21,* 88 FR 28487 (May 4, 2023) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum, ''Extension of Deadline for Final Results,'' dated August 1, 2023.

[3] *See* Memorandum, ''Common Alloy Aluminum Sheet from India: Issues and Decision Memorandum for the Final Results of the Countervailing Duty Administrative Review; 2020–2021,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[4] *See Common Alloy Aluminum Sheet from Bahrain, India, and the Republic of Turkey: Countervailing Duty Orders,* 86 FR 22144 (April 27, 2021) (*Order*).

[5] For a complete description of the scope of the *Order, see Preliminary Results* PDM.

Analysis of Comments Received

All issues raised by the interested parties in their case and rebuttal briefs are addressed in the Issues and Decision Memorandum. A list of topics discussed in the Issues and Decision Memorandum is provided in the appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Based on comments received from interested parties, we revised our analysis for certain programs in this review.[6] However, we made no changes to the calculations of the net countervailable subsidy rates for Hindalco.

Methodology

Commerce conducted this administrative review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we find that there is a subsidy, *i.e.,* a government-provided financial contribution that gives rise to a benefit to the recipient, and that the subsidy is specific.[7] For a full description of the methodology underlying all of Commerce's conclusions, *see* the Issues and Decision Memorandum.

Final Results of Review

As a result of this review, Commerce determines the following net countervailable subsidy rates exist for 2020 and 2021:

Company	Subsidy rate (percent ad valorem) 2020	Subsidy rate (percent ad valorem) 2021
Hindalco Industries Limited[8]	37.90	32.43

Disclosure

Normally, Commerce discloses to interested parties the calculations for the final results of review within five days of public announcement or, if there is no public announcement, within five days of the date of publication of the notice of final results in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because we have made no changes to Hindalco's calculations in the final results, there are no calculations to disclose.

Assessment Rates

In accordance with section 751(a)(2)(C) of the Act and 19 CFR 351.212(b)(2), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries covered by this review for Hindalco at the applicable *ad valorem* assessment rates listed for the corresponding time periods. Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

In accordance with section 751(a)(2)(C) of the Act, Commerce will instruct CBP to collect cash deposits of estimated countervailing duties in the amount established for 2021 for Hindalco with regard to shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review. For all non-reviewed firms, CBP will continue to collect cash deposits of estimated countervailing duties at the all-others rate or the most recent company-specific rate applicable to the company, as appropriate. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Administrative Protective Order

This notice also serves as the final reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing these final results in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: October 31, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discusses in the Issues and Decision Memorandum

I. Summary
II. Background
III. Subsidies Valuation
IV. Analysis of Programs
V. Discussion of the Issues
  Comment 1: Benefit Analysis—Mining Rights Lease Extensions Program
  Comment 2: Whether the Provision of Coal for Less than Adequate Renumeration (LTAR) is Specific
  Comment 3: Whether the Selection of the Coal Benchmark Is Appropriate
  Comment 4: Whether the Remission of Duties and Taxes on Export Products (RODTEP) Program is Countervailable
  Comment 5: Whether to Apply Adverse Facts Available (AFA) to the Programs Discovered at Verification
VI. Recommendation

[FR Doc. 2023–24489 Filed 11–3–23; 8:45 am]

BILLING CODE 3510–DS–P

[6] For a full description of these revisions, *see* the Issues and Decision Memorandum.

[7] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[8] As discussed in the PDM, Commerce has found the following company to be cross-owned with Hindalco: Utkal Alumina International Limited. *See Preliminary Results* PDM at 7.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–588–874]

Certain Hot-Rolled Steel Flat Products From Japan: Preliminary Results and Partial Rescission of Antidumping Duty Administrative Review; 2021–2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that one of the two producers/exporters of hot-rolled steel flat products (hot-rolled steel) from Japan, sold subject merchandise in the United States at prices below normal value during the period of review (POR) October 1, 2021, through September 30, 2022.

DATES: Applicable November 6, 2023.

FOR FURTHER INFORMATION CONTACT: Jack Zhao or Myrna Lobo, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1396 and (202) 482–2371, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce is conducting an administrative review of the antidumping duty order on hot-rolled steel from Japan in accordance with section 751(a)(1)(B) of Tariff Act of 1930, as amended (the Act).[1] Commerce initiated this administrative review of the *Order* on December 5, 2022, covering three producers and/or exporters.[2] We selected two companies, NSC[3] and JFE[4] as the mandatory respondent.[5] On March 3, 2023, Global Tubing LLC withdrew its review request with regard to JFE, pursuant to 19 CFR 351.213(d)(1).[6] As Global Tubing LLC is the only party that requested a review for JFE and the request for withdrawal is timely, Commerce is preliminarily rescinding the review with respect to JFE.[7] Subsequently, Commerce selected Tokyo Steel Manufacturing Co, Ltd. (Tokyo Steel), as a mandatory respondent in this review.[8]

On June 27, 2023, in accordance with section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1), we extended the deadline for the preliminary results of this review until October 31, 2023.[9] For a detailed description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[10]

Scope of the Order

The merchandise covered by the *Order* is hot-rolled steel from Japan. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.[11]

Methodology

Commerce is conducting this administrative review in accordance with section 751(a) of the Act. Export price and constructed export price were calculated in accordance with section 772 of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. A list of topics discussed in the Preliminary Decision Memorandum is attached as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). Access to ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Rescission of Administrative Review, in Part

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the parties that requested a review withdraw the request within 90 days of the date of publication of the notice of initiation. Commerce received timely-filed withdrawal requests for JFE.[12] Because the withdrawal requests were timely filed and no other party requested a review of JFE, in accordance with 19 CFR 351.213(d)(1), Commerce is rescinding this review of the *Order* with respect to JFE.

Preliminary Results

We preliminarily determine the following estimated weighted-average dumping margins for the period October 1, 2021, through September 30, 2022:

Producer/exporter	Weighted-average dumping margin (percent)
Nippon Steel Corporation/Nippon Steel Nisshin Co., Ltd./Nippon Steel Trading Corporation	1.39
Tokyo Steel Manufacturing Co., Ltd	0.00

Disclosure and Public Comment

We intend to disclose the calculations performed for these preliminary results of review to interested parties within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs no later than 30 days after the date of publication of this notice. Rebuttal briefs, the content of which is limited to issues raised in the case briefs, may be filed no later than seven days after the date for filing case briefs.[13] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) a statement of the issue;

[1] *See Certain Hot-Rolled Steel Flat Products from Australia, Brazil, Japan, the Republic of Korea, the Netherlands, the Republic of Turkey, and the United Kingdom: Amended Final Affirmative Antidumping Determinations for Australia, the Republic of Korea, and the Republic of Turkey and Antidumping Duty Orders,* 81 FR 67962 (October 3, 2016) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 87 FR 74404 (December 5, 2022) (*Initiation Notice*).

[3] NSC is a single entity comprised of the following companies: Nippon Steel Corporation; Nippon Steel Nisshin Co., Ltd.; and Nippon Steel Trading Corporation. *See Certain Hot-Rolled Steel Flat Products from Japan: Notice of Final Results of Antidumping Duty Changed Circumstances Review,* 84 FR 46713 (September 5, 2019).

[4] JFE is a single entity comprised of JFE Shoji Corporation and JFE Steel Corporation. *See Certain Hot-Rolled Steel Flat Products from Japan: Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2018–2019, 86 FR 47615 (August 26, 2021).* In the absence of record information indicating that Commerce should reevaluate this determination, we are treating these companies as a single entity for purposes of respondent selection.

[5] *See* Memorandum, ''Respondent Selection for the 2021–2022 Antidumping Duty Administrative Review of Certain Hot-Rolled Steel Flat Products from Japan,'' dated February 23, 2023.

[6] *See* Letter from Global Tubing LLC, ''Withdrawal of Global Tubing LLC's Request for Administrative Review of JFE Steel and JFE Shoji,'' dated March 3, 2023 (JFE Letter of Withdrawal).

[7] *See* 19 CFR 351.213(d)(1).

[8] *See* Memorandum, ''Respondent Selection for the 2021–2022 Antidumping Duty Administrative Review of Certain Hot-Rolled Steel Flat Products from Japan—Selection of Tokyo Steel Manufacturing Co., Ltd. as a Mandatory Respondent,'' dated March 7, 2023.

[9] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,'' dated June 27, 2023.

[10] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Reviews: Certain Hot-Rolled Steel Flat Products from Japan; 2021–2022,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[11] *Id.*

[12] *See* JFE Letter of Withdrawal.

[13] *See* 19 CFR 351.309(d).

(2) a brief summary of the argument; and (3) a table of authorities.[14] Case and rebuttal briefs should be filed using ACCESS [15] and must be served on interested parties.[16] Executive summaries should be limited to five pages total, including footnotes. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[17]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed via ACCESS. An electronically filed request must be received successfully in its entirety by 5:00 p.m. Eastern Time within 30 days of the date of publication of this notice.[18] Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues parties intend to discuss. If a request for a hearing is made, Commerce intends to hold the hearing at a date and time to be determined.[19] Parties should confirm the date, time, and location of the hearing two days before the scheduled date.

Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any case or rebuttal briefs, no later than 120 days after the date of publication of this notice, unless extended.[20]

Assessment Rates

Upon completion of the administrative review, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries. If the weighted-average dumping margins for NSC and Tokyo Steel are not zero or *de minimis* (*i.e.,* less than 0.5 percent) in the final results of this review, we will calculate importer-specific *ad valorem* assessment rates for the merchandise based on the ratio of the total amount of dumping calculated for the examined sales made during the POR to each importer and the total entered value of those same sales, in accordance with 19 CFR 351.212(b)(1). Where an importer-specific *ad valorem* assessment rate is zero or *de minimis* in the final results of review, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties in accordance with 19 CFR 351.106(c)(2). If NSC's and Tokyo Steel's weighted-average dumping margins are zero or *de minimis* in the final results of review, we will instruct CBP not to assess duties on any of its entries in accordance with the *Final Modification for Reviews, i.e.,* ''{w}here the weighted-average margin of dumping for the exporter is determined to be zero or *de minimis,* no antidumping duties will be assessed.'' [21]

For entries of subject merchandise during the POR produced by NSC or Tokyo Steel for which the producer did not know its merchandise was destined for the United States, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company (or companies) involved in the transaction.[22]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of the notice of final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for each specific company listed above will be that established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously investigated companies not participating in this review, the cash deposit will continue to be the company-specific rate published for the most recently-completed segment of this proceeding in which the company participated; (3) if the exporter is not a firm covered in this review, or the underlying investigation, but the manufacturer is, then the cash deposit rate will be the rate established for the most recent segment for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 5.58 percent, the all-others rate established in the less-than-fair-value investigation.[23] These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: October 31, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Rescission of Administrative Review, in Part
V. Discussion of the Methodology
VI. Currency Conversion
VII. Recommendation

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[14] *See* 19 CFR 351.309(c)(2) and (d)(2).

[15] *See, generally,* 19 CFR 351.303.

[16] *See* 19 CFR 351.303(f).

[17] *See Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings; Final Rule,* 88 FR 67069 (September 29, 2023).

[18] *See* 19 CFR 351.310(c).

[19] *See* 19 CFR 351.310(d).

[20] *See* section 751(a)(3)(A) of the Act and 19 CFR 351.213(h).

[21] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings; Final Modification,* 77 FR 8101, 8102 (February 14, 2012) (*Final Modification for Reviews*).

[22] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[23] *See Order.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–062]

Cast Iron Soil Pipe Fittings From the People's Republic of China: Final Results of the Expedited First Sunset Review of the Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) finds that revocation of the antidumping duty (AD) order on cast iron soil pipe fittings (soil pipe fittings) from the People's Republic of China (China) would be likely to lead to the continuation or recurrence of dumping at the levels indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable November 6, 2023.

FOR FURTHER INFORMATION CONTACT: Katherine Johnson, 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) 482–4929.

SUPPLEMENTARY INFORMATION:

Background

On August 31, 2018, Commerce published the AD order on soil pipe fittings from China.[1] On July 3, 2023, Commerce published the notice of initiation of the first sunset review of the *Order,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] On July 18, 2023, Commerce received a notice of intent to participate in this review from the Cast Iron Soil Pipe Institute (the domestic interested party) [3] within the deadline specified in 19 CFR 351.218(d)(1)(i).[4] The domestic interested party claimed interested party status under section 771(9)(E) of the Act, and 19 CFR 351.102(b)(17) and (29)(vii) as a trade or business association, a majority of whose members manufacture or produce the domestic like product in the United States. On August 2, 2023, the domestic interested party provided a complete substantive response for this review within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[5] We received no substantive responses from any other interested parties, nor was a hearing requested. On August 22, 2023, Commerce notified the U.S. International Trade Commission (ITC) that it did not receive an adequate substantive response from respondent interested parties.[6] As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted an expedited (120-day) sunset review of the *Order.*

Scope of the Order

The merchandise covered by the *Order* is cast iron soil pipe fittings, finished and unfinished, regardless of industry or proprietary specifications, and regardless of size. The subject merchandise is currently provided for in item 7307.11.0045 of the Harmonized Tariff Schedule of the United States (HTSUS). Subject merchandise may also enter under HTSUS 7324.29.0000 and 7307.92.3010. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise is dispositive. For a full description of the scope of the *Order, see* the Issues and Decision Memorandum.[7]

Analysis of Comments Received

All issues raised in this review, including the likelihood of continuation or recurrence of dumping in the event of revocation of the *Order* and the magnitude of the margins likely to prevail if the *Order* were revoked, are addressed in the accompanying Issues and Decision Memorandum.[8] A list of topics discussed in the Issues and Decision Memorandum is included as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* A complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Results of Sunset Review

Pursuant to sections 751(c)(1) and 752(c)(1) and (3) of the Act, Commerce determines that revocation of the *Order* would be likely to lead to continuation or recurrence of dumping, and that the magnitude of the margin likely to prevail would be up to 360.30 percent.

Administrative Protective Order

This notice serves as the only reminder to interested parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing these final results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act and 19 CFR 351.218.

Dated: October 31, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. History of the *Order*
V. Legal Framework
VI. Discussion of the Issues
  1. Likelihood of Continuation or Recurrence of Dumping
  2. Magnitude of the Margin of Dumping Likely To Prevail
VII. Final Results of Sunset Review
VIII. Recommendation

[FR Doc. 2023–24477 Filed 11–3–23; 8:45 am]

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[1] *See Cast Iron Soil Pipe Fittings from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order,* 83 FR 44570 (August 31, 2018) (*Order*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 88 FR 42688 (July 3, 2023) (*Initiation Notice*). In the *Initiation Notice,* the product is erroneously listed as ''Cast Iron Soil Pipe,'' but the correct case number for the *Order* is given.

[3] The Cast Iron Soil Pipe Institute's members are Charlotte Pipe & Foundry and McWane, Inc., the parent company of AB&I Foundry and Tyler Pipe, both of which were domestic producers of soil pipe fittings during the sunset period of review.

[4] *See* Domestic Interested Party's Letter, ''Notice of Intent to Participate in the First Five-Year Review,'' dated July 18, 2023.

[5] *See* Domestic Interested Party's Letter, ''Petitioner's Substantive Response to the Notice of Initiation,'' dated August 2, 2023.

[6] *See* Commerce's Letter, ''Sunset Reviews for July 2023,'' dated August 22, 2023.

[7] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited First Sunset Review of the Antidumping Duty Order on Cast Iron Soil Pipe Fittings from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[8] *Id.*

DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–878]

Stainless Steel Flanges From India: Preliminary Results of Countervailing Duty Administrative Review and Partial Rescission of Review; 2021

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily finds that countervailable subsidies are being provided to producers and exporters of stainless steel flanges from India during the period of review, January 1, 2021, through December 31, 2021. Additionally, Commerce is rescinding the review with respect to one company. Interested parties are invited to comment on these preliminary results.

DATES: Applicable November 6, 2023.

FOR FURTHER INFORMATION CONTACT: Eliza DeLong, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3878.

SUPPLEMENTARY INFORMATION:

Background

On October 5, 2018, Commerce published the countervailing duty order on stainless steel flanges from India.[1] On December 5, 2022, Commerce published a notice of initiation of an administrative review of the *Order*.[2] On May 30, 2023, Commerce extended the time period for issuing these preliminary results by 120 days, in accordance with section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), to no later than October 31, 2023.[3]

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[4] A list of topics discussed in the Preliminary Decision Memorandum is included as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Order

The merchandise covered by the *Order* is stainless steel flanges from India. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(A) of the Act. For each of the subsidy programs found countervailable, we preliminarily find that there is a subsidy, *i.e.,* a financial contribution that gives rise to a benefit to the recipient, and the subsidy is specific.[5] For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

Company Not Selected for Individual Review

The Act and Commerce's regulations do not directly address the subsidy rate to be applied to companies not selected for individual examination where Commerce limits its examination in an administrative review pursuant to section 777A(e)(2) of the Act. However, Commerce normally determines the rates for non-selected companies in reviews in a manner that is consistent with section 705(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation. Section 777A(e)(2) of the Act provides that ''the individual countervailable subsidy rates determined under subparagraph (A) shall be used to determine the all-others rate under section 705(c)(5) {of the Act}.'' Section 705(c)(5)(A) of the Act states that for companies not investigated, in general, we will determine an all-others rate by weight-averaging the countervailable subsidy rates established for each of the companies individually investigated, excluding zero and *de minimis* rates or any rates based solely on the facts available.

Accordingly, to determine the rate for companies not selected for individual examination, Commerce's practice is to weight average the net subsidy rates for the selected mandatory respondents, excluding rates that are zero, *de minimis,* or based entirely on facts available.[6] We preliminarily determine that Chandan Steel Limited (Chandan) and Pradeep Metals Limited (Pradeep) received countervailable subsidies that are above *de minimis* and are not based entirely on facts available. Therefore, we preliminarily determine to apply the weighted average of the net subsidy rates calculated for Chandan and Pradeep using publicly-ranged sales data submitted by those respondents to the non-selected company.[7] The company for which a review was requested, and which was not selected as a mandatory respondents or found to be cross-owned with a mandatory respondent, is BFN Forgings Private Limited.

Partial Rescission of Administrative Review

Commerce's practice is to rescind an administrative review of a countervailing duty order, pursuant to 19 CFR 351.213(d)(1), when the interested party that requested a review withdraws the request within 90 days of publication of notice of initiation of the requested review. On March 3, 2023, we received a withdrawal request for Hilton Metal Forging Limited (Hilton).[8] Because no other party besides Hilton requested a review, we are rescinding this review pursuant to 19 CFR 351.213(d)(1) with respect to Hilton. For this company, Commerce intends to assess duties at rates equal to the cash deposits of estimated countervailing duties required at the time of entry, or withdrawn from warehouse, for consumption, during the POR, in accordance with 19 CFR 351.212(c)(2).

Preliminary Results of Review

For the period January 1, 2021, through December 31, 2021, we preliminarily find that the following net subsidy rates exist:

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[1] *See Stainless Steel Flanges from India: Countervailing Duty Order,* 83 FR 50336 (October 5, 2018) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 87 FR 74404 (December 5, 2022), as corrected by *Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 7060 (February 2, 2023).

[3] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Countervailing Duty Administrative Review,'' dated May 30, 2023.

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Countervailing Duty Administrative Review: Stainless Steel Flanges from India; 2021,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[5] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[6] *See, e.g., Certain Pasta from Italy: Final Results of the 13th (2008) Countervailing Duty Administrative Review,* 75 FR 37386, 37387 (June 29, 2010).

[7] *See* Memorandum, ''Calculation of Subsidy Rate for Non-Selected Companies Under Review,'' dated concurrently with this memorandum.

[8] *See* Hilton's Letter, ''AD/CVD Review Request,'' dated March 3, 2023.

Producer/exporter	Subsidy rate (percent *ad valorem*)
Chandan Steel Limited	2.60
Pradeep Metals Limited	4.04
Review-Specific Average Rate Applicable to the Following	
BFN Forgings Private Limited	2.82

Disclosure and Public Comment

We will disclose to parties to this proceeding the calculations performed for these preliminary results within five days of the date of publication of these preliminary results in accordance with 19 CFR 351.224(b).[9]

Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs no later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[10] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) a statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[11] Case and rebuttal briefs should be filed using ACCESS [12] and must be served on interested parties. Executive summaries should be limited to five pages total, including footnotes. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[13]

Interested parties who wish to request a hearing must do so within 30 days of publication of these preliminary results by submitting a written request to the Assistant Secretary for Enforcement and Compliance using Enforcement and Compliance's ACCESS system.[14] Requests should contain the party's name, address, and telephone number, the number of participants, and a list of the issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs.[15] If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm the date and time of the hearing two days before the scheduled date. Parties are reminded that all briefs and hearing requests must be filed electronically using ACCESS and received successfully in their entirety by 5:00 p.m. Eastern Time on the due date.

[9] *See* 19 CFR 351.224(b).

[10] *See* 19 CFR 351.309(c)(1)(ii) and 351.309(d)(1).

[11] *See* 19 CFR 351.309(c)(2) and (d)(2).

[12] *See generally* 19 CFR 351.303.

[13] *See Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings; Final Rule,* 88 FR 67069 (September 29, 2023)

[14] *See* 19 CFR 351.310(c).

[15] *See* 19 CFR 351.310.

Assessment Rates

Consistent with section 751(a)(2)(C) of the Act, upon issuance of the final results, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries in accordance with the final results of this review. If the assessment rate calculated in the final results is zero or *de minimis,* we will instruct CBP to liquidate all appropriate entries without regard to countervailing duties. For the company for which this review is rescinded (*i.e.,* Hilton), Commerce will instruct CBP to assess countervailing duties on all appropriate entries at a rate equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, during the period January 1, 2021, through December 31, 2021, in accordance with 19 CFR 351.212(c)(l)(i).

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

Pursuant to section 751(a)(2)(C) of the Act, Commerce intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown for each of the companies listed above on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review, except where the rate calculated in the final results is zero or *de minimis,* no cash deposit will be required. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits of estimated countervailing duties at the most recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposit instructions, when imposed, shall remain in effect until further notice.

Final Results of Review

Unless the deadline is extended pursuant to section 751(a)(3)(A) of the Act, Commerce intends to issue the final results of this administrative review, including the results of our analysis of the issues raised by the parties in their comments, within 120 days after publication of these preliminary results.

Notification to Interested Parties

This administrative review and notice are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213.

Dated: October 31, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Period of Review
V. Rate for Non-Examined Companies
VI. Subsidies Valuation Information
VII. Benchmarks and Interest Rates
VIII. Analysis of Programs
IX. Recommendation

[FR Doc. 2023–24481 Filed 11–3–23; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–983]

Drawn Stainless Steel Sinks From the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2021–2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that Guangdong Dongyuan Kitchenware Industrial Co., Ltd. (Dongyuan) made sales of subject merchandise at prices below normal value during the period of review (POR) April 1, 2021, through March 31, 2022. Additionally, we find that Guangdong Yingao Kitchen Utensils Co., Ltd. (Yingao) and Shenzhen Kehuaxing Industrial Ltd. (Shenzhen Kehuaxing) have not established their eligibility for a separate rate.

DATES: Applicable November 6, 2023.

FOR FURTHER INFORMATION CONTACT: Ajay Menon, AD/CVD Operations, Office IX, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0208.

SUPPLEMENTARY INFORMATION:

Background

On May 4, 2023, Commerce published the *Preliminary Results*.[1] On July 19, 2023, we extended the deadline for these final results to October 31, 2023.[2] For a complete description of the events that occurred subsequent to the *Preliminary Results, see* the Issues and Decision Memorandum.[3] Commerce conducted this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order [4]

The products covered by the *Order* are drawn stainless steel sinks from the People's Republic of China (China).[5] Imports of subject merchandise are currently classified under the Harmonized Tariff Schedule of the United States (HTSUS) subheadings 7324.10.0000 and 7324.10.0010. While HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

Analysis of Comments Received

We addressed all the issues raised in the case and rebuttal briefs in the Issues and Decision Memorandum. A list of the issues that parties raised is provided in the appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Based on a review of the record and comments received from interested parties regarding the *Preliminary Results,* we have made certain changes to the margin calculations for Dongyuan.[6]

Final Results of Review

As a result of this review, we are assigning the following estimated weighted-average dumping margins for the period April 1, 2021, through March 31, 2022:

Producer or exporter	Weighted-average dumping margin (percent)
Guangdong Dongyuan Kitchenware Industrial Co., Ltd	5.85
Guangdong Yingao Kitchen Utensils Co., Ltd	76.45

Disclosure

Commerce intends to disclose the calculations performed in connection with these final results to interested parties within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b), Commerce determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review.

For Dongyuan, Commerce calculated importer- (or customer-) specific per-unit duty assessment rates based on the ratio of the total amount of dumping calculated for the importer's (or customer's) examined sales to the total sales quantity associated with those sales, in accordance with 19 CFR 351.212(b)(1). Where either Dongyuan's weighted-average dumping margin is zero or *de minimis,* or an importer-specific rate is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

Pursuant to Commerce's assessment practice,[7] for entries that were not reported in the U.S. sales data submitted by Dongyuan, we will instruct CBP to liquidate such entries at the China-wide rate of 76.45 percent.[8] Furthermore, because we find that Shenzhen Kehuaxing and Yingao are part of the China-wide entity, we will also instruct CBP to apply an *ad valorem* assessment rate of 76.45 to all POR entries of subject merchandise that were produced and/or exported by either Shenzhen Kehuaxing or Yingao.

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of these final results. 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 upon publication of the final results of administrative review for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on, or after, the publication date of the final results of review, as provided for by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for Dongyuan will be equal to the dumping margin established in the final results of this review; (2) for a previously investigated or reviewed exporter of subject merchandise not listed in the final results of review that has a separate rate, the cash deposit rate will continue to be the exporter's existing cash deposit rate; (3) for all Chinese exporters of subject merchandise that do not have a separate rate, the cash deposit rate will be the cash deposit rate established for the China-wide entity, *i.e.,* 76.45 percent; [9] and (4) for all exporters of subject merchandise that are not located in China and that are not eligible for a separate rate, the cash deposit rate will be the rate applicable to the China exporter(s) that supplied that non-Chinese exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility

[1] *See Drawn Stainless Steel Sinks from the People's Republic of China: Preliminary Results and Partial Rescission of Antidumping Duty Administrative Review; 2021–2022,* 88 FR 28485 (May 4, 2023) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Extension of Deadline for Final Results,'' dated July 19, 2023.

[3] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the 2021–2022 Antidumping Duty Administrative Review of Drawn Stainless Steel Sinks from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[4] *See Drawn Stainless Steel Sinks from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order,* 78 FR 21592 (April 11, 2013) (*Order*).

[5] For a complete description of the scope of the *Order, see* Issues and Decision Memorandum.

[6] For a full description of these changes, *see* Issues and Decision Memorandum.

[7] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011), for a full discussion of this practice.

[8] The China-wide rate determined in the investigation was 76.53 percent. *See Order,* 78 FR at 21594. This rate was adjusted for export subsidies and estimated domestic subsidy pass through to determine the cash deposit rate (*i.e.,* 76.45 percent) collected for companies in the China-wide entity. *See* explanation in *Drawn Stainless Steel Sinks from the People's Republic of China: Investigation Final Determination,* 78 FR 13019 (February 26, 2013).

[9] *Id.*

under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent assessment of double antidumping duties, and/or an increase in the amount of antidumping duties by the amount of the countervailing duties.

Notification Regarding Administrative Protective Order

This notice also serves as the final reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing these final results of administrative review and notice in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.221(b)(5).

Dated: October 31, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Margin Calculations
IV. Discussion of the Issues
Comment 1: Whether Commerce Should Select Romania as the Primary Surrogate Country
Comment 2: Whether Commerce Should Value Stainless Steel Using Romanian Surrogate Value Data
Comment 3: Surrogate Value Source to Value Clips
Comment 4: Whether Commerce Should Exclude Taiwan Import Data from its Calculation of the Surrogate Value for Stainless Steel
Comment 5: Whether Commerce Will Consider Supplemental Surrogate Value Data for Labor
Comment 6: Whether Commerce Should Apply Adverse Facts Available to Yingao
Comment 7: Whether Commerce Should Grant Dongyuan a Double Remedies Offset in its Margin Calculation
Comment 8: Verification Issues Related to Dongyuan's Reported Product Codes
Comment 9: Whether to Include Dongyuan's Bank Charges Noted at Verification
Comment 10: Whether Commerce Should Grant a Scrap Offset to Dongyuan
V. Recommendation

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–877]

Stainless Steel Flanges From India: Preliminary Results of Antidumping Duty Administrative Review and Partial Rescission; 2021–2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily finds that producers/exporters of stainless steel flanges (flanges) from India did not make sales of subject merchandise in the United States at prices below normal value (NV) during the period of review (POR) October 1, 2021, through September 30, 2022. In addition, we are rescinding this review for one company. We invite interested parties to comment on these preliminary results.

DATES: Applicable November 6, 2023.

FOR FURTHER INFORMATION CONTACT: Benito Ballesteros or Seth Brown, AD/CVD Operations, Office IX, Enforcement and Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4725 or (202) 482–0029, respectively.

SUPPLEMENTARY INFORMATION:

Background

On October 9, 2018, Commerce published in the **Federal Register** an antidumping duty order on flanges from India.[1] On December 5, 2022, based on timely requests for review, Commerce initiated an administrative review of the *Order* covering 15 companies, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).[2] On June 6, 2023, we extended the deadline for the preliminary results of this administrative review until October 31, 2023.[3] For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[4]

Scope of the Order

The merchandise covered by the *Order* is stainless steel flanges from India. For a full description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Partial Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if a party who requested the review withdraws the request within 90 days of the date of publication of the notice of initiation. On March 2, 2023, we received a timely withdrawal request from R.N. Gupta & Company Limited.[5] Because no other party requested a review of this company, Commerce is rescinding this review with respect to R.N. Gupta & Company Limited, in accordance with 19 CFR 351.213(d)(1).

Methodology

Commerce is conducting this review in accordance with sections 751(a) of the Act. We calculated export price and constructed export price in accordance with section 772 of the Act. We calculated NV in accordance with section 773 of the Act.

For a full description of the methodology underlying these preliminary results, see the Preliminary Decision Memorandum. A list of topics included in the Preliminary Decision Memorandum is included as Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is made available to the public via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

[1] *See Stainless Steel Flanges from India: Antidumping Duty Order,* 83 FR 50639 (October 9, 2018) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 87 FR 74404 (December 5, 2022); and *Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 7060 (February 2, 2023) (collectively, *Initiation Notice*).

[3] *See* Memorandum, ''Extension of Deadline for Preliminary Results of 2021–2022 Antidumping Duty Administrative Review,'' dated June 6, 2023.

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review of Stainless Steel Flanges from India; 2021–2022,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[5] *See* R.N. Gupta's Letter, ''Withdrawal of Antidumping Duty Administrative Review,'' dated March 2, 2023.

Preliminary Results of Review

We preliminarily determine the following weighted-average dumping margins exist for the period October 1, 2021, through September 30, 2022:

Exporter/producer	Weighted-average dumping margin (percent)
Chandan Steel Limited	0.00
Kisaan Die Tech Private Limited	0.00
Companies Not Selected for Individual Review [6]	0.00

Review-Specific Rate for Companies Not Selected for Individual Review

The Act and Commerce's regulations do not address the rate to be applied to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in a less-than-fair value (LTFV) investigation, for guidance when calculating the rate for companies which were not selected for individual examination in an administrative review. Under section 735(c)(5)(A) of the Act, the all-others rate is normally an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero or *de minimis* margins, and any margins determined entirely on the basis of facts available.

Where the dumping margins for individually examined respondents are zero, *de minimis,* or determined based entirely on facts available, section 735(c)(5)(B) of the Act provides that Commerce may use ''any reasonable method to establish the estimated all-others rate for exporters and producers not individually investigated . . . .'' In this review, Commerce preliminarily calculated weighted-average dumping margins for Chandan Steel Limited (Chandan) and Kisaan Die Tech Private Limited (KDT) of zero percent. Therefore, we are preliminarily assigning a rate of zero percent to the companies not selected for individual examination, in accordance with section 735(c)(5)(B) of the Act.

Assessment Rates

Upon completion of this administrative review, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries. Pursuant to 19 CFR 351.212(b)(1), because the individually-examined respondents reported the entered value for their U.S. sales, we will calculate importer-specific *ad valorem* antidumping duty assessment rates based on the ratio of the total amount of antidumping duties calculated for the examined sales to the total entered value of those same sales. If either respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c), or an importer-specific rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

Commerce's ''automatic assessment'' practice will apply to entries of subject merchandise during the POR produced by Chandan and KDT for which these companies did not know that the merchandise they sold to an intermediary (*e.g.,* a reseller, trading company, or exporter) was destined for the United States. We will instruct CBP to liquidate those entries at the all-others rate (*i.e.,* 7.00 percent) [7] if there is no rate for the intermediate company(ies) involved in the transaction.[8]

For the companies which were not selected for individual review, we intend to assign an assessment rate based on the review-specific average rate, calculated as noted in the ''Preliminary Results of Review'' section, above. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by this review and for future deposits of estimated duties, where applicable.[9]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for the companies listed above will be equal to the weighted-average dumping margin established in the final results of this review, except if the rate is *de minimis* (*i.e.,* less than 0.50 percent), in which case the cash deposit rate will be zero; (2) for previously reviewed or investigated companies not covered by this review, the cash deposit rate will continue to be the company-specific rate published for the most recently-completed segment of this proceeding in which they were examined; (3) if the exporter is not a firm covered in this review, a prior review, or the LTFV investigation, but the producer is, the cash deposit rate will be the rate established for the most recently-completed segment of this proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 7.00 percent, the all-others rate established in the *Amended Final Determination.*[10] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

We intend to disclose the calculations performed in connection with these preliminary results to interested parties within five days after the date of publication of this notice in the **Federal Register**.[11] Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs no later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than seven days after the date for filing case briefs.[12] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) a statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[13] Case and rebuttal briefs should be filed using ACCESS.[14] Note that Commerce has amended

[6] *See* Appendix II for the list of exporters and/or producers not selected for individual review.

[7] *See Stainless Steel Flanges from India: Notice of Court Decision Not in Harmony with the Final Determination of Antidumping Investigation; Notice of Amended Final Determination,* 86 FR 50325 (September 8, 2021) (*Amended Final Determination*).

[8] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[9] *See* section 751(a)(2)(C) of the Act.

[10] *See Amended Final Determination,* 86 FR at 50326.

[11] *See* 19 CFR 351.224(b).

[12] Commerce is exercising its discretion, under 19 CFR 351.309(d), to alter the time limit for the filing of rebuttal briefs.

[13] *See* 19 CFR 351.309(c)(2) and (d)(2).

[14] *See generally* 19 CFR 351.303.

certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[15]

Interested parties who wish to request a hearing must do so within 30 days of publication of these preliminary results by submitting a written request to the Assistant Secretary for Enforcement and Compliance using Enforcement and Compliance's ACCESS system.[16] Hearing requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants: and (3) a list of the issues to be discussed. Oral presentations at the hearing will be limited to issues raised in the case and rebuttal briefs.[17] Parties are reminded that all briefs and hearing requests must be filed electronically using ACCESS and received successfully in their entirety by 5:00 p.m. Eastern Time on the due date. If a request for a hearing is made, parties will be notified of the time and date for the hearing.[18]

Unless otherwise extended, Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

Notification to Importers

This notice also serves as a reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent assessment of doubled antidumping duties, and/or an increase in the amount of antidumping duties by the amount of countervailing duties.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213 and 351.221(b)(4).

[15] *See Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings; Final Rule,* 88 FR 67069 (September 29, 2023).

[16] *See* 19 CFR 351.310(c).

[17] *See* 19 CFR 351.310.

[18] *See* 19 CFR 351.310(d).

Dated: October 31, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Discussion of the Methodology
V. Recommendation

Appendix II

List of Companies Not Selected for Individual Examination

1. Balkrishna Steel Forge Pvt. Ltd.
2. BFN Forgings Private Limited; Bebitz Flanges Works Private Limited; Fanschen werk Bebitz GmbH; Viraj Alloys, Ltd.; Viraj Forgings, Ltd.; Viraj Impoexpo, Ltd.; and Viraj Profiles Limited [19]
3. Echjay Forgings Private Limited
4. Fivebros Forging Pvt Ltd.[20]
5. Goodluck India Limited
6. Hilton Metal Forging Limited
7. Jai Auto Pvt. Ltd.
8. Jay Jagdamba Forgings Pvt Ltd
9. Jay Jagdamba Ltd
10. Jay Jagdamba Profile Pvt Ltd
11. Pradeep Metals Limited
12. Shree Jay Jagdamba Flanges Pvt. Ltd.

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[19] Commerce has previously found BFN Forgings Private Limited to be part of a collapsed entity. *See, e.g., Stainless Steel Flanges from India: Final Affirmative Determination of Sales at Less Than Fair Value and Final Affirmative Critical Circumstance Determination,* 83 FR 40745 (August 16, 2018). The companies which are part of this collapsed entity are listed above.

[20] We incorrectly listed this company as ''Fivebros Pvt Ltd.'' in the *Initiation Notice. See Initiation Notice,* 87 FR at 74406.

DEPARTMENT OF COMMERCE

International Trade Administration

[C–580–884]

Certain Hot-Rolled Steel Flat Products From the Republic of Korea: Preliminary Results and Partial Rescission of Countervailing Duty Administrative Review, 2021

AGENCY: Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that certain producers/exporters of certain hot-rolled steel flat products (hot-rolled steel) from the Republic of Korea (Korea) received countervailable subsidies during the period of review (POR) January 1, 2021, through December 31, 2021. Additionally, Commerce is rescinding this review with respect to 13 companies. We invite interested parties to comment on these preliminary results.

DATES: Applicable November 6, 2023.

FOR FURTHER INFORMATION CONTACT: Nathan James or Kelsie Hohenberger, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5305 or (202) 482–2517, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 5, 2022, Commerce published a notice of initiation of an administrative review of the countervailing duty order on hot-rolled steel from Korea.[1] On January 4, 2023, Commerce selected Hyundai Steel Company (Hyundai Steel) and POSCO as mandatory respondents in this administrative review.[2] On June 15, 2023, Commerce extended the deadline for the preliminary results of this review to no later than October 31, 2023.[3]

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[4] A list of topics discussed in the Preliminary Decision Memorandum is included as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov*. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx*.

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 87 FR 74404 (December 5, 2022); *see also Certain Hot-Rolled Steel Flat Products from Brazil and the Republic of Korea: Amended Final Affirmative Countervailing Duty Determinations and Countervailing Duty Orders,* 81 FR 67960 (October 3, 2016) (*Order*).

[2] *See* Memorandum, ''Respondent Selection,'' dated January 4, 2023.

[3] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Countervailing Duty Administrative Review,'' dated June 15, 2023.

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Countervailing Duty Administrative Review of Certain Hot-Rolled Steel Flat Products from the Republic of Korea; 2021,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

Scope of the Order

The merchandise covered by the *Order* is hot-rolled steel from Korea. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Rescission of Administrative Review, In Part

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the parties that requested a review withdraw the request within 90 days of the date of publication of the notice of initiation. Commerce received a timely-filed withdrawal request from the petitioners with respect to 13 companies.[5] Because the withdrawal request was timely filed, and no other party requested a review of these companies, in accordance with 19 CFR 351.213(d)(1), Commerce is rescinding this review with respect to the following companies: (1) DCE Inc; (2) Dong Chuel America Inc.; (3) Dong Chuel Industrial Co., Ltd.; (4) Dongbu Incheon Steel Co., Ltd.; (5) Dongbu Steel Co., Ltd.; (6) Dongkuk Industries Co., Ltd.; (7) Dongkuk Steel Mill Co., Ltd.; (8) Hyewon Sni Corporation (H.S.I.); (9) JFE Shoji Trade Korea Ltd.; (10) POSCO Coated & Color Steel Co., Ltd.; (11) POSCO Daewoo Corporation; (12) Soon Hong Trading Co., Ltd.; and (13) Sung-A Steel Co., Ltd.[6]

Methodology

Commerce is conducting this review in accordance with section 751(a)(l)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we preliminarily determine that there is a subsidy, *i.e.,* a financial contribution from an authority that gives rise to a benefit to the recipient, and that the subsidy is specific.[7] For a full description of the methodology underlying our conclusions, *see* the accompanying Preliminary Decision Memorandum.

Preliminary Results of Review

As a result of this review, we preliminarily determine the net countervailable subsidy rates exist for the period, January 1, 2021, through December 31, 2021:

Producer/exporter	Subsidy rate (percent *ad valorem*)
Hyundai Steel Company[8]	0.78
POSCO[9]	0.88

Disclosure and Public Comment

We intend to disclose to interested parties the calculations performed for these preliminary results within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than 30 days after the date of publication of the preliminary results in the **Federal Register**. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the date for case briefs.[10] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this review are encouraged to submit with each argument: (1) a statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities. All briefs must be filed electronically using Enforcement and Compliance's ACCESS system. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[11]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance using ACCESS within 30 days after the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm the date and time of the hearing two days before the scheduled date.

Final Results of Review

Unless the deadline is extended, we intend to issue the final results of this administrative review, which will include the results of our analysis of the issues raised in the case briefs, within 120 days of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

Assessment Rates

Pursuant to section 751(a)(1) of the Act and 19 CFR 351.212(b)(2), upon issuance of the final results, Commerce shall determine, and CBP shall assess, countervailing duties on all appropriate entries of subject merchandise in accordance with the final results of this review. Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

For the companies for which we are rescinding this administrative review, Commerce will instruct CBP to assess countervailing duties on all appropriate entries at a rate equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, during the period January 1, 2021, through December 31, 2021, in accordance with 19 CFR 351.212(c)(l)(i).

Cash Deposit Requirements

In accordance with section 751(a)(1) of the Act, Commerce intends, upon publication of the final results, to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown for each of the companies listed above on shipments of

[5] The petitioners are: Cleveland-Cliffs Inc.; Nucor Corporation; SSAB Enterprises, LLC; Steel Dynamics; Inc.; and United States Steel Corporation.

[6] *See* Petitioners' Letter, ''Partial Withdrawal of Request for Administrative Review,'' dated March 6, 2023.

[7] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[8] Hyundai Steel Company is also known as ''Hyundai Steel Co., Ltd.'' As discussed in the Preliminary Decision Memorandum, Commerce has found the following companies to be cross-owned with Hyundai Steel: Hyundai Green Power Co. Ltd.; and Hyundai ITC.

[9] As discussed in the Preliminary Decision Memorandum, Commerce has found the following companies to be cross-owned with POSCO: Pohang Scrap Recycling Distribution Center Co. Ltd.; POSCO Chemical; POSCO M-Tech; POSCO Nippon Steel RHF Joint Venture Co., Ltd.; POSCO Steel Processing and Service; and POSCO Terminal. The POSCO subsidy rate applies to all cross-owned companies. We note that POSCO has an affiliated trading company through which it exported certain subject merchandise, *i.e.,* POSCO International Corporation (POSCO International). POSCO International was not selected as a mandatory respondent, but was examined in the context of POSCO. Therefore, there is not an individually-established rate for POSCO International; POSCO International's subsidies are accounted for in terms of POSCO's total subsidy rate. Entries of subject merchandise exported by POSCO International will receive the rate of the producer listed on the entry form with U.S. Customs and Border Protection (CBP). Thus, the subsidy rate applied to POSCO (and POSCO's cross-owned affiliates) is also applied to POSCO International for entries of subject merchandise produced by POSCO.

[10] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[11] *See Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings; Final Rule,* 88 FR 67069 (September 29, 2023).

subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review, except, where the rate calculated in the final results is zero or *de minimis,* no cash deposit will be required. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits at the most recent company-specific or all-others rate applicable to the company. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Interested Parties

These preliminary results are issued and published pursuant to sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(d)(4) and 19 CFR 351.221(b)(4).

Dated: October 31, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Period of Review
IV. Partial Rescission of Administrative Review
V. Scope of the *Order*
VI. Diversification of Korea's Economy
VII. Subsidies Valuation Information
VIII. Analysis of Programs
IX. Recommendation

[FR Doc. 2023–24475 Filed 11–3–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–153]

Certain Paper Shopping Bags From the People's Republic of China: Preliminary Affirmative Determination of Countervailable Subsidies, Preliminary Affirmative Determination of Critical Circumstances, and Alignment of Final Determination With Final Antidumping Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that countervailable subsidies are being provided to producers and exporters of certain paper shopping bags (paper bags) from the People's Republic of China (China). The period of investigation (POI) is January 1, 2022, through December 31, 2022. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable November 6, 2023.

FOR FURTHER INFORMATION CONTACT: Seth Brown, AD/CVD Operations, Office IX, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0029.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 703(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this countervailing duty (CVD) investigation on June 26, 2023.[1] On August 7, 2023, Commerce postponed the preliminary determination until October 30, 2023.[2]

For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Investigation

The products covered by this investigation are paper bags from China. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to Commerce's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (scope).[5] We received comments from interested parties commented on the scope of the concurrent antidumping duty (AD) and CVD investigations as it appeared in the *Initiation Notice,* which are listed in the Preliminary Decision Memorandum.[6] We are currently evaluating the scope comments filed by interested parties and intend to issue our preliminary decision regarding the scope of the AD and CVD investigations prior to or concurrently with the AD preliminary determinations. We will incorporate the scope decisions from the AD investigations into the scope of the final CVD determination for this investigation, after considering any relevant comments submitted in scope case and rebuttal briefs.[7]

Preliminary Affirmative Determination of Critical Circumstances

In accordance with section 703(e)(1) of the Act, we preliminarily find that critical circumstances exist with respect to imports of subject merchandise for Dongzheng Paper Bag (Dalian) Factory (Dongzheng), Fujian Nanwang Environment Protection Scien-tech Co., Ltd. (Fujian Nanwan) the non-responsive companies,[8] and all other producers and/or exporters. For a full discussion of our preliminary critical circumstances determination, see the ''Critical Circumstances'' section of the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this investigation in accordance with section 701 of the Act. For each of the subsidy programs found countervailable, Commerce preliminarily determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[9]

Commerce notes that, in making these findings, it relied, in part, on facts

[1] *See Certain Paper Shopping Bags from India and the People's Republic of China: Initiation of Countervailing Duty Investigations,* 88 FR 41380 (June 26, 2023) (*Initiation Notice*).

[2] *See Certain Paper Shopping Bags from the People's Republic of China and India: Postponement of Preliminary Determinations in the Countervailing Duty Investigations,* 88 FR 52122 (August 7, 2023).

[3] *See* Memorandum, ''Decision Memorandum for Preliminary Affirmative Determination of the Countervailing Duty Investigation of Certain Paper Shopping Bags from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[5] *See Initiation Notice,* 88 FR at 41380.

[6] *See* Preliminary Decision Memorandum at 2–3.

[7] The deadline for interested parties to submit scope case and rebuttal briefs will be established in the preliminary scope decision memorandum.

[8] The non-responsive companies are: (1) Bagitan Packaging; (2) Changzhou Anjucheng; (3) Courage Packaging; (4) Evertrust Packaging; (5) Geotegrity EcoPack; (6) GrandIntelligent; (7) Li & Fung; (8) Qindao Chenyu Packaging Co., Ltd.; (9) Shanghai Macolink Supply Chain Management Co., Ltd.; (10) Shanghai Sanxi Paper Co., Ltd.; (11) Xiamen C&D Pulp & Paper Co., Ltd.; (12) Xiamen Champion FMCG; (13) Xiamen New Idea Packaging Co., Ltd.; and (14) Xiamen Wonderful Bag Import and Export Co., Ltd.

[9] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

available, and, because it finds that one or more respondents did not act to the best of their ability to respond to Commerce's requests for information, it drew an adverse inference where appropriate in selecting from among the facts otherwise available.[10] For further information, *see* the ''Use of Facts Otherwise Available and Adverse Inferences'' section of the Preliminary Decision Memorandum.

Alignment

In accordance with section 705(a)(1) of the Act and 19 CFR 351.210(b)(4), Commerce is aligning the final CVD determination in this investigation with the final determination in the companion AD investigation of paper bags from China based on a request made by the Coalition for Fair Trade in Shopping Bags (the petitioner).[11] Consequently, the final CVD determination will be issued on the same date as the final AD determination, which is currently scheduled to be issued no later than March 11, 2024, unless postponed.

All-Others Rate

Sections 703(d) and 705(c)(5)(A) of the Act provide that in the preliminary determination, Commerce shall determine an estimated all-others rate for companies not individually examined. This rate shall be an amount equal to the weighted average of the estimated subsidy rates established for those companies individually examined, excluding any zero and *de minimis* rates and any rates based entirely under section 776 of the Act.

In this investigation, Commerce preliminarily calculated individual estimated countervailable subsidy rates for Dongzheng and Fujian Nanwang that are not zero, *de minimis,* or based entirely on facts otherwise available.[12] Therefore, Commerce calculated the all-others rate using a weighted average of the individually estimated subsidy rates calculated for the examined respondents using each company's public ranged data for the value of its exports of subject merchandise to the United States.[13]

Preliminary Determination

Commerce preliminarily determines that the following estimated countervailable subsidy rates exist:

Company	Subsidy rate (percent *ad valorem*)
Bagitan Packaging	144.03
Changzhou Anjucheng	144.03
Courage Packaging	144.03
Dongzheng Paperbag (DaLian) Factory	12.43
Evertrust Packaging	144.03
Fujian Nanwang Environment Protection Scien-Tech Co., Ltd.[14]	13.96
Geotegrity EcoPack	144.03
GrandIntelligent	144.03
Li & Fung	144.03
Qindao Chenyu Packaging Co., Ltd	144.03
Shanghai Macolink Supply Chain Management Co., Ltd	144.03
Shanghai Shanxi Paper Co., Ltd	144.03
Xiamen C&D Pulp & Paper Co., Ltd	144.03
Xiamen Champion FMCG	144.03
Xiamen New Idea Packaging Co., Ltd	144.03
Xiamen Wonderful Bag Import and Export Co., Ltd	144.03
All Others	13.84

Suspension of Liquidation

In accordance with section 703(e)(2)(A) of the Act, because we find that critical circumstances exist for Dongzhen, Fujian Nanwang, the non-response companies, and all other producers and/or exporters, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after the date 90 days prior to the date of publication of this notice in the **Federal Register**. Further, pursuant to 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the rates indicated above.

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties in this preliminary determination within five days of its public announcement, or if there is no public announcement, within five days of the date of the publication of this notice, in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination.

Public Comment

All interested parties will have the opportunity to submit scope case and rebuttal briefs on the preliminary decision regarding the scope of the AD and CVD investigations. The deadlines to submit scope case and rebuttal briefs will be provided in the preliminary scope decision memorandum. For all scope case and rebuttal briefs, parties must file identical documents simultaneously on the records of the ongoing AD and CVD paper bags investigations. No new factual information or business proprietary information may be included in either scope case or rebuttal briefs.

Case briefs or other written comments on non-scope issues may be submitted to the Assistant Secretary for Enforcement and Compliance. Interested parties will be notified of the timeline for the submission of case briefs and written comments at a later date. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than seven days after the deadline date for case briefs after the deadline date for case briefs.[15] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) a statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[16]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, and a list of the

[10] *See* sections 776(a) and (b) of the Act.

[11] *See* Petitioner's Letter, ''Petitioner's Request to Align Countervailing Duty Investigation Final Determination with Antidumping Duty Investigation Final Determination,'' dated October 5, 2023.

[12] *See* Preliminary Decision Memorandum at Appendix I.

[13] *See* Memorandum, ''Calculations of 'All Others' Rate for the Preliminary Determination of the Countervailing Duty Investigation of Certain Paper Shopping Bags from the People's Republic of China,'' dated concurrently with this notice, at 1.

[14] As discussed in the Preliminary Decision Memorandum, Commerce has found the following companies to be cross-owned with Fujian Nanwang: Zhuhai Zhongyue Paper Cup Container Co., Ltd.; Anhui Nanwang Environmental Protection Technology Co., Ltd., Xianghe Nanwang Environmental Protection Technology Co., Ltd.; and Hubei Nanwang Environmental Protection Technology Co., Ltd.

[15] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[16] *See Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings; Final Rule,* 88 FR 67069 (September 29, 2023).

issues to be discussed. Oral presentations at the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, parties will be notified of the time and date for the hearing.[17]

U.S. International Trade Commission Notification

In accordance with section 703(f) of the Act, Commerce will notify the U.S. International Trade Commission (ITC) of its preliminary determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 703(f) and 777(i)(1) of the Act, and 19 CFR 351.205(c).

Dated: October 30, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The products within the scope of this investigation are paper shopping bags with handles of any type, regardless of whether there is any printing, regardless of how the top edges are finished (*e.g.,* folded, serrated, or otherwise finished), regardless of color, and regardless of whether the top edges contain adhesive or other material for sealing closed. Subject paper shopping bags have a width of at least 4.5 inches and depth of at least 2.5 inches.

Paper shopping bags typically are made of kraft paper but can be made from any type of cellulose fiber, paperboard, or pressboard with a basis weight less than 300 grams per square meter (GSM).

A non-exhaustive illustrative list of the types of handles on shopping bags covered by the scope include handles made from any materials such as twisted paper, flat paper, yarn, ribbon, rope, string, or plastic, as well as die-cut handles (whether the punchout is fully removed or partially attached as a flap).

Excluded from the scope are:

- Paper sacks or bags that are of a 1/6 or 1/7 barrel size (*i.e.,* 11.5–12.5 inches in width, 6.5–7.5 inches in depth, and 13.5–17.5 inches in height) with flat paper handles or die-cut handles;
- Paper sacks or bags with die-cut handles, a grams per square meter weight of less than 62 GSM, and a height of less than 11.5 inches; and
- Shopping bags (i) with non-paper handles made wholly of woven ribbon or other similar woven fabric and (ii) that are finished with folded tops or for which tied knots or t-bar aglets (made of wood, metal, or plastic) are used to secure the handles to the bags.

The above-referenced dimensions are provided for paper bags in the opened position. The height of the bag is the distance from the bottom fold edge to the top edge (*i.e.,* excluding the height of handles that extend above the top edge). The depth of the bag is the distance from the front of the bag edge to the back of the bag edge (typically measured at the bottom of the bag). The width of the bag is measured from the left to the right edges of the front and back panels (upon which the handles typically are located).

This merchandise is currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheadings 4819.30.0040 and 4819.40.0040. The HTSUS subheadings are provided for convenience and customs purposes only; the written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Investigation
IV. Scope Comments
V. Injury Test
VI. Analysis of China's Financial System
VII. Diversification of China's Economy
VIII. Use of Facts Otherwise Available and Adverse Inferences
IX. Subsidies Valuation
X. Benchmarks and Interest Rates
XI. Analysis of Programs
XII. Critical Circumstances
XIII. Recommendation

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[17] *See* 19 CFR 351.310(d).

DEPARTMENT OF COMMERCE

International Trade Administration

[C–821–825]

Phosphate Fertilizers From the Russian Federation: Final Results of Countervailing Duty Administrative Review; 2020–2021

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that Joint Stock Company Apatit (JSC Apatit), a producer/exporter of phosphate fertilizers from the Russian Federation (Russia), received countervailable subsidies during the period of review (POR), November 30, 2020, through December 31, 2021.

DATES: Applicable November 6, 2023.

FOR FURTHER INFORMATION CONTACT: Shane Subler or William Horn, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6241 or (202) 482–4868, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the preliminary results of this administrative review on May 4, 2023.[1] On August 4, 2023, Commerce extended the deadline for the final results of this review to no later than October 31, 2023.[2] For a description of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[3]

We conducted this review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order [4]

The products covered by this *Order* are phosphate fertilizers. For a complete description of the scope of this *Order, see* the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in interested parties' case briefs are addressed in the Issues and Decision Memorandum accompanying this notice. A list of the issues raised by parties, and to which Commerce responded in the Issues and Decision Memorandum, is provided in the appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

[1] *See Phosphate Fertilizers from the Russian Federation: Preliminary Results and Partial Rescission of the Countervailing Duty Administrative Review; 2020–2021,* 88 FR 28505, 28506 (May 4, 2023) (*Preliminary Results*) and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum, ''Extension of Deadline for Final Results of Countervailing Duty Administrative Review,'' dated August 4, 2023.

[3] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Countervailing Duty Administrative Review of Phosphate Fertilizers from the Russian Federation; 2020–2021,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[4] *See Phosphate Fertilizers from the Kingdom of Morocco and the Russian Federation: Countervailing Duty Orders,* 86 FR 18037 (April 7, 2021) (*Order*).

Changes Since the Preliminary Results

Based on a review of the record and comments received from interested parties regarding the *Preliminary Results,* and for the reasons explained in the Issues and Decision Memorandum, we made certain revisions to the subsidy calculations for JSC Apatit. These changes are explained in the Issues and Decision Memorandum.

Final Results of Administrative Review

In accordance with 19 CFR 351.221(b)(4)(i), we calculated an individual net countervailable subsidy rate for JSC Apatit. Commerce determines that, during the POR, the net countervailable subsidy rate for the company under review is as follows:

Company	Subsidy rate (percent *ad valorem*)
Joint Stock Company Apatit[5]	28.50

Disclosure

Commerce intends to disclose the calculations performed for these final results of review within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment Rate

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b)(2), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries of subject merchandise in accordance with the final results of this review, for the above-listed company at the applicable *ad valorem* assessment rate. We intend to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed with the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Rates

In accordance with section 751(a)(1) of the Act, Commerce intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amount shown for JSC Apatit on shipments of the subject merchandise entered, or withdrawn from warehouse for consumption on or after the date of publication of the final results of this administrative review. The cash deposit requirement, effective upon the publication of the final results of this review, shall remain in effect until further notice.

Administrative Protective Order

This notice also serves as a final reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

These final results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: October 31, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Use Of Facts Otherwise Available and Adverse Inferences
V. Subsidies Valuation
VI. Analysis of Programs
VII. Discussion of the Issues
Comment 1: Whether Commerce Should Calculate JSC Apatit's Subsidy Rate Based on Data for the Entire Period of Review or Calendar Year
Provision of Mining Rights for Less Than Adequate Remuneration (LTAR)
Comment 2a: Whether the Provision of Mining Rights Provides a Financial Contribution
Comment 2b: Whether Mining Rights Should Be Valued Based on Phosphate Rock
Comment 2c: Whether Commerce Unlawfully Departed from Its Practice of Applying a Cut-off Date with Respect to Russia
Comment 2d: Whether Commerce Should Use JSC Apatit's Gross Profit Figure in the Profit Ratio Calculation
Comment 2e: Whether Commerce Should Subtract Certain Costs JSC Apatit Incurred to Maintain Its Post-2002 Licenses
Comment 2f: Whether Commerce Erred in Its Calculation of the Tier 3 Benchmark by Double Counting Volumes, Values, and Resulting Average Unit Values (AUVs) for Brazil and South Africa
Comment 2g: Whether Commerce Erroneously Excluded Export Volume and Value Data, and Resulting AUVs, for Togo and Iran in Its Tier 3 Benchmark Calculation
Comment 2h: Whether Commerce Should Calculate the Benchmark in the Manner Proposed by ADM
Comment 2i: Whether Commerce Should Adjust the South Africa Export Data to Eliminate Distorted Export Prices
Comment 2j: Whether Commerce Should Rely on Benchmark Sources Other Than United Nations Comtrade and IHS Markit's Global Trade Atlas
Comment 2k: Whether Commerce Should Revise JSC Apatit's Cost of Sales for the Benefit Calculation
Comment 2l: Whether Commerce Should Add International Ocean Freight Costs to the Benchmark
Comment 2m: Whether Commerce Should Place the Calculation Memorandum and Worksheets from the Preliminary Results of the Phosphate Fertilizers from Morocco 2020–21 Administrative Review on the Record
Provision of Natural Gas for LTAR
Comment 3a: Whether Commerce Should Reject Kazakh Export Data as a Natural Gas Benchmark and Use European International Energy Agency Data Instead
Comment 3b: Whether Commerce Should Countervail JSC Apatit's Natural Gas Purchases from Independent Suppliers
Other Program-Specific Issues
Comment 4: Whether Commerce Properly Determined that the Vologda Region's Support of Industrial Development Program Is *De Facto* Specific
Comment 5: Whether Commerce Should Use a Different Interest Rate Benchmark for the Russian Export Center Joint-Stock Company Lending Program
VIII. Recommendation

[FR Doc. 2023–24474 Filed 11–3–23; 8:45 am]

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[5] As discussed in the *Preliminary Results* PDM, Commerce finds the following companies to be cross-owned with JSC Apatit: PhosAgro Public Joint Stock Company; Limited Liability Company PhosAgro-Region; Limited Liability Company PhosAgro-Belgorod; Limited Liability Company PhosAgro-Don; Limited Liability Company PhosAgro-Kuban; Limited Liability Company PhosAgro-Lipetsk; Limited Liability Company PhosAgro-Kursk; Limited Liability Company PhosAgro-Orel; Limited Liability Company PhosAgro-Stavropol; Limited Liability Company PhosAgro-Volga; Limited Liability Company PhosAgro-SeveroZapad; Limited Liability Company PhosAgro-Tambov; and Limited Liability Company PhosAgro-Sibir.

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–063]

Cast Iron Soil Pipe Fittings From the People's Republic of China: Final Results of the Expedited First Sunset Review of the Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of this expedited sunset review, the U.S. Department of Commerce (Commerce) finds that revocation of the countervailing duty (CVD) order on cast iron soil pipe fittings (soil pipe fittings) from the People's Republic of China (China) would be likely to lead to continuation or recurrence of countervailable subsidies at the levels indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable November 6, 2023.

FOR FURTHER INFORMATION CONTACT: Henry Wolfe, 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)–482–0574.

SUPPLEMENTARY INFORMATION:

Background

On August 31, 2018, Commerce published in the **Federal Register** the CVD order on soil pipe fittings from China.[1] On July 3, 2023, Commerce published the notice of initiation of the first sunset review of the *Order,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] Commerce received a notice of intent to participate from Cast Iron Soil Pipe Institute and its individual members Charlotte Pipe & Foundry and McWane, Inc. (collectively, domestic interested parties) within the deadlines specified in 19 CFR 351.218(d)(1)(i).[3] The domestic interested party claimed interested party status under section 771(9)(E) of the Act, and 19 CFR 351.102(b)(17) and (29)(vii) as a trade or business association, a majority of whose members manufacture or produce the domestic like product in the United States.

On August 2, 2023, Commerce received a complete substantive response for this review from the domestic interested parties within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[4] We did not receive a substantive response from any other interested party in this proceeding, and no party requested a hearing.

On August 22, 2023, Commerce notified the U.S. International Trade Commission (ITC) that it did not receive an adequate substantive response from respondent interested parties.[5] As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted expedited (120-day) sunset review of the *Order.*

Scope of the Order

The product covered by the *Order* is cast iron soil pipe fittings, finished and unfinished, regardless of industry or proprietary specifications, and regardless of size. The subject merchandise is currently provided for in item 7307.11.0045 of the Harmonized Tariff Schedule of the United States (HTSUS). Subject merchandise may also enter under HTSUS 7324.29.0000 and 7307.92.3010. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise is dispositive. For a complete description of the scope of the *Order, see* the Issues and Decision Memorandum.[6]

Analysis of Comments Received

All issues raised in this sunset review are addressed in the Issues and Decision Memorandum.[7] The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Services System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Results of Sunset Review

Pursuant to sections 751(c)(1) and 752(b) of the Act, Commerce determines that revocation of the *Order* would be likely to lead to the continuation or recurrence of countervailable subsidies at the following rates:

Producer/exporter	Subsidy rate (percent *ad valorem*)
Shanxi Xuanshi Industrial Group Co., Ltd	34.87
Wor-Biz International Trading Co., Ltd. (Anhui)	7.37
Shijiazhuang Chengmei Import & Export Co., Ltd	133.94
All Others	23.28

Administrative Protective Order

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a). Timely written notification of the destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing these final results and notice in accordance with sections 751(c), 752(b), and 777(i)(1) of the Act, and 19 CFR 351.218.

Dated: October 31, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. History of the *Order*
V. Legal Framework
VI. Discussion of the Issues
. Likelihood of Continuation or Recurrence of a Countervailable Subsidy
2. Net Countervailable Subsidy Rates Likely to Prevail
3. Nature of the Subsidies
VII. Final Results of Review
VIII. Recommendation

[FR Doc. 2023–24476 Filed 11–3–23; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Cast Iron Soil Pipe Fittings From the People's Republic of China: Countervailing Duty Order,* 83 FR 44566 (August 31, 2018) (*Order*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 88 FR 42688 (July 3, 2023) (*Initiation Notice*). In the *Initiation Notice,* the product is erroneously listed as ''Cast Iron Soil Pipe,'' but the correct case number for the order on soil pipe fittings is given.

[3] *See* Domestic Interested Parties' Letter, ''Cast Iron Soil Pipe Fittings from the People's Republic of China: Notice of Intent to Participate in the First Five-Year Review,'' dated July 18, 2023.

[4] *See* Domestic Interested Parties' Letter, ''Cast Iron Soil Pipe Fittings from the People's Republic of China: Petitioner's Substantive Response to the Notice of Initiation,'' dated August 2, 2023 (Substantive Response).

[5] *See* Commerce's Letter, ''Sunset Reviews for July 2023,'' dated August 22, 2023.

[6] *See* Memorandum, ''Issues and Decision Memorandum for the Expedited First Sunset Review of the Countervailing Duty Order of Cast Iron Soil Pipe Fittings from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[7] *Id.*

DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–918]

Certain Paper Shopping Bags From India: Preliminary Affirmative Determination of Countervailable Subsidies, Preliminary Affirmative Determination of Critical Circumstances in Part, and Alignment of Final Determination With the Final Antidumping Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that countervailable subsidies are being provided to producers and exporters of certain paper shopping bags (paper bags) from India. The period of investigation (POI) is January 1, 2022, through December 31, 2022. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable November 6, 2023.

FOR FURTHER INFORMATION CONTACT: Paul Kebker or Drew Jackson, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2254 or (202) 482–4406, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 703(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this countervailing duty (CVD) investigation on June 26, 2023.[1] On August 7, 2023, Commerce postponed the preliminary determination until October 30, 2023.[2]

For a complete description of events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Investigation

The products covered by this investigation are paper bags from India. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to Commerce's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage, (*i.e.,* scope).[5] We received comments concerning the scope of the concurrent antidumping duty (AD) and CVD investigations of paper bags as it appeared in the *Initiation Notice,* which are listed in the Preliminary Decision Memorandum.[6] We are currently evaluating the scope comments filed by the interested parties and intend to issue our preliminary decision regarding the scope of the AD and CVD investigations prior to or concurrently with the AD preliminary determinations. We will incorporate the scope decisions from the AD investigations into the scope of the final CVD determination for this investigation, after considering any relevant comments submitted in scope case and rebuttal briefs.[7]

Preliminary Affirmative Determination of Critical Circumstances, in Part

In accordance with section 703(e)(1) of the Act, we preliminarily find that critical circumstances exist with respect to imports of subject merchandise for Velvin Paper Products. Additionally, we find that critical circumstances do not exist for Aero Plast Packaging Solutions Private Limited and companies subject to the all-others subsidy rate. For a full discussion of our preliminary critical circumstances determination, *see* the ''Critical Circumstances'' section of the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this investigation in accordance with section 701 of the Act. For each of the subsidy programs found to be countervailable, Commerce preliminarily determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[8]

Commerce notes that, in making these findings, it relied, in part, on facts available. For further information, *see* the ''Use of Facts Otherwise Available'' section in the Preliminary Decision Memorandum.

Alignment

In accordance with section 705(a)(1) of the Act and 19 CFR 351.210(b)(4), Commerce is aligning the final CVD determination in this investigation with the final determination in the companion AD investigation of paper bags from India based on a request made by the Coalition For Fair Trade in Shopping Bags (the petitioner).[9] Consequently, the final CVD determination will be issued on the same date as the final AD determination, which is currently scheduled to be issued no later than March 11, 2024, unless postponed.

All-Others Rate

Sections 703(d) and 705(c)(5)(A) of the Act provide that in the preliminary determination, Commerce shall determine an estimated all-others rate for companies not individually examined. This rate shall normally be an amount equal to the weighted average of the estimated subsidy rates established for those companies individually examined, excluding any zero and *de minimis* rates and any rates based entirely under section 776 of the Act.

In this investigation, Commerce preliminarily calculated individual estimated countervailable subsidy rates for both mandatory respondents that are not zero, *de minimis,* or based entirely on facts otherwise available. Therefore, Commerce calculated the all-others rate using a weighted average of the individually estimated subsidy rates calculated for the examined respondents

[1] *See Certain Paper Shopping Bags from India and the People's Republic of China: Initiation of Countervailing Duty Investigations,* 88 FR 41380 (June 26, 2023) (*Initiation Notice*).

[2] *See Certain Paper Shopping Bags from the People's Republic of China and India: Postponement of Preliminary Determinations in the Countervailing Duty Investigations,* 88 FR 52122 (August 7, 2023).

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Affirmative Determination in the Countervailing Duty Investigation of Certain Paper Shopping Bags from India,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[5] *See Initiation Notice,* 88 FR at 41380–81.

[6] *See* Preliminary Decision Memorandum at 5–6.

[7] The deadline for interested parties to submit scope case and rebuttal briefs will be established in the preliminary scope decision memorandum.

[8] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[9] *See* Petitioner's Letter, ''Petitioner's Request to Align Countervailing Duty Investigation Final Determination with Antidumping Duty Investigation Final Determination,'' dated October 5, 2023.

using each company's public ranged data for the value of its exports of subject merchandise to the United States.[10]

Preliminary Determination

Commerce preliminarily determines that the following estimated countervailable subsidy rates exist:

Company	Subsidy rate (percent ad valorem)
Aero Plast Packaging Solutions Private Limited[11]	5.00
Velvin Paper Products[12]	2.37
All Others	3.47

Suspension of Liquidation

In accordance with section 703(e)(2)(A) of the Act, because we find that critical circumstances exists for Velvin Paper Products, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after the date 90 days prior to the date of publication of this notice in the **Federal Register**. Further, pursuant to 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the rates indicated above.

For Aero Plast Packaging Solutions Private Limited and companies subject to the ''all-others'' subsidy rate, in accordance with section 703(d)(1)(B) and (d)(2) of the Act, Commerce will direct CBP to suspend liquidation of entries of subject merchandise as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after the date of the publication of this notice in the **Federal Register**. Further, pursuant to 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the rates indicated above.

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties in this preliminary determination within five days of its public announcement, or if there is no public announcement, within five days of the date of the publication of this notice, in accordance with 19 CFR 351.244(b).

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination.

Public Comment

All interested parties will have the opportunity to submit scope case and rebuttal briefs on the preliminary decision regarding the scope of the AD and CVD investigations. The deadlines to submit scope case and rebuttal briefs will be provided in the preliminary scope decision memorandum. For all scope case and rebuttal briefs, parties must file identical documents simultaneously on the records of the ongoing AD and CVD investigations. No new factual information or business proprietary information may be included in either scope case or rebuttal briefs.

Case briefs or other written comments on non-scope issues may be submitted to the Assistant Secretary for Enforcement and Compliance. Interested parties will be notified of the timeline for the submission of case briefs and written comments at a later date. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than seven days after the deadline date for case briefs after the deadline date for case briefs.[13] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) a statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[14]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, and a list of the issues to be discussed. Oral presentations at the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, parties will be notified of the time and date for the hearing.[15]

U.S. International Trade Commission Notification

In accordance with section 703(f) of the Act, Commerce will notify the U.S. International Trade Commission (ITC) of its preliminary determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether imports of paper bags from India are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published pursuant to sections 703(f) and 777(i) of the Act, and 19 CFR 351.205(c).

Dated: October 30, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The products within the scope of this investigation are paper shopping bags with handles of any type, regardless of whether there is any printing, regardless of how the top edges are finished (*e.g.,* folded, serrated, or otherwise finished), regardless of color, and regardless of whether the top edges contain adhesive or other material for sealing closed. Subject paper shopping bags have a width of at least 4.5 inches and depth of at least 2.5 inches.

Paper shopping bags typically are made of kraft paper but can be made from any type of cellulose fiber, paperboard, or pressboard with a basis weight less than 300 grams per square meter (GSM).

A non-exhaustive illustrative list of the types of handles on shopping bags covered by the scope include handles made from any materials such as twisted paper, flat paper, yarn, ribbon, rope, string, or plastic, as well as die-cut handles (whether the punchout is fully removed or partially attached as a flap).

Excluded from the scope are:

- Paper sacks or bags that are of a ⅛ or ⅐ barrel size (*i.e.,* 11.5–12.5 inches in width, 6.5- 7.5 inches in depth, and 13.5–17.5 inches in height) with flat paper handles or die-cut handles;
- Paper sacks or bags with die-cut handles, a grams per square meter paper weight of less than 86 GSM, and a height of less than 11.5 inches; and
- Shopping bags (i) with non-paper handles made wholly of woven ribbon or

[10] *See* Memorandum, ''Calculation of the Weighted-Average Dumping Margin for Companies Noy Selected for Individual Examination,'' dated concurrently with this notice.

[11] As discussed in the Preliminary Decision Memorandum, Commerce preliminarily determines that Aero Plast Packaging Solutions Private Limited is cross-owned with Aero Business Solutions Private Limited and Aero Plast Limited.

[12] As discussed in the Preliminary Decision Memorandum, Commerce preliminarily determines that Velvin Paper Products is cross-owned with Velvin Packaging Solutions Private Limited.

[13] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[14] *See Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings; Final Rule,* 88 FR 67069 (September 29, 2023).

[15] *See* 19 CFR 351.310(d).

other similar woven fabric and (ii) that are finished with folded tops or for which tied knots or t-bar aglets (made of wood, metal, or plastic) are used to secure the handles to the bags.

The above-referenced dimensions are provided for paper bags in the opened position. The height of the bag is the distance from the bottom fold edge to the top edge (*i.e.,* excluding the height of handles that extend above the top edge). The depth of the bag is the distance from the front of the bag edge to the back of the bag edge (typically measured at the bottom of the bag). The width of the bag is measured from the left to the right edges of the front and back panels (upon which the handles typically are located).

The merchandise is currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheadings 4819.30.0040 and 4819.40.0040. The HTSUS subheadings are provided for convenience and customs purposes only; the written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Investigation
IV. Scope Comments
V. Injury Test
VI. Preliminary Determination of Critical Circumstances, In Part
VII. Use of Facts Otherwise Available
VIII. Subsidies Valuation
IX. Benchmark Interest Rates and Discount Rates
X. Diversification of India's Economy
XI. Analysis of Programs
XII. Recommendation

[FR Doc. 2023–24472 Filed 11–3–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

[Docket Number: 230818–0199]

Request for Information on Implementation of the United States Government National Standards Strategy for Critical and Emerging Technology (USG NSSCET); Extension of Comment Period

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Notice; extension of comment period.

SUMMARY: The National Institute of Standards and Technology (NIST) is extending the period for submitting comments to support the development of an implementation plan for the United States Government National Standards Strategy for Critical and Emerging Technology (USG NSSCET) until December 22, 2023. In a Request for Information (RFI) that published in the **Federal Register** on September 7, 2023, NIST requested information on behalf of the U.S. Department of Commerce and the U.S. Government to support the development of an implementation plan for the United States Government National Standards Strategy for Critical and Emerging Technology (USG NSSCET). The USG NSSCET is intended to support and complement existing private sector-led activities and plans, including the American National Standards Institute (ANSI) United States Standards Strategy (USSS), with a focus on critical and emerging technology(ies) (CET). The USG NSSCET reinforces the U.S. Government's support of a private sector-led, open, consensus-based international standards system, corresponding to the World Trade Organization (WTO) Technical Barriers to Trade (TBT) Committee decision that articulates and elaborates on principles that are fundamental to the development of an international standards: transparency; openness; impartiality and consensus; effectiveness and relevance; and coherence. To inform the USG NSSCET implementation, including how to best partner with relevant stakeholders, NIST is requesting information that will support the identification and prioritization of key activities that will optimize the USG NSSCET implementation and further enhance the U.S. Government's ability to support a private sector-led, open, consensus-based international standards system, to which the U.S. Government is an active stakeholder and participant.

DATES: Comments must be received by 11:59 p.m. Eastern time on December 22, 2023. Comments received after November 6, 2023 and before publication of this notice are deemed to be timely. Submissions received after December 22, 2023 may not be considered. Those who have already submitted comments need not resubmit.

ADDRESSES: Comments may be submitted by either of the following methods:

- *Electronic submission:* Submit electronic public comments via the Federal eRulemaking Portal.

1. Go to *www.regulations.gov* and enter NIST–2023–0005 in the search field,

2. Click the ''Comment Now!'' icon, complete the required fields, and

3. Enter or attach your comments.

Comments containing references, studies, research, and other empirical data that are not widely published should include copies of the referenced materials. All submissions, including attachments and other supporting materials, will become part of the public record and subject to public disclosure.

All comments responding to this document will be a matter of public record. Relevant comments will generally be available on the Federal eRulemaking Portal at *www.regulations.gov.* After the comment period closes, relevant comments will generally be available on *www.standards.gov.* NIST will not accept comments accompanied by a request that part or all of the material be treated confidentially because of its business proprietary nature or for any other reason. Therefore, do not submit confidential business information or otherwise sensitive, protected, or personal information, such as account numbers, Social Security numbers, or names of other individuals.

For Public Meetings/Webcast: NIST may hold a series of ''Listening Sessions'' or ''Stakeholder Events'' in support of the USG NSSCET implementation. Information on these and any other NIST-sponsored events in connection with the USG NSSCET implementation will be announced at *www.standards.gov.*

FOR FURTHER INFORMATION CONTACT: For questions about this notice please contact: Standards Coordination Office (SCO), NIST via email at *sco@nist.gov* or by phone at (301) 975–5633. Please direct all media inquiries to Public Affairs Office (PAO), NIST via email at *inquires@nist.gov* or by phone at (301) 975–2762.

SUPPLEMENTARY INFORMATION: In an RFI that published in the **Federal Register** on September 7, 2023 (88 FR 61527), NIST requested information on behalf of the U.S. Department of Commerce and the U.S. Government to support the development of an implementation plan for the United States Government National Standards Strategy for Critical and Emerging Technology (USG NSSCET). The USG NSSCET is intended to support and complement existing private sector-led activities and plans, including the American National Standards Institute (ANSI) United States Standards Strategy (USSS), with a focus on critical and emerging technology(ies) (CET). The U.S. standards development system is unique because it is built upon a wide variety of processes that are open, voluntary, decentralized, and led by the private sector. These processes feature openness to participation by materially interested stakeholders with consensus-based decision making. Finalized standards

are primarily published by private sector standards organizations, not the U.S. Government. The U.S. Government supports standards development activities in accordance with the World Trade Organization (WTO) Technical Barriers to Trade Committee decision that articulates principles including transparency, openness, impartiality and consensus, effectiveness, relevance, and coherence. The USG NSSCET reinforces the U.S. Government's support of a private sector-led, open, consensus-based international standards system, to which the U.S. Government is an active stakeholder and participant. To inform the USG NSSCET implementation, including how to best partner with relevant stakeholders, NIST is requesting information that will support the identification and prioritization of key activities that will optimize the USG NSSCET implementation and further enhance the U.S. Government's ability to support a private sector-led, open, consensus-based international standards system. In addition to other agencies and Departments, bureaus across the U.S. Department of Commerce are involved in the USG NSSCET. They include the International Trade Administration (ITA), the Bureau of Industry and Security (BIS), the U.S. Patent and Trademark Office (USPTO), and the National Telecommunications and Information Administration (NTIA).

CET covered under the USG NSSCET include, but are not limited to:

- Communication and Networking Technologies
- Communication and Networking Technologies
- Semiconductors and Microelectronics, including Computing, Memory, and Storage Technologies
- Artificial Intelligence and Machine Learning
- Biotechnologies
- Positioning, Navigation, and Timing Services
- Digital Identity Infrastructure and Distributed Ledger Technologies
- Clean Energy Generation and Storage
- Quantum Information Technologies

There are also specific applications of CET that departments and agencies have determined will impact our global economy and national security. These include, but are not limited to:

- Automated and Connected Infrastructure
- Biobanking
- Automated, Connected, and Electrified Transportation
- Critical Minerals Supply Chains
- Cybersecurity and Privacy
- Carbon Capture, Removal, Utilization, and Storage

A full list of CETs identified by the National Science and Technology Council (NSTC) can be found *https://www.whitehouse.gov/wp-content/uploads/2022/02/02-2022-Critical-and-Emerging-Technologies-List-Update.pdf.*

The national interest in CET and associated areas of standardization demands a new and urgent level of coordination and effort. National policy priorities, as expressed in legislation and other statements of policy, will require new ways for public sector and private sector (*i.e.,* industry, including start-ups and small- and medium-sized enterprises (SMEs), academic community, and civil society organizations) stakeholders to cooperate in order to advance U.S. economic competitiveness and national security.

NIST is extending the comment period announced in the September 7, 2023 RFI from November 6, 2023 to December 15, 2023 in response to stakeholder requests for more time to respond to this important issue.

For Public Meetings/Webcast: NIST may hold a series of ''Listening Sessions'' or ''Stakeholder Events'' in support of the USG NSSCET implementation. Information on these and any other NIST-sponsored events in connection with the USG NSSCET implementation will be announced at *www.standards.gov.*

Alicia Chambers,

NIST Executive Secretariat.

[FR Doc. 2023–24444 Filed 11–3–23; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD435]

Determination of Overfishing or an Overfished Condition

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

ACTION: Notice.

SUMMARY: This action serves as a notice that NMFS, on behalf of the Secretary of Commerce (Secretary), has found that summer flounder is now subject to overfishing and thorny skate remains overfished. NMFS, on behalf of the Secretary, is required to provide this notice whenever it determines that a stock or stock complex is subject to overfishing, overfished, or approaching an overfished condition.

FOR FURTHER INFORMATION CONTACT: Caroline Potter, (301) 427–8522.

SUPPLEMENTARY INFORMATION: Pursuant to section 304(e)(2) of the Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. 1854(e)(2), NMFS, on behalf of the Secretary, must publish a notice in the **Federal Register** whenever it determines that a stock or stock complex is subject to overfishing, overfished, or approaching an overfished condition.

NMFS has determined that summer flounder is now subject to overfishing. The summer flounder determination is based on the most recent assessment, completed in 2023, using data through 2022, which indicates that the stock is subject to overfishing because the fishing mortality rate is greater than the maximum fishing mortality threshold. NMFS has notified the Mid-Atlantic Fishery Management Council of the requirement to end overfishing of summer flounder.

NMFS has determined that thorny skate remains overfished. The thorny skate determination is based on an update assessment completed in 2022, using data through 2021, which indicates that the stock remains overfished because the 2-year average biomass index is less than the minimum stock size threshold. NMFS continues to work with the New England Fishery Management Council to rebuild thorny skate.

Dated: October 31, 2023.

Jennifer M. Wallace,

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

[FR Doc. 2023–24425 Filed 11–3–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Large Pelagic Fishing Survey

AGENCY: National Oceanic & Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on

proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before January 5, 2024.

ADDRESSES: Interested persons are invited to submit written comments to Adrienne Thomas, NOAA PRA Officer, at *NOAA.PRA@noaa.gov.* Please reference OMB Control Number 0648–0380 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to John Foster, National Marine Fisheries Service, Office of Science and Technology, 1315 East-West Hwy./ FST1, Silver Spring, MD 21910, Phone: (301) 427–8130 or *john.foster@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for the extension of a currently approved information collection.

The National Marine Fisheries Service (NMFS) is responsible for monitoring and managing United States (U.S.) marine fisheries resources. Collection of information regarding fishing for large pelagic species (tunas, billfishes, swordfish, and sharks) is necessary to fulfill the following statutory requirements: Atlantic Tunas Convention Act (16 U.S.C. 971 *et seq.*), the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*), and to meet administrative requirements of the National Marine Fisheries Service (NMFS) Marine Recreational Fishery Policy implemented to comply with Executive Order 12962 on Recreational Fisheries.

The Atlantic Tunas Convention Act at 16 U.S.C. 971d(c)(3)(I) provides the Secretary of Commerce the authority to ''require any commercial or recreational fisherman to obtain a permit from the Secretary and report the quantity of catch of a regulated species''. Section 303(a) of the Magnuson-Stevens Act specifies data and analyses to be included in Fishery Management Plans (FMPs), as well as pertinent data, which shall be submitted to the Secretary of Commerce under the plan.

Recommendation One of the NMFS Marine Recreational Fishery (MRF) Policy focuses on developing ''a comprehensive data acquisition and analysis system (participation, catch, effort and socio-economic data) on a regular, continuing basis'' in support of the Executive Order 12962 requirement to assess the implementation and evaluate achievements of the ''Recreational Fishery Resources Conservation Plan.''

Because highly migratory species are only sought on a relatively small proportion of the total marine recreational angler fishing trips made, the fishing effort directed at such species, and the resulting angler catches are generally not estimated very precisely or accurately by general (all species) recreational surveys. Therefore, the Large Pelagics Survey (LPS) was designed as a specialized survey that would focus specifically on the recreational fishery directed at large pelagic, also called highly migratory, species. This specialization has allowed higher levels of sampling needed to provide more precise and accurate estimates of pelagic fishing effort and catches of large pelagic species.

The LPS consists of two complementary surveys: a directory frame telephone survey of tuna and/or HMS permit holders to obtain fishing effort information (Large Pelagic Telephone Survey or LPTS), and a dockside survey which collects catch information and also estimates the proportion of vessels fishing for large pelagics that are not on the telephone frame (Large Pelagic Intercept Survey or LPIS). Results from the two survey components are combined to estimate total landings of Highly Migratory Species. In addition, we are requesting approval to continue to implement the Large Pelagic Biological Survey (LPBS) to collect supplemental weight and length measurements of landed fish through independent dockside sampling, as well as LPIS Validation telephone calls to validate LPIS data. Implementation of certain components will depend on fiscal year funding and NMFS priorities.

NMFS, regional fishery management councils, interstate marine fisheries commissions, and state fishery agencies use the data in developing, implementing and monitoring fishery management programs. This collection has been the key source of data used to monitor recreational quotas for the harvest of bluefin tuna in the Mid-Atlantic and southern New England regions. Catch distributions, harvested size distributions, and other indices obtained in this data collection have formed the basis of fishery management plans and used in stock assessments for Atlantic highly migratory species such as tunas, billfish, swordfish and sharks.

II. Method of Collection

Dockside (in-person) interviews and telephone interviews.

III. Data

OMB Control Number: 0648–0380.

Form Number(s): None.

Type of Review: Regular submission (extension of a current information collection).

Affected Public: Individuals or households; business or other for-profit organizations.

Estimated Number of Respondents: 15,024.

Estimated Time Per Response: 11 minutes for a telephone interview; 5 minutes for a dockside interview, 1½ minutes to respond to a follow-up validation call for dockside interviews; 1 minute for biological sampling of catch.

Estimated Total Annual Burden Hours: 3,608.

Estimated Total Annual Cost to Public: $0 in recordkeeping/reporting costs.

Respondent's Obligation: Mandatory.

Legal Authority: Magnuson-Stevens Fishery Conservation and Management Act, Atlantic Tunas Convention Act.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment

to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2023–24440 Filed 11–3–23; 8:45 am]

BILLING CODE 3510–22–P

U.S. INTERNATIONAL DEVELOPMENT FINANCE CORPORATION

Notice of Public Hearing

AGENCY: U.S. International Development Finance Corporation.

ACTION: Announcement of public hearing.

SUMMARY: The Board of Directors of the U.S. International Development Finance Corporation (''DFC'') will hold a public hearing on December 6, 2023. This hearing will afford an opportunity for any person to present views in accordance with section 1413(c) of the BUILD Act of 2018. Those wishing to present at the hearing must provide advance notice to the agency as detailed below.

DATES: Public hearing: 2:00 p.m. EST, Wednesday, December 6, 2023.

Registration: To attend, present at, or submit a written statement to the Board prior to the public hearing, individuals must notify DFC Acting Deputy Corporate Secretary Abigail Wade at *corporate.secretary@dfc.gov* at by 5:00 p.m. EST, Tuesday, November 28, 2023.

Notices of intent to attend or present at the public hearing must include the individual's name, title, organization, address, email address, phone number, and a concise summary of the subject matter to be presented. Oral presentations may not exceed five minutes and may be reduced proportionately, if necessary, to afford all participants an opportunity to be heard.

Written statements submitted to the Board prior to the public hearing must include the individual's name, title, organization, address, email address, and phone number. Statements must be typewritten, double-spaced, and less than ten pages in length.

Deborah Papadopoulos,

Records Management Specialist.

[FR Doc. 2023–24459 Filed 11–3–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Req No. OS–2024–00032]

Defense Science Board; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Research and Engineering (USD(R&E)), Department of Defense (DoD).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal Advisory Committee meeting of the Defense Science Board (DSB) will take place.

DATES: Closed to the public Wednesday, November 8, 2023, from 8:00 a.m. to 3:50 p.m. and Thursday, November 9, 2023 from 9:00 a.m. to 4:30 p.m.

ADDRESSES: The address of the closed meeting is the Pentagon, Rooms 5E732 and 3A912A, Washington, DC, 20301.

FOR FURTHER INFORMATION CONTACT: Ms. Elizabeth J. Kowalski, Designated Federal Officer (DFO): (703) 571–0081 (Voice), (703) 697–1860 (Facsimile), *elizabeth.j.kowalski.civ@mail.mil,* (Email). Mailing address is Defense Science Board, 3140 Defense Pentagon, Washington, DC 20301–3140. Website: *http://www.acq.osd.mil/dsb/*. The most up-to-date changes to the meeting agenda can be found on the website.

SUPPLEMENTARY INFORMATION: Due to circumstances beyond the control of the Designated Federal Officer, the Defense Science Board was unable to provide public notification required by 41 CFR 102–3.150(a) concerning its November 8–9, 2023 meeting. Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

This meeting is being held under the provisions of chapter 10 of title 5, United States Code (U.S.C.) (commonly known as the ''Federal Advisory Committee Act'' or ''FACA''), 5 U.S.C. 552b (commonly known as the ''Government in the Sunshine Act''), and sections 102–3.140 and 102–3.150 of title 41, Code of Federal Regulations (CFR).

Purpose of the Meeting: The mission of the DSB is to provide independent advice and recommendations on matters relating to the DoD's scientific and technical enterprise. The objective of the meeting is to obtain, review, and evaluate classified information related to the DSB's mission. DSB membership will meet with DoD Leadership to discuss classified current and future national security challenges and priorities within the DoD.

Agenda: The meeting will begin on Wednesday, November 8, 2023 at 8:00 a.m. Eastern Standard time (EST), Ms. Betsy Kowalski, Designated Federal Officer and Dr. Eric Evans, Chair of the DSB, will provide classified opening remarks regarding ongoing studies. Next, the Security Assistance Group-Ukraine will provide a classified briefing on updates regarding the conflict in Ukraine. After a short break, the DSB will receive a classified briefing from Honorable Douglas. R. Bush, Acting Assistant Secretary of the Army (Acquisition, Logistics and Technology) on the Army's acquisition priorities. Following a break, Dr. Katherine McGrady and Dr. Robert Wisnieff, DSB Members, will provide a classified briefing on the Defense Science Board's Task Force to Advise Implementation and Prioritization of National Security Innovation Activities findings and recommendations, followed by a DSB vote. After a break, the board will receive a classified briefing from Mr. Frederick J. Stefany, Acting Assistant Secretary of the Navy for Research, Development and Acquisition on the Navy's acquisition priorities. Lastly, Mr. William B. ''Willie'' Nelson, Deputy to the Commanding General, Army Futures Command, will provide a classified briefing on Army Future Command's acquisition priorities. The meeting will adjourn at 3:50 p.m. EST.

The meeting will continue on Thursday, November 9, 2023 at 9:00 a.m. EST with a classified briefing from Dr. Philip Root [Army Lieutenant Colonel (ret), Ph.D.], Director of the Strategic Technology Office (STO) of Defense Advanced Research Projects Agency on STO's acquisition priorities. This will be followed by a classified briefing provided by Mr. Andrew P. Hunter, Service Acquisition Executive for the United States Air Force (USAF), on the USAF's acquisition priorities. Following a break, Dr. Derek Tournear, Director, Space Development Agency (SDA), will provide a classified overview of SDA's overview. After a break, Dr. Robert Grossman and Dr. Mark Maybury, DSB Members, will provide a classified briefing on the DSB's Task Force on Digital Engineering Capability to Automate Testing and Evaluation findings and recommendations, followed by a DSB vote. After a break, the board will receive a classified briefing from Dr. David Van Wie, DSB Member, regarding the DSB's Task Force on Test and Evaluation findings and recommendations, followed by a DSB

vote. The meeting will adjourn at 4:30 p.m. EST.

Meeting Accessibility: In accordance with 5 U.S.C. 1009(d) and 41 CFR 102–3.155, the DoD has determined that the DSB meeting will be closed to the public. Specifically, the USD(R&E), in consultation with the DoD Office of the General Counsel, has determined in writing that the meeting will be closed to the public because it will consider matters covered by 5 U.S.C. 552b(c)(1). The determination is based on the consideration that it is expected that discussions throughout will involve classified matters of national security concern. Such classified material is so intertwined with the unclassified material that it cannot reasonably be segregated into separate discussions without defeating the effectiveness and meaning of the overall meetings. To permit the meeting to be open to the public would preclude discussion of such matters and would greatly diminish the ultimate utility of the DSB's findings and recommendations to the Secretary of Defense and to the USD(R&E).

Written Statements: In accordance with 5 U.S.C. 1009(a)(3) and 41 CFR 102–3.105(j) and 102–3.140, interested persons may submit a written statement for consideration by the DSB at any time regarding its mission or in response to the stated agenda of a planned meeting. Individuals submitting a written statement must submit their statement to the DSB DFO at the email address provided in the **FOR FURTHER INFORMATION CONTACT** section at any point; however, if a written statement is not received at least three calendar days prior to the meeting, which is the subject of this notice, then it may not be provided to or considered by the DSB until a later date.

Dated: October 30, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–24415 Filed 11–3–23; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Req No. OS–2024 00031–FR]

Defense Business Board; Notice of Federal Advisory Committee Meeting

AGENCY: Office of the Deputy Secretary of Defense, Department of Defense (DoD).

ACTION: Notice of Federal advisory committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal advisory committee meeting of the Defense Business Board (''the Board'') will take place.

DATES: Closed to the public Tuesday, November 14, 2023 from 9:15 a.m. to 11:20 a.m. Eastern Standard Time (EST) and from 5:30 p.m. to 7:35 p.m. EST and on Wednesday, November 15 from 10:55 a.m. to 11:35 a.m. EST. Open to the public Tuesday, November 14 from 11:25 a.m. to 12:30 p.m. EST and from 1:45 p.m. to 4:45 p.m. EST and on Wednesday, November 15, 2023 from 9 a.m. to 10:45 a.m. EST.

ADDRESSES: The open and closed portions of the meeting will be in rooms 1E840 and 4D880 in the Pentagon, Washington DC.

FOR FURTHER INFORMATION CONTACT: Ms. Cara Allison Marshall, Designated Federal Officer (DFO) of the Board in writing at Defense Business Board, 1155 Defense Pentagon, Room 5B1088A, Washington, DC 20301–1155; or by email at *cara.l.allisonmarshall.civ@mail.mil;* or by phone at 703–614–1834.

SUPPLEMENTARY INFORMATION: Due to circumstances beyond the control of the Designated Federal Officer, the Defense Business Board was unable to provide public notification required by 41 CFR 102–3.150(a) concerning its November 14–15, 2023 meeting. Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

This meeting is being held under the provisions of chapter 10 of title 5, United States Code (U.S.C.) (commonly known as the ''Federal Advisory Committee Act'' or ''FACA''), 5 U.S.C. 552b (commonly known as the ''Government in the Sunshine Act''), and 41 CFR 102–3.140 and 102–3.150.

Purpose of the Meeting: The mission of the Board is to examine and advise the Secretary of Defense on overall DoD management and governance. The Board provides independent, strategic-level, private sector and academic advice and counsel on enterprise-wide business management approaches and best practices for business operations and achieving National Defense goals.

Agenda: The Board will begin in closed session on November 14 from 9:15 a.m. to 11:20 a.m. EST. The DFO will begin the closed session followed by a welcome by Board Chair, Honorable (Hon.) Deborah James. The Board will receive a classified discussion on the DoD Budget from Hon. Kathleen Hicks, Deputy Secretary of Defense, followed by a classified overview on Acquiring Capabilities for the United States Space Force (Space Force) from Lieutenant Colonel Raquel Salim, Space Force, Program Element Monitor, Space Domain Awareness & Space Control. This briefing will provide an overview of the Space Force mission, organizational structure, leadership, capabilities, and space acquisition. The DFO will adjourn the closed session. The Board will meet in open session November 14 from 11:25 a.m. to 12:30 p.m. EST. The DFO will open the public session followed by a welcome by the Board Chair. The Board will receive an update on DoD Talent Management from Mr. Brynt Parmeter, Chief Talent Management Officer, and Ms. Angela Cough, Chief Digital and Artificial Intelligence Office Senior Advisor, Digital Workforce Talent & Functional Community Management. After a lunch break, the Board will resume their open session from 1:45 p.m. to 4:45 p.m. EST. The Board Chair will provide remarks, followed by a discussion on Enterprise Digitization: Emerging Technologies and Ecosystem Strategy at the Speed of Artificial Intelligence from Mr. Ryan McManaus, Founder and CEO of Techtonic. After a short break, the Board will receive a presentation on the Board study, Improving the Business Operations Culture of the DoD from General (Gen.) Larry Spencer (Ret), Chair, Talent Management, Culture, & Diversity Subcommittee, and then the Board will deliberate and vote on the study. The DFO will then adjourn the open session. The Board will reconvene in closed session on November 14 from 5:30 p.m. to 7:35 p.m. EST. The DFO will begin the closed session followed by remarks by Board Chair, Hon. Deborah James and Deputy Secretary, Hon. Kathleen Hicks. Next, the Board will hear a classified update on the United States Army's Future Development and Joint Integration from Gen. Randy George, Chief of Staff of the Army. The DFO will adjourn the closed session. The Board will meet in open session November 15, 2023 from 9:00 a.m. to 10:45 a.m. EST. The DFO will begin the closed session followed by the Chair's welcome. Next the Board will receive a presentation on the Board Space Acquisition study from Ms. Linnie Haynesworth, Chair, Business Operations Advisory Subcommittee, and then the Board will deliberate and vote on the study. The DFO will adjourn the open session. The Board will reconvene in closed session on November 15 from 10:55 a.m. to 11:35 a.m. EST. The DFO will begin the closed session followed by a classified discussion on DoD Current Affairs from

Hon. Lloyd Austin, Secretary of Defense. The DFO will then adjourn the closed session.

The latest version of the agenda will be available on the Board's website at: *https://dbb.dod.afpims.mil/Meetings/Meeting-November-2023/*.

Meeting Accessibility: In accordance with 5 U.S.C. 1009(d) and 41 CFR 102–3.155, it is hereby determined that the November 14–15 meeting of the Board will include classified information and other matters covered by 5 U.S.C. 552b(c)(1) and that, accordingly, portions of the meeting will be closed to the public. This determination is based on the consideration that it is expected that discussions throughout the closed portions will involve classified matters of national security. Such classified material is so intertwined with the unclassified material that it cannot reasonably be segregated into separate discussions without defeating the effectiveness and meaning of these portions of the meeting. To permit these portions of the meeting to be open to the public would preclude discussion of such matters and would greatly diminish the ultimate utility of the Board's findings and recommendations to the Secretary of Defense and the Deputy Secretary of Defense. Pursuant to 5 U.S.C. 1009(a)(1) and 41 CFR 102–3.140, the portions of the meeting on November 14 from 11:25 a.m. to 12:30 p.m. EST and from 1:45 p.m. to 4:45 p.m. EST and on November 15, 2023 from 9 a.m. to 10:45 a.m. EST are open to the public virtually. Persons desiring to attend the public sessions are required to register. To attend the public sessions, submit your name, affiliation/organization, telephone number, and email contact information to the Board at *osd.pentagon.odam.mbx.defense-business-board@mail.mil.* Requests to attend the public sessions must be received no later than 4:00 p.m. EST on Friday, November 10, 2023. Upon receipt of this information, the Board will provide further instructions for virtually attending the meeting.

Written Comments and Statements: Pursuant to 41 CFR 102–3.105(j) and 102–3.140 and 5 U.S.C. 1009(a)(3) of the FACA, the public or interested organizations may submit written comments or statements to the Board in response to the stated agenda of the meeting or regarding the Board's mission in general. Written comments or statements should be submitted to Ms. Cara Allison Marshall, the DFO, via electronic mail (the preferred mode of submission) at the address listed in the **FOR FURTHER INFORMATION CONTACT** section. Each page of the comment or statement must include the author's name, title or affiliation, address, and daytime phone number. The DFO must receive written comments or statements submitted in response to the agenda set forth in this notice by Friday, November 10, 2023, to be considered by the Board. The DFO will review all timely submitted written comments or statements with the Board Chair and ensure the comments are provided to all members of the Board before the meeting. Written comments or statements received after this date may not be provided to the Board until its next scheduled meeting. Please note that all submitted comments and statements will be treated as public documents and will be made available for public inspection, including, but not limited to, being posted on the Board's website.

Dated: October 30, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–24451 Filed 11–3–23; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Req No. OS–2024–00033–FR]

Defense Advisory Committee on Diversity and Inclusion; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness (USD(P&R)), Department of Defense (DoD).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: DoD is publishing this notice to announce that the following Federal Advisory Committee meeting of the Defense Advisory Committee on Diversity and Inclusion (DACODAI) will occur.

DATES: DACODAI will hold an open-to-the-public meeting—Thursday, December 14, 2023, from 9:00 a.m. to 12:15 p.m. (EST) and Friday, December 15, 2023, from 9:00 a.m. to 12:20 p.m. EST.

ADDRESSES: The in-person meeting will be held at the Association of the United States Army (AUSA) Conference and Event Center, 2425 Wilson Blvd., Arlington, VA 22201. In addition, the meeting will be held via videoconference. Participant access information will be provided after registering.

FOR FURTHER INFORMATION CONTACT: Designated Federal Officer (DFO), Ms. Shirley Raguindin, (571) 645–6952 (voice), *osd.mc-alex.ousd-p-r.mbx.dacodai@mail.mil* (email). Additional information is also available at the DACODAI website: *https://www.dhra.mil/DACODAI.*

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of chapter 10 of title 5, United States Code (U.S.C.) (commonly known as the ''Federal Advisory Committee Act'' or ''FACA''), 5 U.S.C. 552b (commonly known as the ''Government in the Sunshine Act''), and 41 Code of Federal Regulations (CFR) 102–3.140 and 102–3.150.

Availability of Materials for the Meeting: Additional information, including the agenda or any updates to the agenda, is available on the DACODAI website: *https://www.dhra.mil/DACODAI/*. Materials presented in the meeting may also be obtained on the DACODAI website. *Purpose of the Meeting:* The purpose of the meeting is for the DACODAI to receive briefings and have discussions on topics related to racial/ethnic diversity, inclusion, and equal opportunity within the Armed Forces of the United States. In addition, the committee members will vote on the 2023 DACODAI proposed recommendations for the Secretary of Defense. *Agenda:* Thursday, December 14, 2023, from 9:00 a.m. to 12:15 p.m. EST. DACODAI will begin in open session on December 14, 2023, from 9:00 a.m. to 12:15 p.m. EST with opening remarks by Ms. Shirley Raguindin, the DFO and the DACODAI's Chair, General (Gen.) (Ret.) Lester Lyles, The DACODAI will receive the following briefings: (1) the United States Africa Command (AFRICOM) on Diversity and Inclusion by Colonel Lynn Ray, Chief Diversity and Inclusion Officer, AFRICOM (2) the Office of Diversity, Equity, and Inclusion Progress by Dr. Lisa Arfaa, Director, Office for Diversity, Equity, and Inclusion; and (3) the Defense Testing and Assessment Center Diversity and Inclusion Efforts by Dr. Tia Fechter. Closing remarks will be provided by the Chair, Gen. (Ret.) Lyles, and Ms. Shirley Raguindin, DACODAI DFO, will adjourn the meeting.

Friday, December 15, 2023, from 9:00 a.m. to 12:20 p.m. EST. The DACODAI will begin in an open session on December 15, 2023, from 9:00 a.m. to 12:20 p.m. EST with opening remarks by Ms. Shirley Raguindin, the DFO and the DACODAI's Chair, Gen. (Ret.) Lester Lyles. The DACODAI will vote on proposed recommendations for the Secretary of Defense. Closing remarks will be provided by the Chair, Gen.

(Ret.) Lyles, and Ms. Shirley Raguindin, DACODAI DFO, will adjourn the meeting.

Meeting Accessibility: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 and 102–3.150, this meeting is open to the public from 9:00 a.m. to 12:15 p.m. EST on December 14, 2023; and from 9:00 a.m. to 12:20 p.m. EST on December 15, 2023. The meeting will be held via videoconference. The number of participants is limited and is on a first-come basis. All members of the public who wish to participate must register by contacting DACODAI at *osd.mc-alex.ousd-p-r.mbx.dacodai@mail.mil* or by contacting Ms. Shirley Raguindin at (571) 645–6952 no later than Friday, December 8, 2023 (by 5:00 p.m. EST). Once registered, the web address and/or audio number will be provided.

Special Accommodations: Individuals requiring special accommodations to access the public meeting should contact the DFO, Ms. Shirley Raguindin at *osd.mc-alex.ousd-p-r.mbx.dacodai@mail.mil* or (571) 645–6952 no later than Friday, December 8, 2023 (by 5:00 p.m. EST) so appropriate arrangements can be made.

Written Statements: Pursuant to 41 CFR 102–3.140(c) and section 10(a)(3) of the FACA, the public or interested parties may submit written statements to the DACODAI membership about the DACODAI's mission and functions. Written statements may be submitted at any time or in response to the stated agenda of planned meetings of the DACODAI. All written statements shall be submitted to the DFO, Ms. Shirley Raguindin, for the DACODAI, who will ensure that the written statements are provided to the membership for their consideration. All written statements will be submitted to mailing address, 4800 Mark Center Drive, Suite 06E22, Alexandria, VA 22350. Members of the public interested in making an oral statement must submit a written statement. If a statement is not received by Friday, December 8, 2023, it may not be provided to or considered by the DACODAI during this biannual business meeting. After reviewing the written statements, the Chair and the DFO will determine if the requesting person(s) can make an oral presentation. The DFO will review all timely submissions with the DACODAI Chair and ensure they are provided to the members of the DACODAI.

Members of the public may also email written statements to *osd.mc-alex.ousd-p-r.mbx.dacodai@mail.mil*. Written statements pertaining to the meeting agenda for the DACODAI's meeting on December 14, 2023, must be submitted no later than 5:00 p.m. EST, Friday, December 8, 2023, to be considered by the DACODAI membership prior to its December 14, 2023 meeting.

Dated: October 31, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–24417 Filed 11–3–23; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Req No. OS–2024–00029–FR]

Defense Advisory Committee on Women in the Services; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal Advisory Committee meeting of the Defense Advisory Committee on Women in the Services (DACOWITS) will take place.

DATES: DACOWITS will hold an open to the public meeting—Tuesday, December 5, 2023, from 8:00 a.m. to 3:00 p.m. (EST).

ADDRESSES: The meeting will take place at the Association of the United States Army Conference Center, located at 2425 Wilson Boulevard, Arlington, Virginia, 22201. The meeting will also be held virtually. To participate in the meeting, see the Meeting Accessibility section for instructions.

FOR FURTHER INFORMATION CONTACT: LTC Samantha Frazier, Designated Federal Officer (DFO), (202) 650–2943 (voice), *Samantha.j.frazier11.mil@mail.mil* (email). The most up-to-date changes to the meeting agenda can be found on the website: *https://dacowits.defense.gov*.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of chapter 10 of title 5 United States Code (U.S.C.) (commonly known as the ''Federal Advisory Committee Act'' or ''FACA''), 5 U.S.C. 552(b) (commonly known as the ''Government in the Sunshine Act''), and 41 Code of Federal Regulations (CFR) 102–3.140 and 102–3.150.

Availability of Materials for the Meeting: Additional information, including the agenda or any updates to the agenda, is available at the DACOWITS website, *https://dacowits.defense.gov/*. Materials presented in the meeting may also be obtained on the DACOWITS website.

Purpose of the Meeting: The purpose of the meeting is for the DACOWITS to receive briefings and have discussions on topics related to the recruitment, retention, employment, integration, well-being, and treatment of women in the Armed Forces of the United States. Additionally, the Committee will vote on some additional 2023 recommendations.

Agenda: Tuesday, December 5, 2023, from 8:00 a.m. to 3:00 p.m.—Welcome, Introductions, Announcements, Request for Information Status Update, Briefings, Public Comment Period, Vote on Recommendations, and DACOWITS discussion.

Meeting Accessibility: Pursuant to 5 U.S.C. 552(b) and 41 CFR 102–3.140 through 102–3.165, this meeting is open to the public, subject to availability of space, from 8:00 a.m. to 3:00 p.m. on December 5, 2023. The meeting will also be streamed by videoconference. The number of participants is limited and is on a first-come basis. Any member of the public who wishes to participate via videoconference must register by contacting DACOWITS at *osd.pentagon.ousd-p-r.mbx.dacowits@mail.mil* or by contacting Mr. Robert Bowling at (703) 380–0116 no later than Monday, November 27, 2023. Once registered, the videoconference information will be provided.

Special Accommodations: Individuals requiring special accommodations to access the public meeting should contact Mr. Robert Bowling no later than Monday, November 27, 2023, so appropriate arrangements can be made.

Written Statements: Pursuant to 41 CFR 102–3.140, and section 10(a)(3) of the FACA, interested persons may submit a written statement to the DACOWITS. Individuals submitting a written statement must submit their statement no later than 5:00 p.m. EST, Monday, November 27, 2023, to Mr. Robert Bowling at (703) 380–0116 (voice) or to *robert.d.bowling1.mil@mail.mil* (email). Mailing address is 4800 Mark Center Drive, Suite 04J25–01, Alexandria, VA 22350. Members of the public interested in making an oral statement, must submit a written statement. If a statement is not received by Monday, November 27, 2023, it may not be provided to or considered by the Committee during this quarterly business meeting. After reviewing the written statements, the Chair and the DFO will determine if the requesting persons are permitted to make an oral presentation. The DFO will review all timely submissions with the DACOWITS Chair and ensure they are

provided to the members of the Committee.

Dated: October 26, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–24416 Filed 11–3–23; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Req No. OS–2024–00030–FR]

Defense Advisory Committee on Military Personnel Testing; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness, (USD(P&R)) Department of Defense (DoD).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal Advisory Committee meeting of the Defense Advisory Committee on Military Personnel Testing (DACMPT) will take place.

DATES: Open to the public Tuesday, December 19, 2023 from 1:00 p.m. to 3:00 p.m., Eastern Time.

ADDRESSES: This will be a virtual meeting using Microsoft Teams. Link is: *https://usg01.safelinks.protection.office365.us/ap/t-59584e83/?url=https%3A%2F%2Fteams.microsoft.com%2Fl%2Fmeetup-join%2F19%253ameeting_MWE2Y2Q3ZmMtNWY5ZS00OWJlLTllOWItYWRmOTNmODI4ZTQx%2540thread.v2%2F0%3Fcontext%3D%257b%2522Tid%2522%253a%2522ca9c4d2f-3529-4c0f-b5ad-059f3b26b20c%2522%252c%2522Oid%2522%253a%2522223e7d39-62a6-4864-9b9d-3547a173a97f%2522%257d&data=05%7C01%7Csofiya.velgach.civ%40mail.mil%7C66506e89361c4912ff6708dbcb4c6b82%7C102d0191eeae4761b1cb1a83e86ef445%7C0%7C0%7C638327301326942569%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=geeh06J4hqhVfbdPRwbl1TkmJaMD0070xz4Zsaq5oZE%3D&reserved=0;*.

Dial-in: (571) 429–6145; Phone Conference ID: 234 784 596#.

Additional meeting details will be posted on: *https://dacmpt.com*.

FOR FURTHER INFORMATION CONTACT: Designated Federal Officer (DFO), Dr. Sofiya Velgach, (703) 697–9271 (Voice), 703 614–9272 (Facsimile), *osd.pentagon.ousd-p-r.mbx.dacmpt@mail.mil* (Email). Mailing address is DFO, Accession Policy, Office of the USD(P&R), Room 3D1066, The Pentagon, Washington, DC 20301–4000. The most up-to-date changes to the meeting can be found on the website: *https://dacmpt.com*.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of chapter 10 of title 5, United States Code (U.S.C.) (commonly known as the ''Federal Advisory Committee Act'' or ''FACA''); 5 U.S.C. 552b (commonly known as the ''Government in the Sunshine Act''); and 41 Code of Federal Regulations (CFR) 102–3.140 and 102–3.150.

Purpose of the Meeting: The purpose of the meeting is to provide an overview and obtain DACMPT members' recommendation on the methodology and proposed way forward for allowing the use of calculators on the quantitative sections of the Armed Services Vocational Aptitude Battery (ASVAB). Additional information can be found at *https://dacmpt.com*.

Agenda:

Tuesday, December 19, 2023

1:00 p.m.–1:05 p.m. Welcome and Opening Remarks, Dr. Sofiya Velgach, Office of the Assistant Secretary of Defense for Manpower and Reserve Affairs/Accession Policy

1:05 p.m.–2:00 p.m. Calculators on the ASVAB, Dr. David M. Trippe, Office of People Analytics/Defense Testing and Assessment Center

2:00 p.m.–2:45 p.m. Immediate Implementation of Calculators, Mr. Ethan Blankenship Office of the Assistant Secretary of Defense for Manpower and Reserve Affairs/Accession Policy

2:45 p.m.–2:55 p.m. Public Comments

2:55 p.m.–3:00 p.m. Closing Comments. Dr. Nancy Tippins, Chair

Latest version of the agenda will be posted on *https://dacmpt.com*.

Meeting Accessibility: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, and the availability of space, this meeting is virtually open to the public. Dial-in and access availability is based on first-come, first-served basis. All members of the public who wish to attend the public meeting must contact the DFO no later than 12:00 p.m. on Monday, December 4, 2023, as listed in the **FOR FURTHER INFORMATION CONTACT** section.

Written Statements: Pursuant to 41 CFR 102–3.105(j) and 102–3.140 and section 10(a)(3) of the FACA, interested persons may submit written statements to the DACMPT at any time about its approved agenda or at any time on the DACMPT's mission. Written statements should be submitted to the DACMPT's DFO at the address or facsimile number listed in the **FOR FURTHER INFORMATION CONTACT** section. If statements pertain to a specific topic being discussed at the planned meeting, then these statements must be submitted no later than five (5) business days prior to the meeting in question. Written statements received after this date may not be provided to, or not considered by the DACMPT until its next meeting. The DFO will review all timely submitted written statements and provide copies to all the DACMPT members before the meeting that is the subject of this notice. Please note that since the DACMPT operates under the provisions of the FACA, all submitted comments and public presentations will be treated as public documents and will be made available for public inspection. Opportunity for public comments will be provided at the end of each day. Public comments will be limited to 2 minutes per person, as time allows.

Dated: October 30, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–24402 Filed 11–3–23; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF EDUCATION

Accrediting Agencies Currently Undergoing Review for the Purpose of Recognition by the U.S. Secretary of Education

AGENCY: Accreditation Group, Office of Postsecondary Education, U.S. Department of Education.

ACTION: Call for written third-party comments.

SUMMARY: This notice provides information to members of the public on submitting written comments for accrediting agencies currently undergoing review for the purpose of recognition by the U.S. Secretary of Education.

FOR FURTHER INFORMATION CONTACT: Herman Bounds, Director, Accreditation Group, Office of Postsecondary Education, U.S. Department of Education, 400 Maryland Avenue SW, Fifth Floor, Washington, DC 20202,

telephone: (202) 453–7615, or email: *herman.bounds@ed.gov.*

SUPPLEMENTARY INFORMATION: This request for written third-party comments concerning the performance of accrediting agencies under review by the Secretary of Education is required by 496(n)(1)(A) of the Higher Education Act (HEA) of 1965, as amended, and pertains to the winter 2025 meeting of the National Advisory Committee on Institutional Quality and Integrity (NACIQI). The meeting date and location have not been determined but will be announced in a later **Federal Register** notice. In addition, a later **Federal Register** notice will describe how to register to provide oral comments at the meeting. *Note:* Written comments about the specific agencies identified below will not be accepted or provided to NACIQI members if those comments are submitted after the deadline provided in this **Federal Register** notice, which is December 8, 2023. Written comments must be submitted to the mailbox identified below. Do not submit written comments directly to Department officials or to NACIQI members.

Agencies under Review and Evaluation: The Department requests written comments from the public on the following accrediting agencies, which are currently undergoing review and evaluation by the Accreditation Group, and which will be reviewed at the winter 2025 NACIQI meeting. The agencies are listed by the type of application or report each agency has submitted. Please note, each agency's current scope of recognition is indicated below. If any agency requested to expand its scope of recognition, identified are both the current scope of recognition and the requested scope of recognition.

Compliance Reports

1. American Occupational Therapy Association, Accreditation Council for Occupational Therapy Education. Scope of Recognition: The accreditation and preaccreditation of occupational therapy educational programs offering the professional master's degree and occupational therapy doctorate (OTD) degree; the accreditation of occupational therapy assistant programs offering a baccalaureate degree and associate degree; and the accreditation of these programs offered via distance education. Geographic Area of Accrediting Activities: The United States. The compliance report includes findings of noncompliance with certain criteria in 34 Code of Federal Regulations (CFR) part 602 identified in the October 19, 2022, letter from the senior Department official (SDO) following the July 19, 2022, NACIQI meeting. The SDO letter is available under NACIQI meeting date 7/19/2022, at *https://surveys.ope.ed.gov/erecognition/#/public-documents.*

2. Association for Clinical Pastoral Education. Scope of Recognition: The preaccreditation and accreditation of CPE Level I/Level II programs and Certified Educator CPE programs, and the accreditation of these programs offered via distance education. Geographic Area of Accrediting Activities: The United States. The compliance report includes findings of noncompliance with certain criteria in 34 CFR part 602 identified in the November 10, 2022, letter from the SDO following the July 19, 2022, NACIQI meeting. The SDO letter is available under NACIQI meeting date 7/19/2022, at *https://surveys.ope.ed.gov/erecognition/#/public-documents.*

3. Accrediting Council for Pharmacy Education. Scope of Recognition: The accreditation and pre-accreditation of professional degree programs in pharmacy leading to the degree of Doctor of Pharmacy, including those programs offered via distance education. Geographic Area of Accrediting Activities: The United States. The compliance report includes findings of noncompliance with certain criteria in 34 CFR part 602 identified in the November 7, 2022, letter from the SDO following the July 19, 2022, NACIQI meeting. The SDO letter is available under NACIQI meeting date 7/19/2022, at *https://surveys.ope.ed.gov/erecognition/#/public-documents.*

4. Middle States Commission on Secondary Schools. Scope of Recognition: The accreditation of institutions with postsecondary, non-degree granting career and technology programs, to include the accreditation of postsecondary, non-degree granting institutions that offer all or part of their educational programs via distance education modalities. Geographic Area of Accrediting Activities: The United States. The compliance report includes findings of noncompliance with certain criteria in 34 CFR part 602 identified in the October 19, 2022, letter from the SDO following the July 19, 2022, NACIQI meeting. The SDO letter is available under NACIQI meeting date 7/19/2022, at *https://surveys.ope.ed.gov/erecognition/#/public-documents.*

5. Southern Association of Colleges and Schools, Commission on Colleges. Scope of Recognition: The accreditation and pre-accreditation (''Candidate for Accreditation'') of degree-granting institutions of higher education in Alabama, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, Texas, and Virginia, including the accreditation of educational programs offered via distance and correspondence education, and direct assessment within these institutions. The accreditation status of these institutions and their recognition extends to the SACSCOC Board of Trustees, Executive Council, and the Appeals Committee of the Collegiate College Delegate Assembly on cases of initial candidacy or initial accreditation and for continued accreditation or candidacy. The compliance report includes findings of noncompliance with certain criteria in 34 CFR part 602 identified in the November 7, 2022, letter from the SDO following the July 19, 2022, NACIQI meeting. The SDO letter is available under NACIQI meeting date 7/19/2022, at *https://surveys.ope.ed.gov/erecognition/#/public-documents.*

Submission of Written Comments Regarding a Specific Accrediting Agency Under Review

Written comments about the recognition of any of the accrediting agencies listed above must be received by December 8, 2023, in the *ThirdPartyComments@ed.gov mailbox.* Please include in the subject line ''Written Comments: (agency name).'' The electronic mail (email) must include the name(s), title, organization/affiliation, mailing address, email address, and telephone number of the person(s) making the comment. Comments should be submitted as a PDF, Microsoft Word document or in a medium compatible with Microsoft Word that is attached to an email or provided in the body of an email message. Comments about an agency that has submitted a compliance report scheduled for review by the Department must relate to the criteria for recognition cited in the SDO letter that requested the compliance report following the July 19, 2022, NACIQI meeting, or in the Secretary's appeal decision, if any. The SDO letters for the specific agencies referenced in this **Federal Register** notice are available under NACIQI meeting date 7/19/2022, at *https://surveys.ope.ed.gov/erecognition/#/public-documents.*

Only written materials submitted by the deadline to the email address listed in this notice, and in accordance with these instructions, become part of the official record concerning agencies scheduled for review and are considered by the Department and NACIQI in their deliberations. Written comments about the specific agencies identified in this

Federal Register notice that are submitted after the deadline will not be considered by the Department or provided to NACIQI for purposes of the current review. However, comments may be provided orally at the winter 2025 NACIQI meeting, which has not yet been scheduled, but which will be announced in a future **Federal Register** notice.

Electronic Access to this Document: The official version of this document is the document published in the **Federal Register**. Free internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site, you can view this document, as well as all other documents of the Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site. You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Authority: 20 U.S.C. 1011c; 20 U.S.C. 1099b.

Nasser Paydar,

Assistant Secretary for the Office of Postsecondary Education.

[FR Doc. 2023–24434 Filed 11–3–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: Department of Energy.

ACTION: Notice of request for comments.

SUMMARY: The Department of Energy (DOE), pursuant to the Paperwork Reduction Act of 1995, intends to extend for three years, an information collection request with the Office of Management and Budget (OMB).

DATES: Comments regarding this proposed information collection must be received on or before January 5, 2024. If you anticipate any difficulty in submitting comments within that period, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section as soon as possible.

ADDRESSES: Written comments may be sent to Aisha I. Miranda Rivera, *aisha.miranda-rivera@hq.doe.gov,* or at Department of Energy, Grid Deployment Office, 1000 Independence Avenue SW, Suite 4H–065, Washington, DC 20585, (240) 429–5213.

FOR FURTHER INFORMATION CONTACT: Aisha Miranda Rivera, *aisha.miranda-rivera@hq.doe.gov,* or at Department of Energy, Grid Deployment Office, 1000 Independence Avenue SW, Suite 4H–065, Washington, DC 20585, (240) 429–5213.

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) Whether the extended collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

This information collection request contains:

(1) *OMB No.:* 1910–5200;

(2) *Information Collection Request Titled:* Puerto Rico Energy Resiliency Fund (PR–ERF), Household Intake Form.

(3) *Type of Review:* Extension of a currently approved emergency collection.

(4) *Purpose:* To authorize the use of the 'Household Intake Form' to collect homeowner data necessary to qualify households as eligible to receive rooftop solar and battery storage installations as prescribed under the DOE Grid Deployment Office's (GDO) PR–ERF. Eligibility is limited to very low-income, single-family households that (1) reside in a Last Mile Community [1] or (2) include an individual with an energy-dependent disability.

The PR–ERF, a $1 billion initiative authorized by Congress under the Consolidated Appropriations Act of 2023, Public Law 117–328, will incentivize the installation of rooftop solar and battery storage technologies for eligible households.

GDO plans to initiate installations of solar PV and battery storage systems before the 2024 hurricane season to address the harm and risk represented by the fragility of the islands' power system. Failure to collect the information necessary to verify eligibility in a timely manner will cause delays in providing assistance necessary to reestablish the reliability of electric service to these vulnerable residents. This narrow scope in purpose necessitates the need for a diligent verification process to demonstrate to Congress, Senior Leadership, and the public that this specific demographic has been served. GDO developed an in-person application process recognizing that the demographic served will lack access to broadband and have limited mobility but that it is essential to program operation to verify beneficiary eligibility for participation in the program.

(5) *Annual Estimated Number of Respondents:* 40,200.

(6) *Annual Estimated Number of Total Responses:* 80,000.

(7) *Annual Estimated Number of Burden Hours:* 56,800.

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $845,520.

Statutory Authority: The Consolidated Appropriations Act of 2023, Public Law 117–328,[2] directs the Department of Energy to improve the resilience of the Puerto Rican electric grid, including grants for low-and-moderate-income households and households that include individuals with disabilities for the purchase and installation of renewable energy, energy storage, and other grid technologies. This narrow scope in purpose necessitates the need for a diligent verification process to demonstrate to Congress, Senior Leadership, and the public that this specific demographic has been served.

Signing Authority

This document of the Department of Energy was signed on October 20, 2023, by Maria D. Robinson, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

[1] *https://clausa.app.carto.com/map/9d2a8e25-2f54-4f88-b95b-7151739bd3c7.*

[2] FY23 Summary of Appropriations Provisions.pdf (*house.gov*).

Signed in Washington, DC, on November 1, 2023.

Treena V. Garrett,

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

[FR Doc. 2023–24457 Filed 11–3–23; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 15293–001]

Nature and People First New Mexico PHS, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On July 12, 2023, Nature and People First New Mexico PHS, LLC, filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Chuska Mountain Pumped Storage Project to be located in San Juan and McKinley Counties, New Mexico, near the San Juan River, and approximately 5.6 miles west of the town of Two Grey Hills on Navajo Nation Lands. The sole purpose of a preliminary permit is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The pumped storage hydropower project would consist of all new facilities including: (1) Upper Reservoir North with a surface area of 15,800 acres and a storage volume of 500,000 acre-feet at a maximum water surface elevation (WSE) of 8,810 above mean sea level (msl); (2) Upper Reservoir Center with a surface area of 7,400 acres and a storage volume of 235,000 acre-feet at a maximum WSE of 8,810 feet msl; (3) Upper Reservoir South with a surface area of 16,300 acres and a storage volume of 510,000 acre-feet at a maximum WSE of 8,810 feet msl; (4) Lower Reservoir North 1 with a surface area of 9,000 acres and a storage volume of 385,000 acre-feet at a maximum WSE of 6,010 feet msl; (5) Lower Reservoir North 2 with a surface area of 2,700 acres and a storage volume of 115,000 acre-feet at a maximum WSE of 6,010 feet msl; (6) Lower Reservoir Center with a surface area of 2,900 acres and a storage volume of 235,000 acre-feet at a maximum WSE of 6,010 feet msl; (7) Lower Reservoir South with a surface area of 3,200 acres and a storage volume of 510,000 acre-feet at a maximum WSE of 6,010 feet msl; (8) a 30-foot-wide and 39,800-foot-long concrete-lined power conduit tunnel to North Powerhouse 1; (9) a 60-foot-wide, 700-foot-long, and 100-foot high subterranean North Powerhouse 1 with seven pump/turbines each rated at 250 megawatts (MW); (10) seven 12-foot-wide and 1,000-foot-long concrete lined North Powerhouse 1 conduit tunnels discharging into Lower Reservoir North 1; (11) a 30-foot-wide and 19,800-foot-long concrete-lined power conduit to Powerhouse 2; (12) a 60-foot-wide, 700-foot-long, and 100-foot-high subterranean North Powerhouse 2 with seven pump/turbines each rated at 250 MW; (13) seven 12-foot-wide and 1,000-foot-long concrete lined North Powerhouse 2 conduit tunnels discharging into Lower Reservoir North 2; (14) a 30-foot-wide and 43,300-foot-long concrete-lined tunnel power conduit to the Center Powerhouse; (15) a 60-foot-wide, 700-foot-long, and 100-foot-high subterranean Center Powerhouse with seven pump/turbines each rated at 250 MW; (16) seven 12-foot-wide and 1,000-foot-long concrete lined North Powerhouse 1 conduit tunnels discharging into Lower Reservoir Center; (17) a 45-foot-wide and 30,300-foot-long concrete lined tunnel to the South Powerhouse; (18) a 60-foot-wide, 1,400-foot-long, and 100-foot-high subterranean South Powerhouse with 15 pump/turbines each rated at 250 MW; (19) fifteen 12-foot-wide, 1,000-foot-long concrete-lined tunnels discharging into Lower Reservoir South; and (20) approximately 100 miles of 345-kilovolt transmission lines for interconnection to the existing Shiprock, San Juan, and Four Corners substations. The estimated annual energy production of the project would be approximately 19,710,000 megawatt hours.

Applicant Contact: Mr. Denis Payre, Nature and People First New Mexico PHS, LLC, 405 Waltham St., Suite 145, Lexington, MA 02421; email: *denis.payre@natureandpeoplefirst.com;* phone: (781) 491–5364.

FERC Contact: Shannon Archuleta; email: *shannon.archuleta@ferc.gov;* phone (503) 552–2739.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members, and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.* Comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications should be submitted within 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at *https://ferconline.ferc.gov/FERC.aspx.* Commenters can submit brief comments up to 6,000 characters without prior registration using the eComment system at https://ferconline..gov/QuickComment.aspx. You must include your name and contact information at the end of your comments. For assistance, please get in touch with FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll-free), or (202) 502–8659 (TTY). Instead of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–15293–001.

More information about this project, including a copy of the application, can be viewed on the Commission's website (*http://www.ferc.gov)* using the ''eLibrary'' link. Enter the docket number (P–15293) in the docket number field to access the document. For assistance, do not hesitate to get in touch with FERC Online Support.

Dated: October 31, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–24465 Filed 11–3–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP24–7–000]

ANR Pipeline Company; Notice of Application and Establishing Intervention Deadline

Take notice that on October 17, 2023, ANR Pipeline Company (ANR), 700 Louisiana Street, Suite 1300, Houston, Texas 77002–2700, filed an application under section 7(b) of the Natural Gas Act (NGA), and Part 157 of the Commission's regulations requesting authorization for its Abandonment of Certain Compression Facilities at EG Hill Compressor Station (Project). The Project consists of abandoning three reciprocating compressor units and related appurtenances, located in Hansford County, Texas. The Project will eliminate the need for future operating and maintenance expenditures on outdated facilities that are no longer needed to satisfy current firm service obligations. ANR estimates the total cost of the Project to be $482,728, 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 (*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. For assistance, contact the Federal Energy Regulatory Commission at *FercOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TTY (202) 502–8659.

Any questions regarding the proposed project should be directed to ANR Pipeline Company, David A. Alonzo, Manager, Project Authorizations, 700 Louisiana Street, Suite 1300, Houston, Texas 77002–2700 by phone at 832.320.5477, or by email at *david_alonzo@tcenergy.com.*

Pursuant to Section 157.9 of the Commission's Rules of Practice and Procedure,[1] within 90 days of this Notice the Commission staff will either: complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file comments on the project, you can protest the filing, and you can file a motion to intervene in the proceeding. There is no fee or cost for filing comments or intervening. The deadline for filing a motion to intervene is 5:00 p.m. Eastern Time on November 21, 2023. How to file protests, motions to intervene, and comments is explained below.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Comments

Any person wishing to comment on the project may do so. Comments may include statements of support or objections, to the project as a whole or specific aspects of the project. The more specific your comments, the more useful they will be.

Protests

Pursuant to sections 157.10(a)(4)[2] and 385.211[3] of the Commission's regulations under the NGA, any person[4] may file a protest to the application. Protests must comply with the requirements specified in section 385.2001[5] of the Commission's regulations. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

To ensure that your comments or protests are timely and properly recorded, please submit your comments on or before November 21, 2023.

There are three methods you can use to submit your comments or protests to the Commission. In all instances, please reference the Project docket number CP24–7–000 in your submission.

(1) You may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You may file your comments or protests electronically by using the eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Comment on a Filing''; or

(3) You can file a paper copy of your comments or protests by mailing them to the following address below. Your written comments must reference the Project docket number (CP24–7–000).

To file via USPS: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426

To file via any other courier: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852

The Commission encourages electronic filing of comments (options 1 and 2 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Persons who comment on the environmental review of this project will be placed on the Commission's environmental mailing list, and will receive notification when the environmental documents (EA or EIS) are issued for this project and will be notified of meetings associated with the Commission's environmental review process.

The Commission considers all comments received about the project in

[1] 18 CFR (Code of Federal Regulations) 157.9.

[2] 18 CFR 157.10(a)(4)

[3] 18 CFR 385.211

[4] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[5] 18 CFR 385.2001

determining the appropriate action to be taken. However, the filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding. For instructions on how to intervene, see below.

Interventions

Any person, which includes individuals, organizations, businesses, municipalities, and other entities,[6] has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure [7] and the regulations under the NGA [8] by the intervention deadline for the project, which is November 21, 2023. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

There are two ways to submit your motion to intervene. In both instances, please reference the Project docket number CP24–7–000 in your submission.

(1) You may file your motion to intervene by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Intervention.'' The eFiling feature includes a document-less intervention option; for more information, visit *https://www.ferc.gov/docs-filing/efiling/document-less-intervention.pdf.;* or

(2) You can file a paper copy of your motion to intervene, along with three copies, by mailing the documents to the address below. Your motion to intervene must reference the Project docket number CP24–7–000.

To file via USPS: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other courier: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of motions to intervene (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Protests and motions to intervene must be served on the applicant either by mail or email at: David A. Alonzo, Manager, Project Authorizations, 700 Louisiana Street, Suite 1300, Houston, Texas 77002–2700 or at *david_alonzo@tcenergy.com.* Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online. Service can be via email with a link to the document.

All timely, unopposed [9] motions to intervene are automatically granted by operation of Rule 214(c)(1).[10] Motions to intervene that are filed after the intervention deadline are untimely, and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations.[11] A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Intervention Deadline: 5:00 p.m. Eastern Time on November 21, 2023.

Dated: October 31, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–24464 Filed 11–3–23; 8:45 am]

BILLING CODE 6717–01–P

[6] 18 CFR 385.102(d).

[7] 18 CFR 385.214.

[8] 18 CFR 157.10.

[9] The applicant has 15 days from the submittal of a motion to intervene to file a written objection to the intervention.

[10] 18 CFR 385.214(c)(1).

[11] 18 CFR 385.214(b)(3) and (d).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC24–14–000.

Applicants: Crooked Lake Solar, LLC.

Description: Application for Authorization Under Section 203 of the Federal Power Act of Crooked Lake Solar, LLC.

Filed Date: 10/30/23.

Accession Number: 20231030–5276.

Comment Date: 5 p.m. ET 11/20/23.

Docket Numbers: EC24–15–000.

Applicants: American Falls Solar, LLC, American Falls Solar II, LLC, CSOLAR IV South, LLC, CSOLAR IV West, LLC.

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act of American Falls Solar, LLC, et al.

Filed Date: 10/30/23.

Accession Number: 20231030–5278.

Comment Date: 5 p.m. ET 11/20/23.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1819–038; ER10–1820–041; ER10–1818–036; ER10–1817–029.

Applicants: Southwestern Public Service Company, Public Service Company of Colorado, Northern States Power Company, a Wisconsin corporation, Northern States Power Company, a Minnesota corporation.

Description: Notice of Change in Status of Northern States Power Company, a Minnesota corporation, et al.

Filed Date: 10/30/23.

Accession Number: 20231030–5283.

Comment Date: 5 p.m. ET 11/20/23.

Docket Numbers: ER10–2042–049; ER10–1862–042; ER10–1873–020; ER10–1875–020; ER10–1876–021; ER10–1878–020; ER10–1883–020; ER10–1884–020; ER10–1885–020; ER10–1888–020; ER10–1893–042; ER10–1934–042; ER10–1938–043; ER10–1941–020; ER10–1942–040; ER10–1947–021; ER10–2985–046; ER10–3049–047; ER10–3051–047; ER11–4369–027; ER12–1987–018; ER12–2261–019; ER12–2645–013; ER13–1407–015; ER16–2218–028; ER17–696–028; ER19–1127–010; ER20–1699–008; ER23–944–005.

Applicants: Calpine Community Energy, LLC, Johanna Energy Center, LLC, Calpine King City Cogen, LLC, Calpine Energy Solutions, LLC, North American Power Business, LLC, CCFC Sutter Energy, LLC, Pastoria Energy Facility L.L.C., Russell City Energy Company, LLC, O.L.S. Energy-Agnews, Inc., North American Power and Gas, LLC, Champion Energy, LLC, Champion Energy Services, LLC, Champion Energy Marketing LLC, Otay Mesa Energy Center, LLC, Calpine Construction Finance Co., L.P., Calpine Gilroy Cogen, L.P., Calpine Power America—CA, LLC, CES Marketing IX, LLC, CES Marketing X, LLC, Creed Energy Center, LLC, Delta Energy Center, LLC, Geysers Power Company, LLC, Gilroy Energy Center, LLC, Goose Haven Energy Center, LLC, Los Esteros Critical Energy Facility, LLC, Los Medanos Energy Center LLC, Metcalf Energy Center, LLC, Power Contract Financing, L.L.C., Calpine Energy Services, L.P.

Description: Notice of Change in Status of Calpine Energy Services, L.P., et al.

Filed Date: 10/30/23.

Accession Number: 20231030–5219.

Comment Date: 5 p.m. ET 11/20/23.

Docket Numbers: ER10–2895–026; ER10–1427–007; ER10–2466–024; ER10–2917–026; ER10–2921–026; ER10–2922–026; ER10–2966–026; ER10–3167–019; ER11–2201–029; ER11–2383–022; ER11–4029–023; ER12–161–028; ER12–1311–023; ER12–2068–023; ER13–203–018; ER13–1613–019; ER13–2143–019; ER14–1964–018; ER16–287–012; ER17–482–012; ER19–529–013; ER19–1074–013; ER19–1075–013; ER20–1447–008; ER20–2028–003; ER22–192–007; ER22–1010–005; ER23–2481–001.

Applicants: Crystal Hill Solar, LLC, TerraForm IWG Acquisition Holdings II, LLC, Evolugen Trading and Marketing LP, Bitter Ridge Wind Farm, LLC, Brookfield Energy Marketing US LLC, Brookfield Renewable Energy Marketing US LLC, Brookfield Energy Marketing Inc., Brookfield Renewable Trading and Marketing LP, BREG Aggregator LLC, BIF III Holtwood LLC, BIF II Safe Harbor Holdings, LLC, Black Bear Development Holdings, LLC, Brookfield White Pine Hydro LLC, Black Bear SO, LLC, Blue Sky East, LLC, Stetson Holdings, LLC, Bishop Hill Energy LLC, Vermont Wind, LLC, Safe Harbor Water Power Corporation, Evergreen Wind Power III, LLC, Black Bear Hydro Partners, LLC, Rumford Falls Hydro LLC, Hawks Nest Hydro LLC, Great Lakes Hydro America, LLC, Brookfield Power Piney & Deep Creek LLC, Stetson Wind II, LLC, Brookfield Energy Marketing LP, Bear Swamp Power Company LLC.

Description: Notice of Change in Status of Bear Swamp Power Company LLC, et al.

Filed Date: 10/30/23.

Accession Number: 20231030–5282.

Comment Date: 5 p.m. ET 11/20/23.

Docket Numbers: ER15–1905–014.

Applicants: Amazon Energy LLC.

Description: Notice of Change in Status of Amazon Energy LLC.

Filed Date: 10/30/23.

Accession Number: 20231030–5280.

Comment Date: 5 p.m. ET 11/20/23.

Docket Numbers: ER18–1197–008; ER10–2125–027; ER10–2127–024; ER10–2128–026; ER10–2129–017; ER10–2132–026; ER10–2133–027; ER10–2134–015; ER10–2764–026; ER11–3872–028; ER20–2444–006; ER20–2445–006; ER21–1838–005; ER22–1999–004.

Applicants: Number Three Wind LLC, Orangeville Energy Storage LLC, Prineville Solar Energy LLC, Millican Solar Energy LLC, Stony Creek Energy LLC, Vantage Wind Energy LLC, Hardee Power Partners Limited, Sheldon Energy LLC, Willow Creek Energy LLC, Grays Harbor Energy LLC, Wolverine Creek Energy LLC, Invenergy TN LLC, Judith Gap Energy LLC, Camilla Solar Energy LLC.

Description: Notice of Change in Status of Camilla Solar Energy LLC, et al.

Filed Date: 10/30/23.

Accession Number: 20231030–5281.

Comment Date: 5 p.m. ET 11/20/23.

Docket Numbers: ER23–207–001.

Applicants: Golden Spread Electric Cooperative, Inc.

Description: Compliance filing: Final Order 676J Compliance Filing to be effective 2/1/2024.

Filed Date: 10/31/23.

Accession Number: 20231031–5005.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER23–816–000.

Applicants: System Energy Resources, Inc.

Description: Refund Report: SERI UPSA Compliance (EL18–152 and ER23–816) to be effective N/A.

Filed Date: 10/27/23.

Accession Number: 20231027–5223.

Comment Date: 5 p.m. ET 11/17/23.

Docket Numbers: ER23–1319–001.

Applicants: Baldy Mesa Solar, LLC.

Description: Notice of Change in Status of Baldy Mesa Solar, LLC.

Filed Date: 10/30/23.

Accession Number: 20231030–5220.

Comment Date: 5 p.m. ET 11/20/23.

Docket Numbers: ER23–1589–001.

Applicants: AES ES Westwing, LLC.

Description: Notice of Change in Status of AES ES Westwing, LLC.

Filed Date: 10/30/23.

Accession Number: 20231030–5238.

Comment Date: 5 p.m. ET 11/20/23.

Docket Numbers: ER23–1669–002; ER23–1668–002.

Applicants: Estrella Solar, LLC, Raceway Solar 1, LLC.

Description: Notice of Change in Status of Raceway Solar 1, LLC, et al.

Filed Date: 10/30/23.

Accession Number: 20231030–5271.

Comment Date: 5 p.m. ET 11/20/23.

Docket Numbers: ER23–2346–001.

Applicants: Oak Ridge Solar, LLC.

Description: Notice of Change in Status of Oak Ridge Solar, LLC.

Filed Date: 10/30/23.

Accession Number: 20231030–5272.

Comment Date: 5 p.m. ET 11/20/23.

Docket Numbers: ER23–2568–001.

Applicants: Duke Energy Carolinas, LLC.

Description: Tariff Amendment: DEC-Response to Letter of Deficiency to be effective 1/1/2023.

Filed Date: 10/30/23.

Accession Number: 20231030–5227.

Comment Date: 5 p.m. ET 11/20/23.

Docket Numbers: ER24–231–001.

Applicants: West Penn Power Company, PJM Interconnection, L.L.C.

Description: Tariff Amendment: West Penn Power Company submits tariff filing per 35.17(b): Errata to West Penn Power Revisions to OATT, Att. H–11A in ER24–231 to be effective 1/1/2023.

Filed Date: 10/30/23.

Accession Number: 20231030–5236.

Comment Date: 5 p.m. ET 11/20/23.

Docket Numbers: ER24–251–000.

Applicants: Duke Energy Florida, LLC.

Description: § 205(d) Rate Filing: DEF-Bartow-FPL RS No. 422 Reimbursement Agmt to be effective 1/1/2024.

Filed Date: 10/30/23.

Accession Number: 20231030–5201.

Comment Date: 5 p.m. ET 11/20/23.

Docket Numbers: ER24–252–000.

Applicants: Metropolitan Edison Company, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Metropolitan Edison Company submits tariff filing per 35.13(a)(2)(iii: Met-Ed amends Nine ECSAs (6414 6415 6416 6417 6418 6485 6486 6488 6494) to be effective 12/31/9998.

Filed Date: 10/30/23.

Accession Number: 20231030–5204.

Comment Date: 5 p.m. ET 11/20/23.

Docket Numbers: ER24–253–000.

Applicants: Northern Indiana Public Service Company LLC.

Description: § 205(d) Rate Filing: Supplement to WVPA IA to be effective 12/31/2023.

Filed Date: 10/30/23.

Accession Number: 20231030–5237.

Comment Date: 5 p.m. ET 11/20/23.

Docket Numbers: ER24–254–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Central Power Electric Cooperative, Inc. Formula Rate Revisions to be effective 1/1/2024.

Filed Date: 10/31/23.

Accession Number: 20231031–5007.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER24–255–000.

Applicants: CPV Stagecoach Solar, LLC.

Description: Baseline eTariff Filing: Application for Market-Based Rate Authority to be effective 12/8/2023.

Filed Date: 10/31/23.

Accession Number: 20231031–5013.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER24–256–000.

Applicants: Dominion Energy South Carolina, Inc.

Description: Tariff Amendment: Notice of Termination of PSA with Orangeburg to be effective 12/31/2023.

Filed Date: 10/31/23.

Accession Number: 20231031–5033.

Comment Date: 5 p.m. ET 11/21/23.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: October 31, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–24487 Filed 11–3–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #3

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2135–017; ER10–2124–026.

Applicants: Spring Canyon Energy LLC, Spindle Hill Energy LLC.

Description: Notice of Change in Status of Spindle Hill Energy LLC, et al.

Filed Date: 10/31/23.

Accession Number: 20231031–5246.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER10–2881–041; ER10–2882–041; ER10–2883–039; ER10–2884–039; ER16–2509–010; ER17–2400–011; ER17–2401–011; ER17–2403–011; ER17–2404–011.

Applicants: SP Sandhills Solar, LLC, SP Pawpaw Solar, LLC, SP Decatur Parkway Solar, LLC, SP Butler Solar, LLC, Rutherford Farm, LLC, Georgia Power Company, Mississippi Power Company, Southern Power Company, Alabama Power Company.

Description: Notice of Non-Material Change in Status of Alabama Power Company, et al.

Filed Date: 10/31/23.

Accession Number: 20231031–5241.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER10–3050–013; ER10–3053–013.

Applicants: Whitewater Hill Wind Partners, LLC, Cabazon Wind Partners, LLC.

Description: Notice of Non-Material Change in Status of Cabazon Wind Partners, LLC, et al.

Filed Date: 10/31/23.

Accession Number: 20231031–5227.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER21–9–005; ER21–86–005; ER21–88–005.

Applicants: Orange County Energy Storage 3 LLC, Orange County Energy Storage 2 LLC, Henrietta D Energy Storage LLC.

Description: Notice of Non-Material Change in Status of Henrietta D Energy Storage LLC, et al.

Filed Date: 10/31/23.

Accession Number: 20231031–5248.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER21–136–005.

Applicants: Flat Ridge 3 Wind Energy, LLC.

Description: Notice of Change in Status of Flat Ridge 3 Wind Energy, LLC.

Filed Date: 10/31/23.

Accession Number: 20231031–5243.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER21–330–004.

Applicants: Specialty Products US, LLC.

Description: Notice of Change in Status of Specialty Products US, LLC.

Filed Date: 10/31/23.

Accession Number: 20231031–5245.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER21–2137–009.

Applicants: IR Energy Management LLC.

Description: Notice of Change in Status of IR Energy Management LLC.

Filed Date: 10/31/23.

Accession Number: 20231031–5225.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER24–269–000.

Applicants: NSTAR Electric Company.

Description: Initial rate filing: NSTAR–HQUS Transfer Agreement (ENE Use Rights) to be effective 11/26/2023.

Filed Date: 10/31/23.

Accession Number: 20231031–5204.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER24–270–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Revisions to Attachment AE to Clarify Resource/Load Aggregation to be effective 1/3/2024.

Filed Date: 10/31/23.

Accession Number: 20231031–5219.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER24–271–000.

Applicants: Southwestern Public Service Company, Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Southwestern Public Service Company submits tariff filing per 35.13(a)(2)(iii):

SPS Formula Rate Revisions to Incorporate Changes Accepted in ER23–2845 to be effective 1/1/2023.

Filed Date: 10/31/23.

Accession Number: 20231031–5240.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER24–272–000.

Applicants: ISO New England Inc., The United Illuminating Company.

Description: § 205(d) Rate Filing: ISO New England Inc. submits tariff filing per 35.13(a)(2)(iii): UI; Req for Approval of Updated Depreciation Rates & Rev. to Append D of Att F to be effective 9/1/2023.

Filed Date: 10/31/23.

Accession Number: 20231031–5244.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER24–273–000.

Applicants: Goleta Energy Storage, LLC.

Description: Compliance filing: Notice of Non-Material Change in Status and Revised Market-Based Rate Tariff to be effective 11/1/2023.

Filed Date: 10/31/23.

Accession Number: 20231031–5249.

Comment Date: 5 p.m. ET 11/21/23.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES23–14–000.

Applicants: Transource Maryland, LLC, Transource Missouri, LLC, Transource Oklahoma, LLC, Transource Pennsylvania, LLC, Transource West Virginia, LLC.

Description: Report of Securities Issued of Transource Pennsylvania, LLC.

Filed Date: 10/31/23.

Accession Number: 20231031–5222.

Comment Date: 5 p.m. ET 11/21/23.

Take notice that the Commission received the following electric reliability filings

Docket Numbers: RD24–1–000.

Applicants: North American Electric Reliability Corporation.

Description: North American Electric Reliability Corporation submits Petition for Approval of Proposed Reliability Standards EOP–011–4 and TOP–002–5 and Request for Expedited Action.

Filed Date: 10/30/23.

Accession Number: 20231030–5285.

Comment Date: 5 p.m. ET 11/30/23.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

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The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: October 31, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–24486 Filed 11–3–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas and Oil Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP24–80–000.

Applicants: Millennium Pipeline Company, LLC.

Description: § 4(d) Rate Filing: Negotiated Rate Agmts, Eff. 11.1.23 to be effective 11/1/2023.

Filed Date: 10/30/23.

Accession Number: 20231030–5177.

Comment Date: 5 p.m. ET 11/13/23.

Docket Numbers: RP24–81–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: Non-Conforming—Adelphia West Ridge Interconnect—2023 to be effective 12/1/2023.

Filed Date: 10/30/23.

Accession Number: 20231030–5194.

Comment Date: 5 p.m. ET 11/13/23.

Docket Numbers: RP24–82–000.

Applicants: Texas Eastern Transmission, LP.

Description: § 4(d) Rate Filing: TETLP PCB DEC 2023 Filing to be effective 12/1/2023.

Filed Date: 10/30/23.

Accession Number: 20231030–5207.

Comment Date: 5 p.m. ET 11/13/23.

Docket Numbers: RP24–83–000.

Applicants: Equitrans, L.P.

Description: § 4(d) Rate Filing: Negotiated Rate Agreements—11/1/2023 to be effective 11/1/2023.

Filed Date: 10/31/23.

Accession Number: 20231031–5001.

Comment Date: 5 p.m. ET 11/13/23.

Docket Numbers: RP24–84–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: § 4(d) Rate Filing: AGT FRQ 2023 Filing to be effective 12/1/2023.

Filed Date: 10/31/23.

Accession Number: 20231031–5008.

Comment Date: 5 p.m. ET 11/13/23.

Docket Numbers: RP24–85–000.

Applicants: Fayetteville Express Pipeline LLC.

Description: Compliance filing: Fuel Filing on 10–31–23 to be effective N/A.

Filed Date: 10/31/23.

Accession Number: 20231031–5018.

Comment Date: 5 p.m. ET 11/13/23.

Docket Numbers: RP24–86–000.

Applicants: ETC Tiger Pipeline, LLC.

Description: § 4(d) Rate Filing: Fuel Filing on 10–31–23 to be effective 12/1/2023.

Filed Date: 10/31/23.

Accession Number: 20231031–5026.

Comment Date: 5 p.m. ET 11/13/23.

Docket Numbers: RP24–87–000.

Applicants: Trunkline Gas Company, LLC.

Description: Compliance filing: Annual Interruptible Storage Revenue Credit filed 10–31–23 to be effective N/A.

Filed Date: 10/31/23.

Accession Number: 20231031–5031.

Comment Date: 5 p.m. ET 11/13/23.

Docket Numbers: RP24–88–000.

Applicants: Kern River Gas Transmission Company.

Description: § 4(d) Rate Filing: 2023 World Fuels Contract 1908 Amendment Filing to be effective 11/1/2023.

Filed Date: 10/31/23.

Accession Number: 20231031–5058.

Comment Date: 5 p.m. ET 11/13/23.

Docket Numbers: RP24–89–000.

Applicants: Trunkline Gas Company, LLC.

Description: § 4(d) Rate Filing: Negotiated Rate Filing—17 (NextEra Energy & Ford) to be effective 11/1/2023.

Filed Date: 10/31/23.
Accession Number: 20231031–5066.
Comment Date: 5 p.m. ET 11/13/23.

Docket Numbers: RP24–90–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: § 4(d) Rate Filing: Non-Conforming Agreement Update (Sterling) to be effective 11/1/2023.
Filed Date: 10/31/23.
Accession Number: 20231031–5071.
Comment Date: 5 p.m. ET 11/13/23.

Docket Numbers: RP24–91–000.
Applicants: Tennessee Gas Pipeline Company, L.L.C.
Description: § 4(d) Rate Filing: Non-Conforming Agreement Filing (TC Energy 382826) to be effective 11/1/2023.
Filed Date: 10/31/23.
Accession Number: 20231031–5082.
Comment Date: 5 p.m. ET 11/13/23.

Docket Numbers: RP24–92–000.
Applicants: Rockies Express Pipeline LLC.
Description: § 4(d) Rate Filing: REX 2023–10–31 System Map URL to be effective 12/1/2023.
Filed Date: 10/31/23.
Accession Number: 20231031–5101.
Comment Date: 5 p.m. ET 11/13/23.

Docket Numbers: RP24–93–000.
Applicants: Tallgrass Interstate Gas Transmission, LLC.
Description: § 4(d) Rate Filing: TIGT 2023–10–31 System Map URL to be effective 12/1/2023.
Filed Date: 10/31/23.
Accession Number: 20231031–5108.
Comment Date: 5 p.m. ET 11/13/23.

Docket Numbers: RP24–94–000.
Applicants: Trailblazer Pipeline Company LLC.
Description: § 4(d) Rate Filing: TPC 2023–10–31 System Map URL to be effective 12/1/2023.
Filed Date: 10/31/23.
Accession Number: 20231031–5109.
Comment Date: 5 p.m. ET 11/13/23.

Docket Numbers: RP24–95–000.
Applicants: Tennessee Gas Pipeline Company, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement (Con Ed 389644) to be effective 11/1/2023.
Filed Date: 10/31/23.
Accession Number: 20231031–5114.
Comment Date: 5 p.m. ET 11/13/23.

Docket Numbers: RP24–96–000.
Applicants: Texas Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (Jay-Bee 34446 to Spotlight 54357) to be effective 11/1/2023.
Filed Date: 10/31/23.
Accession Number: 20231031–5118.
Comment Date: 5 p.m. ET 11/13/23.

Docket Numbers: RP24–97–000.
Applicants: Texas Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmts (SABIC 35304,35303, 35305 to CIMA 57386,57387,57384) to be effective 11/1/2023.
Filed Date: 10/31/23.
Accession Number: 20231031–5122.
Comment Date: 5 p.m. ET 11/13/23.

Docket Numbers: RP24–98–000.
Applicants: Destin Pipeline Company, L.L.C.
Description: Compliance filing: Destin Pipeline Annual Fuel Retention Adjustment to be effective N/A.
Filed Date: 10/31/23.
Accession Number: 20231031–5125.
Comment Date: 5 p.m. ET 11/13/23.

Docket Numbers: RP24–99–000.
Applicants: Wyoming Interstate Company, L.L.C.
Description: § 4(d) Rate Filing: Fuel_LU Quarterly Update Filing Eff Dec 2023 to be effective 12/1/2023.
Filed Date: 10/31/23.
Accession Number: 20231031–5128.
Comment Date: 5 p.m. ET 11/13/23.

Docket Numbers: RP24–100–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Negotiated Rates—Con Ed 910950 Releases 11–01–23 to be effective 11/1/2023.
Filed Date: 10/31/23.
Accession Number: 20231031–5150.
Comment Date: 5 p.m. ET 11/13/23.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP22–1033–005.
Applicants: Northern Natural Gas Company.
Description: Refund Report: 20231031 Refund Report to be effective N/A.
Filed Date: 10/31/23.
Accession Number: 20231031–5115.
Comment Date: 5 p.m. ET 11/13/23.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: October 31, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–24484 Filed 11–3–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG24–22–000.
Applicants: CPV Stagecoach Solar, LLC.
Description: CPV Stagecoach Solar, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 10/31/23.
Accession Number: 20231031–5050.
Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: EG24–23–000.
Applicants: Faraday Interconnection LLC.
Description: Faraday Interconnection LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 10/31/23.
Accession Number: 20231031–5116.
Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: EG24–24–000.
Applicants: Faraday Solar B LLC.
Description: Faraday Solar B LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 10/31/23.
Accession Number: 20231031–5117.

Comment Date: 5 p.m. ET 11/21/23.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–2029–009; ER10–2596–013; ER12–2200–009.

Applicants: Mehoopany Wind Energy LLC, Fowler Ridge II Wind Farm LLC, Cedar Creek II, LLC.

Description: Notice of Change in Status of Cedar Creek II, LLC, et al.

Filed Date: 10/31/23.

Accession Number: 20231031–5196.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER16–2449–004; ER21–628–004.

Applicants: Harry Allen Solar Energy LLC, Boulder Solar II, LLC.

Description: Notice of Change in Status of Boulder Solar II, LLC, et al.

Filed Date: 10/31/23.

Accession Number: 20231031–5197.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER19–1575–010; ER10–2488–027; ER13–1586–022; ER14–2871–021; ER15–463–020; ER15–621–020; ER15–622–020; ER16–72–016; ER16–182–016; ER16–902–013; ER17–47–013; ER17–48–014; ER18–47–013; ER18–2240–009; ER18–2241–009; ER19–427–009; ER19–1660–009; ER19–1662–009; ER19–1667–009; ER20–71–009; ER20–72–009; ER20–75–009; ER20–76–011; ER20–77–009; ER20–79–009; ER21–1368–005; ER21–1369–006; ER21–1371–006; ER21–1373–007; ER21–1376–007; ER21–2782–006; ER22–149–006; ER22–1439–006; ER22–1440–006; ER22–1441–006; ER22–1442–004; ER22–2419–002; ER22–2420–002; ER23–562–003; ER23–1048–002; ER23–2001–002.

Applicants: Sagebrush ESS II, LLC, Lockhart ESS, LLC, TGP Energy Management II, LLC, Lockhart Solar PV II, LLC, Lockhart Solar PV, LLC, EdSan 1B Group 3, LLC, EdSan 1B Group 2, LLC, EdSan 1B Group 1 Sanborn, LLC, EdSan 1B Group 1 Edwards, LLC, Sagebrush Line, LLC, Sagebrush ESS, LLC, ES 1A Group 3 Opco, LLC, ES 1A Group 2 Opco, LLC, Edwards Sanborn Storage II, LLC, Edwards Sanborn Storage I, LLC, Valley Center ESS, LLC, Voyager Wind IV Expansion, LLC, Painted Hills Wind Holdings, LLC, Tehachapi Plains Wind, LLC, Oasis Alta, LLC, Coachella Wind Holdings, LLC, Coachella Hills Wind, LLC, Terra-Gen VG Wind, LLC, Mojave 16/17/18 LLC, Mojave 3/4/5 LLC,LUZ Solar Partners IX, Ltd., Garnet Wind, LLC, Yavi Energy, LLC, Voyager Wind II, LLC, Terra-Gen Mojave Windfarms, LLC, DifWind Farms LTD VI, Voyager Wind I, LLC, Cameron Ridge II, LLC, San Gorgonio Westwinds II—Windustries, LLC, Ridgetop Energy, LLC, Pacific Crest Power, LLC, San Gorgonio Westwinds II, LLC, Cameron Ridge, LLC, TGP Energy Management, LLC, Oasis Power Partners, LLC, Alta Oak Realty, LLC.

Description: Notice of Non-Material Change in Status of Alta Oak Realty, LLC, et al.

Filed Date: 10/31/23.

Accession Number: 20231031–5206.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER20–391–008; ER21–2557–003; ER22–2662–003; ER22–2663–003; ER22–2664–003; ER23–1275–001; ER23–1276–001; ER23–1277–001.

Applicants: Aron Energy Prepay 23 LLC, Aron Energy Prepay 22 LLC, Aron Energy Prepay 21 LLC, Aron Energy Prepay 16 LLC, Aron Energy Prepay 15 LLC, Aron Energy Prepay 14 LLC, Aron Energy Prepay 5 LLC, J. Aron & Company LLC.

Description: Notice of Non-Material Change in Status of J. Aron & Company LLC, et al.

Filed Date: 10/31/23.

Accession Number: 20231031–5213.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER22–2419–003; ER22–2420–003.

Applicants: Lockhart Solar PV II, LLC, Lockhart Solar PV, LLC.

Description: Notice of Non-Material Change in Status of Lockhart Solar PV, LLC, et al.

Filed Date: 10/31/23.

Accession Number: 20231031–5208.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER23–2562–001.

Applicants: Merelec USA LLC.

Description: Tariff Amendment: Per Deficiency Letter (ER23–2562) to be effective 10/3/2023.

Filed Date: 10/31/23.

Accession Number: 20231031–5177.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER24–257–000.

Applicants: NorthWestern Corporation, Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: NorthWestern Corporation submits tariff filing per 35.13(a)(2)(iii: NorthWestern Corp—Name Change to NorthWestern Energy Public Service Corp. to be effective 1/1/2024.

Filed Date: 10/31/23.

Accession Number: 20231031–5072.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER24–258–000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: TMCR termination—Amending Appendix XI to be effective 1/1/2024.

Filed Date: 10/31/23.

Accession Number: 20231031–5076.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER24–259–000.

Applicants: Startrans IO, LLC.

Description: § 205(d) Rate Filing: Startrans IO, LLC TRBAA 2024 Update to be effective 1/1/2024.

Filed Date: 10/31/23.

Accession Number: 20231031–5089.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER24–260–000.

Applicants: Midcontinent Independent System Operator, Inc., Dairyland Power Cooperative.

Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: 2023–10–31_DPC Incentive Rate Request to be effective 1/1/2024.

Filed Date: 10/31/23.

Accession Number: 20231031–5120.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER24–261–000.

Applicants: New York Independent System Operator, Inc.

Description: § 205(d) Rate Filing: NYISO 205: EPC Agreement for CY2017 LI System Deliverability Upgrade (SA2776) to be effective 10/17/2023.

Filed Date: 10/31/23.

Accession Number: 20231031–5123.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER24–262–000.

Applicants: Mustang Hills, LLC.

Description: § 205(d) Rate Filing: Notice of Non-Mat. Change in Status & MBR Tariff Revisions to be effective 12/31/2023.

Filed Date: 10/31/23.

Accession Number: 20231031–5129.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER24–263–000.

Applicants: BE-Pine 1 LLC.

Description: § 205(d) Rate Filing: Normal filing 2023 to be effective 11/1/2023.

Filed Date: 10/31/23.

Accession Number: 20231031–5130.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER24–264–000.

Applicants: DesertLink, LLC.

Description: Compliance filing: DesertLink LLC Annual TRBAA Filing to be effective 1/1/2024.

Filed Date: 10/31/23.

Accession Number: 20231031–5134.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER24–265–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Revisions to Attachment W to Update Index of Grandfathered Agreements to be effective 1/1/2024.

Filed Date: 10/31/23.

Accession Number: 20231031–5168.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER24–266–000.

Applicants: Solar of Alamosa LLC.

Description: Baseline eTariff Filing: Market-Based Rate Application to be effective 11/1/2023.

Filed Date: 10/31/23.

Accession Number: 20231031–5175.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER24–267–000.

Applicants: Duke Energy Carolinas, LLC.

Description: § 205(d) Rate Filing: DEC–DESC Orangeburg Dynamic Transfer Agmt RS No. 618 to be effective 1/1/2024.

Filed Date: 10/31/23.

Accession Number: 20231031–5190.

Comment Date: 5 p.m. ET 11/21/23.

Docket Numbers: ER24–268–000.

Applicants: Florida Power & Light Company.

Description: § 205(d) Rate Filing: FPL OATT Updated Stated Rate for NITS & P-to-P Trans Service on FPL Pen FL Sys to be effective 1/1/2024.

Filed Date: 10/31/23.

Accession Number: 20231031–5192.

Comment Date: 5 p.m. ET 11/21/23.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

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Dated: October 31, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–24485 Filed 11–3–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP24–8–000]

Natural Gas Pipeline Company of America LLC; Notice of Application and Establishing Intervention Deadline

Take notice that on October 18, 2023, Natural Gas Pipeline Company of America LLC (NGPL), 3250 Lacey Road, Suite 700, Downers Grove, Illinois 60515, filed an application pursuant to section 7(c) of the Natural Gas Act (NGA), and Part 157 of the Commission's regulations requesting authorization for its Texas-Louisiana Expansion Project (Project). The Project consists of construction and operation of new and modified facilities at the existing Compressor Station (CS) 302 located in Montgomery County, Texas and CS 343 located in Liberty County, Texas. The Project will create 300,000 dekatherms per day of incremental firm eastbound transportation capacity on NGPL's existing mainline facilities along the Texas and Louisiana Gulf Coast region. NGPL estimates the total cost of the Project to be $72 million. NGPL requests presumption of rolled-in rate treatment and proposes to establish an incremental fuel retention rate for firm transportation service to be provided on Project facilities, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

Specifically, NGPL proposes to install one new 18,340 horsepower (hp) Electric Motor Driven (EMD) compressor unit and to uprate existing EMD compressor Units 7 and 8 by 1,600 hp each at its existing CS 302. NGPL also proposes to re-wheel the existing compressor Units 7, 8, and 9 at CS 302 and Units 9 and 10 at its existing CS 343. Finally, NGPL will install various section 2.55(a) auxiliary facilities at CS 302 and CS 343, including additional gas cooling equipment, a motor control center building for new gas coolers and a new EMD compressor unit, a new filter separator, and station yard piping.

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 (*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. For assistance, contact the Federal Energy Regulatory Commission at *FercOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TTY (202) 502–8659.

Any questions regarding the proposed Project should be directed to Francisco Tarin, Director, Regulatory, for Kinder Morgan Inc., as Operator of Natural Gas Pipeline Company of America LLC, at 2 North Nevada Avenue, Colorado Springs, Colorado 80903, at (719) 667–7515, or *francisco_tarin@kindermorgan.com.*

Pursuant to Section 157.9 of the Commission's Rules of Practice and Procedure,[1] within 90 days of this Notice the Commission staff will either: complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file comments on the project, you can protest the filing, and you can file a motion to intervene in the proceeding. There is no fee or cost for filing comments or intervening. The deadline for filing a motion to intervene is 5:00 p.m. Eastern Time on November 21, 2023. How to file protests, motions to intervene, and comments is explained below.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice

[1] 18 CFR (Code of Federal Regulations) 157.9.

communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Comments

Any person wishing to comment on the project may do so. Comments may include statements of support or objections, to the project as a whole or specific aspects of the project. The more specific your comments, the more useful they will be.

Protests

Pursuant to sections 157.10(a)(4)[2] and 385.211[3] of the Commission's regulations under the NGA, any person[4] may file a protest to the application. Protests must comply with the requirements specified in section 385.2001[5] of the Commission's regulations. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

To ensure that your comments or protests are timely and properly recorded, please submit your comments on or before November 21, 2023.

There are three methods you can use to submit your comments or protests to the Commission. In all instances, please reference the Project docket number CP24–8–000 in your submission.

(1) You may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You may file your comments or protests electronically by using the eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Comment on a Filing''; or

(3) You can file a paper copy of your comments or protests by mailing them to the following address below. Your written comments must reference the Project docket number (CP24–8–000).

To file via USPS: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other courier: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of comments (options 1 and 2 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Persons who comment on the environmental review of this project will be placed on the Commission's environmental mailing list, and will receive notification when the environmental documents (EA or EIS) are issued for this project and will be notified of meetings associated with the Commission's environmental review process.

The Commission considers all comments received about the project in determining the appropriate action to be taken. However, the filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding. For instructions on how to intervene, see below.

Interventions

Any person, which includes individuals, organizations, businesses, municipalities, and other entities,[6] has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure[7] and the regulations under the NGA[8] by the intervention deadline for the project, which is November 21, 2023. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

There are two ways to submit your motion to intervene. In both instances, please reference the Project docket number CP24–8–000 in your submission.

(1) You may file your motion to intervene by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Intervention.'' The eFiling feature includes a document-less intervention option; for more information, visit *https://www.ferc.gov/docs-filing/efiling/document-less-intervention.pdf.;* or

(2) You can file a paper copy of your motion to intervene, along with three copies, by mailing the documents to the address below. Your motion to intervene must reference the Project docket number CP24–8–000.

To file via USPS: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other courier: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of motions to intervene (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Protests and motions to intervene must be served on the applicant either by mail or email at: Francisco Tarin, Director, Regulatory, for Kinder Morgan Inc., as Operator of Natural Gas Pipeline Company of America LLC, at 2 North Nevada Avenue, Colorado Springs, Colorado 80903 or at *francisco_tarin@kindermorgan.com.* Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online. Service can be via email with a link to the document.

All timely, unopposed[9] motions to intervene are automatically granted by operation of Rule 214(c)(1).[10] Motions to

[2] 18 CFR 157.10(a)(4).

[3] 18 CFR 385.211.

[4] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[5] 18 CFR 385.2001.

[6] 18 CFR 385.102(d).

[7] 18 CFR 385.214.

[8] 18 CFR 157.10.

[9] The applicant has 15 days from the submittal of a motion to intervene to file a written objection to the intervention.

[10] 18 CFR 385.214(c)(1).

intervene that are filed after the intervention deadline are untimely, and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations.[11] A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Intervention Deadline: 5:00 p.m. Eastern Time on November 21, 2023.

Dated: October 31, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–24463 Filed 11–3–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Southeastern Power Administration

Revision To Power Marketing Policy Cumberland System of Projects

AGENCY: Southeastern Power Administration, DOE.

ACTION: Notice of revision to power marketing policy.

SUMMARY: Southeastern Power Administration (Southeastern or SEPA) announces revision to the power marketing policy for the Cumberland System of Projects to include a procedure for distribution of renewable energy certificates (RECs). The Cumberland System power marketing policy was published on August 5, 1993, and is reflected in contracts for the sale of system power, which are maintained in Southeastern's headquarters office. Pursuant to the Procedure for Public Participation in the Formulation of Marketing Policy, published in the **Federal Register** on July 6, 1978, Southeastern published on October 21, 2021, a notice of intent to revise the power marketing policy to include provisions regarding RECs from the Cumberland System. The proposed revision to the Cumberland System Power Marketing Policy was published in the **Federal Register** on April 25, 2023. A virtual web based public information and comment forum was held on June 29, 2023, with written comments due on or before July 14, 2023.

DATES: The power marketing policy revision will become effective December 6, 2023.

FOR FURTHER INFORMATION CONTACT: Mr. Douglas Spencer, Engineer, Southeastern Power Administration, 1166 Athens Tech Road, Elberton, GA 30635, (706) 213–3855, Email: *douglas.spencer@sepa.doe.gov.*

SUPPLEMENTARY INFORMATION:

Background

Southeastern published a ''Notice of Issuance of Final Power Marketing Policy Cumberland System of Projects'' in the **Federal Register** on August 5, 1993 (58 FR 41762). The policy establishes the marketing area for system power and addresses the utilization of area utility systems for essential purposes. The policy also addresses wholesale rates, resale rates, and conservation measures, but does not address RECs.

Under Section 5 of the Flood Control Act of 1944 (16 U.S.C. 825s), Southeastern, through delegated authority, is responsible for the transmission and disposition of electric power and energy from reservoir projects operated by the U.S. Army Corps of Engineers. Furthermore, Southeastern must transmit and dispose of power and energy in such a manner as to encourage the most widespread use at the lowest possible rates to consumers consistent with sound business principles. Rate schedules are developed with regard to the recovery of the cost of producing and transmitting such electric energy.

Southeastern's authority to formulate the policy and perform the functions are derived from section 302(a) of the Department of Energy Organization Act, 42 U.S.C. 7152. By Delegation Order No. S1–DEL–RATES–2016, effective November 19, 2016, the Secretary of Energy delegated: (1) the authority to develop power and transmission rates to the SEPA Administrator; (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary of Energy; and (3) the authority to confirm, approve, and place into effect on a final basis, or to remand or disapprove such rates, to FERC. By Delegation Order No. S1–DEL–S3–2023, effective April 10, 2023, the Secretary of Energy also delegated the authority to confirm, approve, and place such rates into effect on an interim basis to the Under Secretary for Infrastructure. By Redelegation Order No. S3–DEL–SEPA1–2023, effective April 10, 2023, the Under Secretary for Infrastructure further redelegated the authority to confirm, approve, and place such rates into effect on an interim basis to SEPA's Administrator.

The Cumberland System consist of nine projects: Barkley, Center Hill, Cheatham, Cordell Hull, Dale Hollow, Laurel, Old Hickory, J. Percy Priest, and Wolf Creek. The power from the projects is currently marketed to Preference Customers located in the service areas of Tennessee Valley Authority, Big Rivers Electric Corporation, Duke Energy Progress, East Kentucky Power Cooperative, Kentucky Utilities, Municipal Electric Agency of Mississippi, Mississippi Delta Energy Agency, the seven-member Cooperative Energy currently receiving Cumberland power, and Southern Illinois Power Cooperative.

Southeastern has been using the Generation Attribute Tracking System (GATS) provided through the PJM Interconnection, LLC, for the Kerr-Philpott System of Projects. The attributes are unbundled from the megawatt-hour of energy produced and recorded onto a certificate. These certificates may be used by electricity suppliers and other energy market participants to comply with relevant state policies and regulatory programs and to support voluntary ''green'' electricity markets. Southeastern will use the similar M–RETS product for distributing certificates to current Preference Customers with allocations of power from the Cumberland System.

Through this RECs tracking system Southeastern is capable of tracking environmental attributes used for voluntary claims in all state, provinces, and territories in North America. Under the following revision of the 1994 power marketing policy, Southeastern will distribute the M–RETS created certificates to current Preference

[11] 18 CFR 385.214(b)(3) and (d).

Customers with allocations of power from the Cumberland System.

Public Notice and Comment

Southeastern published a proposed revision in the **Federal Register**, 88 FR 24981, dated April 25, 2023. Southeastern held a web-based information and comment forum on June 29, 2023. Southeastern received no comments.

Revision to the Power Marketing Policy

Southeastern revises the Power Marketing Policy for the System to include the following additional provisions for RECs associated with hydroelectric generation:

Renewable Energy Certificates: The M–RETS Tracking System creates and tracks certificates reporting generation attributes, by generating unit, for each megawatt-hour (MWh) of energy produced by registered generators. The System projects are registered generators within M–RETS. The RECs potentially satisfy Renewable Portfolio Standards, state policies, and other regulatory or voluntary clean energy standards in a number of states. Southeastern has subscribed to M–RETS and has an account in which RECs are collected and tracked for each MWh of energy produced from the System. Within M–RETS, certificates can be transferred to other M–RETS subscribers or to a third-party tracking system.

M–RETS creates a REC for every MWh of renewable energy produced by registered generators, tracks the life cycle of each REC created, and ensures against any double-counting or double-use of each REC. These RECs may be used by electricity suppliers and other energy market participants to comply with relevant state policies and regulatory programs and to support voluntary ''green'' electricity markets.

Southeastern will distribute M–RETS-created RECs to Preference Customers with allocations of power from the System.

REC Distribution: M–RETS (or a successor application) will be the transfer mechanism for all RECs related to the System. Southeastern shall maintain an account with M–RETS and collect RECs from the generation at the System projects. Southeastern will verify the total amount of RECs each month. Preference Customers with an allocation of power from the System are eligible to receive RECs by transfer from Southeastern's M–RETS account to their M–RETS account or that of their agent. M–RETS (or a successor application) will be the transfer mechanism for all RECs related to the Kerr-Philpott System. Any further transfer, sale use, or trade transaction would be the sole responsibility of a Preference Customer. Transfers to each customer will be based on the customer's monthly invoices during the same three-month period (quarter). Where applicable, RECs will be project-specific based on the customer's contractual arrangements. Customers receiving energy under the TVA/TVPPA contract will receive their distributions pursuant to the percentages in TVA Area Preference Customer 1978 Load document (revised March 2022).

All RECs distributed by Southeastern shall be transferred within forty-five days of the end of a quarter. Each customer must submit to Southeastern, by the tenth business day after the quarter, any notice of change to M–RETS account or agent. Any REC transfers that were not claimed or if a transfer account was not provided to Southeastern will be forfeited if they become nontransferable as described in the M–RETS terms of service, procedures, policies, or definitions of reporting and trading periods, or any subsequent rules and procedures for transfers as established.

The initial transfer process in M–RETS will be accomplished by the sixtieth day after the end of the first completed quarter subsequent to publication of the final policy revision. Any balance of RECs that exist in Southeastern's M–RETS account, other than the first quarter after policy revision publication, may also be transferred to Preference Customers according to the customer's invoiced energy at the time of the REC creation.

Rates: No rates shall be established by Southeastern for RECs transferred to Preference Customers. Any cost to Southeastern, such as the M–RETS subscription, will be incorporated into marketing costs and included in recovery through the energy and capacity rates of the System.

Determination Under Executive Order 12866

Southeastern is exempted from centralized regulatory review under Executive Order 12866; accordingly, no clearance of this notice by the Office of Management and Budget is required.

Environmental Compliance

SEPA has determined this action fits within the following categorical exclusions listed in appendix B to subpart D of 10 CFR part 1021: B4.1 (Contracts, policies, and marketing and allocation plans for electric power). Categorically excluded projects and activities do not require preparation of either an environmental impact statement or an environmental assessment.

Signing Authority

This document of the Department of Energy was signed on October 23, 2023, by Virgil G. Hobbs III, Administrator, Southeastern Power Administration, pursuant to the delegated authority from the Secretary of Energy. That document, with the original signature and date, is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE **Federal Register** Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on November 1, 2023.

Treena V. Garrett,

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

[FR Doc. 2023–24456 Filed 11–3–23; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–10082–02–OMS]

Privacy Act of 1974; System of Records

AGENCY: Security Management Division, Environmental Protection Agency (EPA).

ACTION: Notice of a modified system of records.

SUMMARY: The U.S. Environmental Protection Agency's (EPA or Agency) Personnel Security Branch (PSB) is giving notice that it proposes to modify a system of records pursuant to the provisions of the Privacy Act of 1974. The Personnel Security System (PSS) 2.0 is being modified to include a new module, which the Agency will use to administer its Insider Threat Program. The new module will collect records about individuals to assist the Agency with insider threat inquiry management and coordination. The module will retain insider threat inquiry-related data and help EPA personnel coordinate responses to those inquiries. Collecting this data ensures the effective and timely processing of records.

DATES: Persons wishing to comment on this system of records notice must do so by December 6, 2023.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OMS–2019–0371, by one of the following methods:

Federal eRulemaking Portal: https://www.regulations.gov. Follow the online instructions for submitting comments.

Email: docket_oms@epa.gov. Include the Docket ID number in the subject line of the message.

Fax: (202) 566–1752.

Mail: OMS Docket, Environmental Protection Agency, Mail Code: 2822T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

Hand Delivery: OMS Docket, EPA/DC, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OMS–2019–0371. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *https://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Controlled Unclassified Information (CUI) or other information for which disclosure is restricted by statute. Do not submit information that you consider to be CUI or otherwise protected through *https://www.regulations.gov.* The *https://www.regulations.gov* website is an ''anonymous access'' system for the EPA, which means the EPA will not know your identity or contact information. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. If you send an email comment directly to the EPA without going through *https://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about the EPA public docket, visit the EPA Docket Center homepage at *https://www.epa.gov/dockets.*

Docket: All documents in the docket are listed in the *https://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CUI or other information for which disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *https://www.regulations.gov* or in hard copy at the OMS Docket, EPA/DC, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20460. The Public Reading Room is normally open from 8:30 a.m. to 4:30 p.m., Monday through Friday excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OMS Docket is (202) 566–1752. Further information about EPA Docket Center services and current operating status is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: John Goldsby, Branch Chief, Personnel Security Branch, Environmental Protection Agency, William Jefferson Clinton North Building, Mail Code 3206A, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (202) 564–1569; email address: *Goldsby.John@epa.gov.*

SUPPLEMENTARY INFORMATION: Currently, EPA's Personnel Security Branch (PSB) uses PSS 2.0 to track and maintain background investigation documents for federal and non- federal personnel working for EPA. This includes background investigation documents for all ''covered individuals'' who have access to classified information or who hold a sensitive position. EPA is required to maintain this information for the employee onboarding process, and to manage background investigations for personnel during their time at the EPA (*i.e.,* when there are promotions, position changes, etc.).

PSB is adding a new Insider Threat module to PSS 2.0 that provides EPA with insider threat inquiry management and coordination capabilities. Specifically, the Agency is modifying PSS 2.0 to include an inquiry management function to maintain and safeguard insider threat-related data. PSS 2.0 will also allow the Agency to easily share necessary information with authorized personnel to conduct insider threat inquiries. The insider threat module will contain records derived from EPA security incidents, summaries, or reports containing information about potential insider threats or the data loss prevention program; information related to analytical efforts by EPA insider threat personnel; reports about potential insider threats obtained through the management and operation of the EPA Insider Threat Program; and reports about potential insider threats obtained from other Federal Governments sources. The records contained in this system could include information related to actual, potential, or alleged criminal, or administrative violations and law enforcement actions.

The insider threat module will contain information relevant to insider threat inquiries on cleared individuals with access to EPA resources, including facilities, information, equipment, networks, and systems. The insider threat module may also contain information obtained as a result of a background investigation conducted on cleared personnel. Further, at a later date, and once relevant authorities are updated, the insider threat module will also contain information on uncleared individuals with access to EPA resources.

SYSTEM NAME AND NUMBER:

Personnel Security System (PSS) 2.0, EPA–83.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

The system will be managed by the Personnel Security Branch, Environmental Protection Agency, 1301 Constitution Ave. NW, Washington, DC 20460. Electronically stored information is hosted at the EPA National Computer Center (NCC), 109 TW Alexander Drive, Research Triangle Park, Durham, NC 27711.

SYSTEM MANAGER(S):

John Goldsby, Branch Chief, Personnel Security Branch, Environmental Protection Agency, William Jefferson Clinton North Building, Mail Code 3206A, 1200 Pennsylvania Avenue NW, Washington, DC 20460; Telephone Number: (202) 564–1569; Email address: *goldsby.john@epa.gov.*

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Executive Order 13467, Reforming Processes for Security Clearances, Suitability and Fitness for Employment, and Credentialing, and Related Matters *as amended;* Code of Federal Regulations 5, Parts 731 (Suitability), 732 (National Security Positions), 736 (Personnel Investigations), and 1400 (Designation of National Security Positions in the Competitive Service, and Related Matters); Executive Order 12968—Access to Classified Information; Executive Order 13467—

Reforming Processes Related to Suitability for Government Employment, Fitness for Contractor Employees, and Eligibility for Access to Classified National Security Information; Executive Order 13488—Granting Reciprocity on Excepted Service and Federal Contractor Employee Fitness and Reinvestigating Individuals in Positions of Public Trust; Executive Order 13741—Amending E.O. 13467 To Establish the Roles and Responsibilities of the National Background Investigations Bureau and Related Matters; Executive Order 13764—Amending the Civil Service Rules, Executive Order 13488; E.O. 13467 To Modernize the Executive Branch-Wide Governance Structure and Processes for Security Clearances, Suitability and Fitness for Employment, and Credentialing, and Related Matters; Responsibilities for the Maintenance of Records About Individuals by Federal Agencies [OMB Circular A–108, as amended]; Trusted Workforce 2.0, Managements Responsibility for Internal Control [OMB Circular A–123, Revised 12/21/04]; Managing Information as a Strategic Resource [OMB Circular A–130]; Records Management by Federal Agencies [44 U.S.C. 31]; Federal Information Security Modernization Act (Pub. L. 104–106, sec. 5113); Electronic Government Act (Pub. L. 104–347, sec. 203); the Paperwork Reduction Act of 1995 (44 U.S.C. 3501); the Government Paperwork Elimination Act (Pub. L. 105–277, 44 U.S.C. 3504).

PURPOSE(S) OF THE SYSTEM:

The purpose of PSS 2.0 is to assist PSB with coordinating and managing background investigations on federal and non-federal personnel working for EPA by collecting, maintaining, and tracking the documentation associated with such background investigations. Data in the system will be transferred to the identity card management provider so that access cards can be issued to personnel. The data in the system will also be used by the Agency to start the employee onboarding process, and to manage personnel throughout their employment at EPA. Additionally, the insider threat module will be used by OHS to collect information on individuals, relevant to insider threat inquiries. EPA will use the insider threat module to manage information related to the inquiries, and support EPA's responses to such inquiries.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Federal employees, contractors, grantees, students, interns, volunteers, other non-federal employees, and individuals formerly in any of these positions including individuals who require access to EPA-controlled facilities, information technology systems, or information classified in the interest of national security, and applicants for employment or to work on a contract, grant or other activity for the Agency.

CATEGORIES OF RECORDS IN THE SYSTEM:

Information in the system may include: an individual's first, middle, and last name; social security number (SSN); date and place of birth; employment organization; office and home addresses; office, home, and cell phone numbers; job series; pay grade; current and previous employment details; dates and locations of overseas/foreign travel; military service information; financial and credit information; court documents; biometric data including fingerprint results; Office of Personnel Management's or Defense Counterintelligence and Security Agency's background investigations; driver's license information; passport and visa information; photographs; emergency contacts; business or other involvement with foreign governments or foreign nationals; foreign contacts; ownership of foreign property information; foreign bank account information; information on arrests in foreign countries; and insider threat inquiry details.

RECORD SOURCE CATEGORIES:

The data maintained in PSS 2.0 is obtained from subjects of a background investigation, individuals interviewed as part of a background investigation or insider threat inquiry, current and prospective EPA personnel, internal EPA systems such as the Human Resources Line of Business (HRLoB) system (EPA–93), external systems such as the General Service Administration (GSA)'s USAccess system (GSA/GOVT–7), and from other external sources such as vendors, applicants, other federal agencies, other law enforcement systems and other public source materials.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

The routine uses below are both related to and compatible with the original purpose for which the information was collected.

General routine uses A, B, C, D, E, F, G, H, I, J, K, L, and M apply to this system (86 FR 62527).

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

These records are maintained electronically on computer storage devices located at the EPA National Computer Center (NCC), 109 TW Alexander Drive, Research Triangle Park, Durham, NC 27711.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Personal information may be retrieved using an individual's SSN, name, date of birth, email address, personal identification number or background investigation case number. The SSN is used in the Suitability, Credentialing and Security Executive Agents' systems, and is therefore used as the connecting data to enable the various systems to communicate with each other and transfer data when needed. PSS 2.0 displays a reminder about the appropriate PII and SPII handling procedures every time a user begins to enter data for a new background investigation.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are retained and disposed of in accordance with National Archives and Records Administration (NARA) records retention schedules appropriate to the retention of background investigation related data, as well as EPA's Records Schedules 100 & 1008.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Security controls used to protect personal sensitive data in PSS 2.0 are commensurate with those required for an information system rated MODERATE for confidentiality, integrity, and availability, as prescribed in NIST Special Publication, 800–53, ''Security and Privacy Controls for Information Systems and Organizations,'' Revision 5.

1. Administrative Safeguards: Personnel are instructed to lock their computer when they leave their desks. Personnel are regularly reminded about appropriate sensitive personally identifiable information (SPII) and personally identifiable information (PII) handling procedures. All personnel are required to take annual Information Technology Security and Privacy Training. In addition to the agency's Rules of Behavior, PSS 2.0 users are required to sign a PSS 2.0-specific Rules of Behavior document prior to their access being granted to the system.

Additionally, Contracting Officer's Representatives will also be required to review and understand PSS 2.0 user guides, which explain how SPII/PII should be handled.

2. Technical Safeguards: Electronic records are maintained in a secure, password-protected environment. Access to records is limited to those

who have a need to know. Electronic records are restricted to authorized users with appropriate security privileges, including the use of 2- factor PIV Card authentication and permission level assignments. After 15 minutes of inactivity, a user is automatically logged out of the system. Additionally, PSS 2.0 displays a reminder about the appropriate PII and SPII handling procedures each time a user begins to enter data for a new background investigation.

3. Physical Safeguards: All records are maintained in secure, access-controlled areas or buildings. EPA employees and contractors involved in the management, design, development, implementation, and execution of the program will have monitored access to the application. Only individuals who have the proper authorization and who perform functions related to PSS 2.0 are allowed to access information.

RECORD ACCESS PROCEDURES:

Pursuant to 5 U.S.C. 552a(k)(2), certain records maintained in PSS 2.0 are exempt from specific access and accounting provisions of the Privacy Act. See 40 CFR 16.12. However, EPA may, in its discretion, grant individual requests for access if it determines that the exercise of these rights will not interfere with an interest that the exemption is intended to protect. Requests for access must be made in accordance with the procedures described in EPA's Privacy Act regulations at 40 CFR part 16.

Specifically, all requests for access to personal records should cite the Privacy Act of 1974 and reference the type of request being made (*i.e.,* access). Requests must include: (1) the name and signature of the individual making the request; (2) the name of the Privacy Act system of records to which the request relates; (3) a statement whether a personal inspection of the records or a copy of them by mail is desired; and (4) proof of identity. A full description of EPA's Privacy Act procedures for requesting access to records is available at 40 CFR part 16.

CONTESTING RECORD PROCEDURES:

Pursuant to 5 U.S.C. 552a(k)(2), certain records maintained in PSS 2.0 are exempt from specific correction and amendment provisions of the Privacy Act. See 40 CFR 16.12. However, EPA may, in its discretion, grant individual requests for correction and amendment if it determines that the exercise of these rights will not interfere with an interest that the exemption is intended to protect. Requests for correction and amendment must identify the record to be changed and the corrective action sought and must be made in accordance with the procedures described in EPA's Privacy Act regulations at 40 CFR part 16.

NOTIFICATION PROCEDURES:

Pursuant to 5 U.S.C. 552a(k)(2) and (k)(5), certain records maintained in PSS 2.0 are exempt from specific notification provisions of the Privacy Act. See 40 CFR 16.12. However, EPA may, in its discretion, grant individual notification requests if it determines that notification will not interfere with an interest that the exemption is intended to protect. Generally, individuals who wish to be informed whether a Privacy Act system of records maintained by EPA contains any record pertaining to them, should make a written request to the EPA, Attn: Agency Privacy Officer, MC 2831T, 1200 Pennsylvania Ave. NW, Washington, DC 20460, or by email at: *privacy@epa.gov.* A full description of EPA's Privacy Act procedures is included in EPA's Privacy Act regulations at 40 CFR part 16.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

Under 5 U.S.C. 552a (k)(2), certain records in PSS 2.0 are exempt from the following provisions of the Privacy Act of 1974, as amended, subject to the limitations set forth in this subsection: 5 U.S.C. 552a(c)(3); (d); (e)(1). In particular, the following types of records in PSS 2.0 are exempt from the aforementioned provisions under subsection (k)(2): (1) background investigation records compiled to investigate personnel/an applicant that is/would be responsible for law enforcement and/or national security matters; (2) background investigation records compiled to investigate personnel suspected of illegal or inappropriate activity; (3) information compiled to identify potential insider threats and facilitate insider threat inquiries; (4) information compiled to identify pattens of illegal activity, or that may form the predicate or be the catalyst of a law enforcement investigation; and (5) information otherwise compiled to identify violations of law or national security breaches.

However, if any individual is denied a right, privilege, or benefit to which the individual would otherwise be entitled by Federal law or for which the individual would otherwise be eligible, access will be granted, except to the extent that the disclosure would reveal the identity of a source who furnished information to the Government under an express promise of confidentiality.

Further, under 5 U.S.C. 552a(k)(5), investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, military service, Federal contracts, or access to classified information that, if disclosed, would reveal the identity of a confidential source is exempt from 5 U.S.C. 552a (c)(3) and (d), subject to the limitations set forth in the subsections.

EPA may maintain in PSS 2.0 records obtained from other agencies or components, which have exempted those records from certain Privacy Act requirements under 5 U.S.C. 552a (j) and (k). As such records do not lose exempt status when added to another system, these records will continue to be exempt in PSS 2.0 on the same basis and from the same requirements as in the source system. Although certain records in PSS 2.0 have been exempted from certain provisions of the Privacy Act, EPA may, in its discretion, fully grant individual requests for access and correction if it determines that the exercise of these rights will not interfere with an interest that the exemption is intended to protect. However, if any individual is denied any right, privilege, or benefit that they would otherwise be entitled by federal law, or for which they would otherwise be eligible, as a result of the maintenance of these records, the records shall be provided to the individual, except to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence.

HISTORY:

85 FR 32380 (May 29, 2020).

Vaughn Noga,

Senior Agency Official for Privacy.

[FR Doc. 2023–24492 Filed 11–3–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–11527–01–OAR]

Announcing Upcoming Meeting of Mobile Sources Technical Review Subcommittee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Pursuant to the Federal Advisory Committee Act, the Environmental Protection Agency (EPA) announces an upcoming meeting of the

Mobile Sources Technical Review Subcommittee (MSTRS), which is a subcommittee under the Clean Air Act Advisory Committee (CAAAC). This is a virtual meeting and open to the public. The meeting will include discussion of current topics and presentations about activities being conducted by EPA's Office of Transportation and Air Quality. MSTRS listserv subscribers will receive notification when the agenda is available on the Subcommittee website. To subscribe to the MSTRS listserv, send an email to *MSTRS@epa.gov.*

DATES: EPA will hold a virtual public meeting on Wednesday, November 29th from 9 a.m. to 5 p.m. eastern standard time (EST). Please monitor the website *https://www.epa.gov/caaac/mobile-sources-technical-review-subcommittee-mstrs-caaac* for any changes to meeting logistics. The final meeting agenda will be posted on the website.

ADDRESSES: For information on the public meeting or to register to attend, please contact *MSTRS@epa.gov.*

FOR FURTHER INFORMATION CONTACT: Any member of the public who wishes to attend the meeting or provide comments should express this intent by emailing *MSTRS@epa.gov* no later than Monday, November 20, 2023. Further information concerning this public meeting and general information concerning the MSTRS can be found at: *https://www.epa.gov/caaac/mobile-sources-technical-review-subcommittee-mstrs-caaac.* Other MSTRS inquiries can be directed to Jessie Mroz, the Designated Federal Officer for MSTRS, Office of Transportation and Air Quality, at 202–564–1094 or *mroz.jessica@epa.gov.*

SUPPLEMENTARY INFORMATION: During the meeting, the Subcommittee may also hear progress reports from its workgroups as well as updates and announcements on Office of Transportation and Air Quality activities of general interest to attendees.

Participation in virtual public meetings. The virtual public meeting will provide interested parties the opportunity to participate in this Federal Advisory Committee meeting.

For individuals with disabilities: For information on access or services for individuals with disabilities, please email *MSTRS@epa.gov.* To request accommodate of a disability, please email *MSTRS@epa.gov,* preferably at least 10 business days prior to the meeting, to give EPA as much time as possible to process your request.

EPA is asking all meeting attendees, even those who do not intend to speak, to register for the meeting by sending an email to the address listed in the **FOR FURTHER INFORMATION CONTACT** section above, by Monday, November 20, 2023. This will help EPA ensure that sufficient participation capacity will be available.

Please note that any updates made to any aspect of the meeting logistics, including potential additional sessions, will be posted online at *https://www.epa.gov/caaac/mobile-sources-technical-review-subcommittee-mstrs-caaac.* While EPA expects the meeting to go forward as set forth above, please monitor the website for any updates.

Jessica Mroz,

Designated Federal Officer, Mobile Source Technical Review Subcommittee, Office of Transportation and Air Quality.

[FR Doc. 2023–24430 Filed 11–3–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–11450–01–ORD]

Ambient Air Monitoring Reference and Equivalent Methods; Designation of Two New Equivalent Methods

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of the designation of two new equivalent methods for monitoring ambient air quality.

SUMMARY: Notice is hereby given that the Environmental Protection Agency (EPA) has designated one new equivalent method for measuring concentrations of Lead (pb), and one new equivalent method for measuring concentrations of Particulate Matter (PM_{10}) in ambient air.

FOR FURTHER INFORMATION CONTACT: Robert Vanderpool, Air Methods and Characterization Division (MD–D205–03), Center for Environmental Measurements and Modeling, U.S. EPA, Research Triangle Park, North Carolina 27711. Phone: 919–541–7877. Email: *Vanderpool.Robert@epa.gov.*

SUPPLEMENTARY INFORMATION: In accordance with regulations at 40 CFR part 53, the EPA evaluates various methods for monitoring the concentrations of those ambient air pollutants for which EPA has established National Ambient Air Quality Standards (NAAQS) as set forth in 40 CFR part 50. Monitoring methods that are determined to meet specific requirements for adequacy are designated by the EPA as either reference or equivalent methods (as applicable), thereby permitting their use under 40 CFR part 58 by States and other agencies for determining compliance with the NAAQS. A list of all reference or equivalent methods that have been previously designated by EPA may be found at *http://www.epa.gov/ttn/amtic/criteria.html.*

The EPA hereby announces the designation of one new equivalent method for measuring concentrations of Pb, and one new equivalent method for measuring concentrations of PM_{10} in ambient air. These designations are made under the provisions of 40 CFR part 53, as amended on October 26, 2015 (80 FR 65291–65468).

The new equivalent method for Pb is a manual method that uses the sampling procedure specified in the Reference Method for the Determination of Lead in Suspended Particulate Matter Collected from Ambient Air (High-Volume Sampler), 40 CFR part 50, appendix G, with a different extraction and analytical procedure. The method is identified as follows:

EQL–0723–261, ''Microwave Assisted Digestion and Quadrupole Inductively Coupled Plasma—Mass Spectrometry (South Coast Air Quality Management District Laboratory)'' ''*Determination of Lead (Pb) on TSP Hi-Volume Filters by Microwave Assisted Digestion and Quadrupole Inductively Coupled Plasma Mass Spectrometry (Quadrupole ICP–MS).*'' A sample of total suspended particulate matter (TSP) is collected on a glass or quartz fiber filter, using the sampler and procedure of the EPA Reference Method for the Determination of Suspended Particulate Matter in the Atmosphere (High-Volume Method) (40 CFR part 50, appendix B). The TSP sample is extracted with a nitric acid solution and digested in a microwave system, centrifuged and brought to a final acid concentration of 2–3%. The lead content of the sample extract is analysed by Quadrupole Inductively Coupled Plasma Mass Spectrometry (Quadrupole ICP–MS), based on EPA Method IO–3.5.

The application for equivalent method determination for this Pb method was submitted by South Coast Air Quality Management District, 21865 Copley Drive, Diamond Bar, CA 91765 and was received by the Office of Research and Development on July 11, 2023.

The new equivalent method for PM_{10} is an automated monitoring method (monitor) utilizing the measurement principle based on beta-ray attenuation. This newly designated equivalent method is identified as follows:

EQPM–0923–262, ''Vasthi Instruments Pvt. Ltd Vair-9009 $p.m._{10}$ Monitor,'' beta-ray monitor operated in a range of 0–5mg/m^3, with an operational temperature range of 0 °C to

40 °C. The unit is configured for 24, 1-hour average measurements of PM_{10} by beta attenuation, using a glass fiber paper tape roll (VPM–1006). The unit operates at a sample flow rate of 16.67 liters/min, with PM_{10} inlet meeting 40 CFR part 50 appendix L specifications, and heated inlet to control sample relative humidity to 35%. Instrument must be operated in accordance with the Vair-9009 Operating Manual. This designation applies to PM_{10} measurements only.

This application for an equivalent method determination for this PM_{10} method was received by the Office of Research and Development on July 11, 2023. This monitor is commercially available from the applicant, Vasthi Instruments, Guntur 522 001, Andhra Pradesh, India.

A representative test analyzer was tested in accordance with the applicable test procedures specified in 40 CFR part 53, as amended on October 26, 2015. After reviewing the results of those tests and other information submitted by the applicant, EPA has determined, in accordance with 40 CFR part 53, that these methods should be designated as equivalent methods.

As designated equivalent methods, these methods are acceptable for use by states and other air monitoring agencies under the requirements of 40 CFR part 58, Ambient Air Quality Surveillance. For such purposes, these methods must be used in strict accordance with the operation or instruction manual associated with the method and subject to any specifications and limitations (*e.g.,* configuration or operational settings) specified in the designated method description (see the identification of the methods above).

Use of the methods also should be in general accordance with the guidance and recommendations of applicable sections of the ''Quality Assurance Handbook for Air Pollution Measurement Systems, Volume I,'' EPA/600/R–94/038a and ''Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II, Ambient Air Quality Monitoring Program,'' EPA–454/B–13–003, (both available at *http://www.epa.gov/ttn/amtic/qalist.html*). Provisions concerning modification of such methods by users are specified under section 2.8 (Modifications of Methods by Users) of appendix C to 40 CFR part 58.

Consistent or repeated noncompliance with any of these conditions should be reported to: Director, Air Methods and Characterization Division (MD–D205–03), Center for Environmental Measurements and Modeling, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

Designation of these equivalent methods are intended to assist the States in establishing and operating their air quality surveillance systems under 40 CFR part 58. Questions concerning the commercial availability or technical aspects of these methods should be directed to the applicants.

Alice Gilliland,

Acting Director, Center for Environmental Measurements and Modeling.

[FR Doc. 2023–24495 Filed 11–3–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2022–0223; FRL–11467–01–OCSPP]

Final Cancellation Order for Certain Chlorpyrifos Registrations and Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) hereby announces its final cancellation order for the cancellations and amendments to terminate uses voluntarily requested by the registrants and accepted by the Agency, of the products in Table 1 and Table 2 of Unit II, pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This final cancellation order follows a May 3, 2023, **Federal Register** Notice of Receipt of Requests from the registrants listed in Table 3 of Unit II, to voluntarily cancel or amend these product registrations. In the May 3, 2023, notice, EPA indicated that it would issue a final order implementing the cancellations and amendments, unless the Agency received substantive comments within the 30-day comment period that would merit further review of these requests, or unless the registrants withdrew their requests. The Agency received two comments on the notice, which are summarized in Unit III.B. EPA's responses to these comments and its determination that these comments do not merit further review of these cancellation and amendment requests are included in Unit III.C. None of the registrants withdrew their request for these voluntary cancellations or amendments. Accordingly, EPA hereby grants the requested cancellations and amendments to terminate uses as shown in this cancellation order. Any distribution, sale, or use of existing stocks of these products subject to this cancellation order is permitted only in accordance with the terms of this order.

DATES: The cancellations and amendments are effective November 6, 2023.

FOR FURTHER INFORMATION CONTACT: Patricia Biggio, Pesticide Re-Evaluation Division (7508M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–0700; email address: *OPPChlorpyrifosInquiries@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2022–0223, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744. Please review the additional information about the docket available at *https://www.epa.gov/dockets.*

II. What action is the Agency taking?

This document announces the cancellations and amendments through termination of certain uses, as requested by registrants, of products registered under FIFRA section 3 (7 U.S.C. 136a). These registrations are listed in sequence by registration number in Table 1 and Table 2 of this Unit.

TABLE 1—PRODUCT CANCELLATIONS

EPA registration No.	Company No.	Product name	Active ingredients
228–620	228	Nufarm Chlorpyrifos SPC 2.32% G Insecticide	Chlorpyrifos.
228–621	228	Nufarm Chlorpyrifos SPC 1.0% MCB Insecticide	Chlorpyrifos.
228–624	228	Nufarm Chlorpyrifos SPC 4 Insecticide	Chlorpyrifos.
228–625	228	Nufarm Chlorpyrifos SPC 2 Insecticide	Chlorpyrifos.
53883–394	53883	CSI 16–150 Chlorpyrifos 42	Chlorpyrifos.
53883–407	53883	CSI 16–149 Chlorpyrifos 20	Chlorpyrifos.
84229–25	84229	Chlorpyrifos 4E AG	Chlorpyrifos.
84229–26	84229	Chlorpyrifos 15G	Chlorpyrifos.

TABLE 2—CHLORPYRIFOS REGISTRATIONS WITH SPECIFIC USES TO BE TERMINATED

Registration No.	Company No.	Product name	Uses to be terminated
11678–58	11678	Pyrinex Chlorpyrifos Insecticide	Food processing plants.
66222–19	66222	Chlorpyrifos 4E AG	Food processing and food manufacturing sites.
66222–233	66222	Vulcan	Food processing and food manufacturing sites.
85724–10	85724	Akofos 48 EC	*Food uses:* Alfalfa, apple (including apple tree trunk), asparagus, cherries, citrus fruits (calamondin, chironja, citrus citron, citrus hybrids, grapefruit, kumquat, lemons, limes, mandarin (tangerine), oranges, pummelo, satsuma mandarin, tangelo, tangor, and other citrus fruit, small transplanted grapefruit, orange, and other citrus trees), corn, cotton, cranberries, figs, grapes, legume vegetables (legume vegetables including adzuki bean, asparagus bean, bean, blackeyed pea, broad bean (dry and succulent), catjang, chickpea, Chinese longbean, cowpea, crowder pea, dwarf pea, edible pod pea, English pea, fava bean, field bean, field pea, garbanzo bean, garden pea, grain lupin, green pea, guar, hyacinth bean, jackbean, kidney bean, lablab bean, lentil, lima bean, moth bean, mung bean, navy bean, pea, pigeon pea, pinto bean, rice bean, runner bean, snap bean, snow pea, English pea, southern pea, sugar snap pea, sweet lupin, sword bean, tepary bean, urd bean, wax bean, white lupin, white sweet lupin, yardlong bean), mint (peppermint and spearmint), nectarines, peaches, almonds, onions, peanuts, pears, sorghum grain (milo), soybeans, strawberries, sugar beets, sunflowers, sweet potatoes, tree fruits (apples, pears, plums, prunes, peaches, nectarines), tree nuts (almonds, filberts, pecans, walnuts), vegetables (rutabaga, broccoli, Brussels sprout, cabbage, cauliflower, Chinese cabbage, collards, kale, kohlrabi, turnips, radishes), wheat, and food processing plants. *Nonfood uses:* Tobacco.

TABLE 3—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION OR TERMINATION OF USES

EPA company No.	Company name and address
228	NuFarm, 4020 Aerial Center Pkwy., Suite 101, Morrisville, NC 27560.
11678	ADAMA US, 3120 Highwoods Boulevard, Suite 100, Raleigh, NC 27604.
53883	Control Solutions, Inc., 5903 Genoa Red Bluffs Road, Pasadena, TX 77507.
66222	ADAMA US, 3120 Highwoods Boulevard, Suite 100, Raleigh, NC 27604.
84229	Tide International USA, Inc., Agent Name: Pyxis Regulatory Consulting, INC., 4110 136TH Street CT NW, Gig Harbor, WA 98332.

TABLE 3—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION OR TERMINATION OF USES—Continued

EPA company No.	Company name and address
85724	AAKO B.V., c/o Ceres International LLC, 1087 Heartsease Drive, West Chester, PA 19382.

III. Public Comments

A. Brief History

EPA issued a rule in the **Federal Register** on August 30, 2021 (86 FR 48315) (FRL–5993–04–OCSPP) revoking chlorpyrifos tolerances on the grounds that they were not safe (the ''Final Rule''). Pursuant to the procedures set forth in FFDCA section 408(g)(2), objections to, requests for evidentiary hearings on those objections, and/or requests for a stay of the Final Rule were filed on or before the close of the objections period on October 29, 2021. EPA issued an Order published in the **Federal Register** on February 28, 2022 (87 FR 11222) (FRL–5993–05–OCSPP), denying all objections to the Final Rule and requests for hearing on those objections, as well as requests for stay of the Final Rule (the ''Denial Order'').

Since the objections process did not result in any changes to the Final Rule, chlorpyrifos tolerances expired on February 28, 2022, under the terms of the Final Rule. Once the tolerances expired, use of pesticide products containing chlorpyrifos on food or feed crops would result in adulterated food, which cannot be sold in interstate commerce. After EPA alerted registrants of chlorpyrifos products of the lack of tolerances and the options for their products, several registrants submitted requests to voluntarily cancel their registered chlorpyrifos products or

amend their chlorpyrifos pesticide products to remove food uses. The registrants identified in Table 3 of Unit II, among others, submitted such requests. Notice of EPA's receipt of these requests was published for comment in the **Federal Register** on May 3, 2023 (''Notice of Receipt''). The 30-day public comment period closed on June 2, 2023.

B. Summary of Comments Received

During the public comment period, EPA received two comments in response to the Notice of Receipt. The comments can be found in the docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2022–0223, available at *https://www.regulations.gov* and are briefly summarized here. One comment was submitted by the American Sugarbeet Growers Association, U.S. Beet Sugar Association, and the Beet Sugar Development Foundation. A second comment was submitted anonymously by a private citizen generally supporting the cancellation of the pesticide.

The comment from the American Sugarbeet Growers Association, U.S. Beet Sugar Association, and the Beet Sugar Development Foundation opposed the voluntary cancellation of the products in the Notice of Receipt. In particular, these commenters specified concerns that the voluntary cancellation of chlorpyrifos registrations and termination of certain uses is premature while there is ongoing litigation regarding the Final Rule and Denial Order in the U.S. Court of Appeals for the Eighth Circuit, *Red River Valley Sugarbeet Growers Ass'n et al.,* v. *Regan, et al.,* Nos. 22–1422, 22–1530 (8th Cir.). These commenters also specified concerns that the loss of chlorpyrifos as a pest management tool will result in substantial increased costs, lost profits, decreased crop yields, and a larger environmental impact from more frequent use of less effective alternatives.

C. EPA Response to Comments

Regarding the comments submitted by the American Sugarbeet Growers Association, U.S. Beet Sugar Association, and the Beet Sugar Development Foundation, the cancellations and amendments requested by the registrants listed in Table 3 are appropriate at this time because section 6(f)(1) of FIFRA allows registrants to submit, at any time, a request that EPA cancel their registrations or amend their registrations to terminate one or more uses. 7 U.S.C. 136d(f)(1)(A). A registrant may have a variety of reasons for requesting voluntary cancellation of a pesticide product registration at any time, including, for example, lack of interest in maintaining the registration, market conditions, costs of maintaining the registration, or the pesticide no longer being marketed.

EPA cannot compel registrants to maintain registrations if they request to voluntarily cancel them. The resolution and timing of the litigation in the Eighth Circuit is still unknown, and therefore, retention of the registrations could subject registrants to additional maintenance fees and responsibilities for those registrations which the registrants requested cancellation or amendment. See, *e.g.,* 40 CFR part 152, subpart G (registrant responsibilities); 7 U.S.C. 136a–1(i)(1) (maintenance fee obligations); 7 U.S.C. 136e (production reporting requirements); 7 U.S.C. 136f (recordkeeping requirements).

Moreover, retention of these registrations will not make chlorpyrifos products available for use on sugarbeets as the commenters desire. As noted in Unit III.A. above, all tolerances for residues of chlorpyrifos have been revoked. The revocation of the tolerances means that application of chlorpyrifos to food or feed crops, including sugarbeets, will result in adulterated food and/or feed which cannot be shipped in interstate commerce. While cancellation of the eight products in Table 1 and amendment of four products in Table 2 does not terminate the last of the chlorpyrifos products registered in the United States, these products (and other remaining chlorpyrifos products) cannot be applied to food crops.

IV. The Cancellation Order

Pursuant to FIFRA section 6(f) (7 U.S.C. 136d(f)(1)), EPA hereby approves the requested cancellations and amendments to terminate uses of the registrations identified in Table 1 and Table 2 of Unit II. Accordingly, the Agency hereby orders that the product registrations identified in Table 1 of Unit II are cancelled and the uses identified on the products listed in Table 2 of Unit II are terminated.

The cancellations and amendments addressed in this Order are effective November 6, 2023. Any distribution, sale, or use of existing stocks of the products identified in Tables 1 and 2 of Unit II in a manner inconsistent with any of the provisions for disposition of existing stocks set forth in Unit V will be a violation of FIFRA.

V. What is the Agency's authority for taking these actions?

Section 6(f)(1) of FIFRA (7 U.S.C. 136d(f)(1)) provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be cancelled or amended to terminate one or more registered uses. Section 6(f)(1)(B) of FIFRA (7 U.S.C. 136d(f)(1)(B)) further provides that, before acting on the request for voluntary cancellation or amendment, EPA must publish a notice of receipt of any such request in the **Federal Register** and provide a 30-day public comment period on the request for voluntary cancellation or use termination. Following the public comment period, the EPA Administrator may approve such a request. The notice for this action was published for comment in the **Federal Register** on May 3, 2023 (88 FR 27882) (FRL–10923–01–OCSPP). The 30-day public comment period closed on June 2, 2023.

VI. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products that are currently in the United States and that were packaged, labeled, and released for shipment prior to the effective date of the cancellation action.

Because all chlorpyrifos tolerances expired on February 28, 2022, use of chlorpyrifos in or on food will result in adulterated food, which cannot be delivered into interstate commerce. Such use would be inconsistent with the provisions of FIFRA. EPA is allowing existing stocks of chlorpyrifos products identified in Tables 1 and 2 that are already in the hands of end-users to be used only for non-food uses identified on the existing labels, until those existing stocks are exhausted, as long as such use is consistent with the label. All other use of existing stocks of these chlorpyrifos products are prohibited.

Because sale and distribution of chlorpyrifos products bearing labeling for use on food is inconsistent with the purposes of FIFRA, all sale and distribution of the chlorpyrifos products identified in Table 1 and Table 2 of Unit II. is prohibited with the following exceptions:

1. Existing stocks of all products listed in Tables 1 and 2 may be sold or distributed for export consistent with FIFRA section 17 (7 U.S.C. 136o*) and for* proper disposal.

2. Since the issuance of the May 3, 2023, Notice, EPA has realized that some of the products listed in Table 1 do not bear any labeling for use on food.

Accordingly, existing stocks of those products, which are listed below, may be sold or distributed for one year after the date of this cancellation order:

- Nufarm Chlorpyrifos SPC 2.32% G Insecticide (EPA Reg. No. 228–620).
- Nufarm Chlorpyrifos SPC 1.0% MCB Insecticide (EPA Reg. No. 228–621).
- Nufarm Chlorpyrifos SPC 4 Insecticide (EPA Reg. No. 228–624).
- Nufarm Chlorpyrifos SPC 2 Insecticide (EPA Reg. No. 228–625).

3. Existing stocks of the following products may be distributed consistent with the Control Solutions, Inc. (''CSI'') return program agreement that EPA approved on October 12, 2023.

- CSI 16–150 Chlorpyrifos 42 (EPA Reg. No. 53883–394).
- CSI 16–149 Chlorpyrifos 20 (EPA Reg. No. 53883–407).
- Quali-Pro Chlorpyrifos 4E (EPA Reg. No. 66222–19). Quali-Pro Chlorpyrifos 4E is an alternate brand name for Chlorpyrifos 4E AG (EPA Reg. No. 66222–19).

EPA notified CSI of the approval of their return program agreement on October 12, 2023.

This cancellation order also amends the cancellation order published in the **Federal Register** on May 4, 2023 (88 FR 28541) (FRL–10924–01–OCSPP) by clarifying that any products with the EPA Reg. No. 66222–19 and bearing the alternate brand name of Quali-Pro Chlorpyrifos 4E may be distributed to CSI pursuant to the CSI return program agreement referenced above. Products with the EPA Reg. No. 66222–19 and bearing the primary brand name of Chlorpyrifos 4E AG may continue to be returned to Adama as per the return program agreement approved by EPA on April 19, 2023, under the terms of the May 4 cancellation order.

Additional information regarding the chlorpyrifos return program for Control Solutions, Inc. may be found in *https://www.regulations.gov/docket/EPA-HQ-OPP-2022-0223* or by contacting the registrant at: Control Solutions, Inc. (800) 242–5562 or email: *csi-customer-service@controlsolutionsinc.com.*

Dated: October 26, 2023.

Mary Elissa Reaves,

Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2023–24462 Filed 11–3–23; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Termination of Receiverships

The Federal Deposit Insurance Corporation (FDIC or Receiver), as Receiver for each of the following insured depository institutions, was charged with the duty of winding up the affairs of the former institutions and liquidating all related assets. The Receiver has fulfilled its obligations and made all dividend distributions required by law.

NOTICE OF TERMINATION OF RECEIVERSHIPS

Fund	Receivership name	City	State	Termination date
10047	FirstCity Bank	Stockbridge	GA	11/01/2023
10055	First Bank of Idaho, FSB	Ketchum	ID	11/01/2023
10058	Citizens Community Bank	Ridgewood	NJ	11/01/2023
10064	Bank of Lincolnwood	Lincolnwood	IL	11/01/2023
10100	Community Bank of Nevada	Las Vegas	NV	11/01/2023
10217	Tamalpais Bank	San Rafael	CA	11/01/2023
10224	Wheatland Bank	Naperville	IL	11/01/2023
10333	First Community Bank	Taos	NM	11/01/2023
10363	The Park Avenue Bank	Valdosta	GA	11/01/2023
10396	Bank of The Commonwealth	Norfolk	VA	11/01/2023
10434	Bank of The Eastern Shore	Cambridge	MD	11/01/2023

The Receiver has further irrevocably authorized and appointed FDIC-Corporate as its attorney-in-fact to execute and file any and all documents that may be required to be executed by the Receiver which FDIC-Corporate, in its sole discretion, deems necessary, including but not limited to releases, discharges, satisfactions, endorsements, assignments, and deeds. Effective on the termination dates listed above, the Receiverships have been terminated, the Receiver has been discharged, and the Receiverships have ceased to exist as legal entities.

(Authority: 12 U.S.C. 1819.)

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on November 1, 2023.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2023–24453 Filed 11–3–23; 8:45 am]

BILLING CODE 6714–01–P

GENERAL SERVICES ADMINISTRATION

[Notice–Q–2023–05; Docket No. 2023–0002; Sequence No. 438]

Federal Secure Cloud Advisory Committee Notification of Upcoming Meeting

AGENCY: Federal Acquisition Service (Q), General Services Administration (GSA).

ACTION: Meeting notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act (FACA), GSA is hereby giving notice of an open public meeting of the Federal Secure Cloud Advisory Committee (FSCAC). Information on attending and providing public comment is under the **SUPPLEMENTARY INFORMATION** section.

DATES: The open public meeting will be held on Thursday, November 16, 2023, from 1 p.m. to 3 p.m., eastern standard time (EST). The agenda for the meeting will be made available prior to the meeting online at *https://gsa.gov/fscac.*

ADDRESSES: The meetings will be accessible via webcast. Registrants will receive the webcast information before the meeting.

FOR FURTHER INFORMATION CONTACT: Michelle White, Designated Federal Officer (DFO), FSCAC, GSA, 703–489–4160, *fscac@gsa.gov.* Additional information about the Committee, including meeting materials and agendas, will be available online at *https://gsa.gov/fscac.*

SUPPLEMENTARY INFORMATION:

Background

GSA, in compliance with the FedRAMP Authorization Act of 2022, established the FSCAC, a statutory advisory committee in accordance with the provisions of FACA (5 U.S.C. 10). The Federal Risk and Authorization

Management Program (FedRAMP) within GSA is responsible for providing a standardized, reusable approach to security assessment and authorization for cloud computing products and services that process unclassified information used by agencies.

Due to circumstances beyond the control of the DFO, the **Federal Register** notice for this meeting is being published fewer than 15 calendar days prior to the meeting due to unforeseen administrative difficulties.

The FSCAC will provide advice and recommendations to the Administrator of GSA, the FedRAMP Board, and agencies on technical, financial, programmatic, and operational matters regarding the secure adoption of cloud computing products and services. The FSCAC will ensure effective and ongoing coordination of agency adoption, use, authorization, monitoring, acquisition, and security of cloud computing products and services to enable agency mission and administrative priorities. The purposes of the Committee are:

- To examine the operations of FedRAMP and determine ways that authorization processes can continuously be improved, including the following:
  - Measures to increase agency reuse of FedRAMP authorizations.
  - Proposed actions that can be adopted to reduce the burden, confusion, and cost associated with FedRAMP authorizations for cloud service providers.
  - Measures to increase the number of FedRAMP authorizations for cloud computing products and services offered by small businesses concerns (as defined by section 3(a) of the Small Business Act (15 U.S.C. 632(a)).
  - Proposed actions that can be adopted to reduce the burden and cost of FedRAMP authorizations for agencies.
- Collect information and feedback on agency compliance with, and implementation of, FedRAMP requirements.
- Serve as a forum that facilitates communication and collaboration among the FedRAMP stakeholder community.

The FSCAC will meet no fewer than three (3) times a calendar year. Meetings shall occur as frequently as needed, called, and approved by the DFO.

Purpose of the Meeting and Agenda

The November 16, 2023 public meeting will be dedicated to the Committee members' feedback and discussion on OMB's draft memo titled ''Modernizing the Federal Risk Authorization Management Program (FedRAMP).'' The Committee will then finalize and vote on their deliverable to the GSA Administrator regarding their recommendations on the OMB memo. The meeting agenda and draft OMB memo will be posted on *https://gsa.gov/fscac* prior to the November 16, 2023 meeting.

Meeting Attendance

This virtual meeting is open to the public. Meeting registration and information is available at *https://gsa.gov/fscac.* Registration for attending the virtual meeting is highly encouraged by 5 p.m. EST, on Monday, November 13, 2023. After registration, individuals will receive instructions on how to attend the meeting via email.

For information on services for individuals with disabilities, or to request accommodation for a disability, please email the FSCAC staff at *FSCAC@gsa.gov* at least 10 days prior to the meeting date. Live captioning may be provided virtually.

Public Comment

Members of the public will have the opportunity to provide oral public comment during the FSCAC meeting by indicating their preference when registering. Written public comments can be submitted at any time by completing the public comment form on our website, *https://gsa.gov/fscac.* All written public comments will be provided to FSCAC members in advance of the meeting if received by Wednesday, November 8, 2023.

Elizabeth Blake,

Senior Advisor, Federal Acquisition Service, General Services Administration.

[FR Doc. 2023–24431 Filed 11–3–23; 8:45 am]

BILLING CODE 6820–34–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0250; Docket No. 2023–0001; Sequence No. 6]

Information Collection; General Services Administration Acquisition Regulation; Federal Supply Schedule Contract Administration Information

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Notice of request for comments regarding an extension to an existing OMB information collection.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget a request to review and approve an extension of a previously approved information collection regarding Federal Supply Schedule contract administration information.

DATES: Submit comments on or before: January 5, 2024.

ADDRESSES: Submit comments identified by Information Collection 3090–0250, Federal Supply Schedule (FSS) Contract Administration Information via *http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching the OMB control number 3090–0250. Select the link ''Comment Now'' that corresponds with ''Information Collection 3090–0250, FSS Contract Administration Information''. Follow the instructions provided on the screen. Please include your name, company name (if any), and ''Information Collection 3090–0250, FSS Contract Administration Information'' on your attached document.

Instructions: Please submit comments only and cite Information Collection 3090–0250, FSS Contract Administration Information, in all correspondence related to this collection. Comments received generally will be posted without change to *regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *regulations.gov,* approximately two-to-three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Ms. Vernita Misidor, Procurement Analyst, at *GSARpolicy@gsa.gov* or 202–357–9681.

SUPPLEMENTARY INFORMATION:

A. Purpose

GSA requires information from Federal Supply Schedule contractors that will be used to conduct award oversight or generate mandatory reports during contract administration. For these contractors, providing commercial supplies and services, much of this information is readily available to the public at large, or is routinely exchanged by firms during the normal course of business. This general information collection covers these contract administration requirements, as outlined in GSAR Subpart 538.2—Establishing and Administering Federal Supply Schedules.

B. Annual Reporting Burden

This information collection requires no expenditure of resources to gather the information for submission, as the information is often exchanged by commercial business firms in their

catalogs or other public documents during the normal course of business. The nominal amount of burden imposed on the public is simply to relay the requested information.

Respondents: 14,000.
Responses per Respondent: 1.
Total Annual Responses: 14,000.
Hours per Response: 0.03 (2 minutes).
Total Burden Hours: 420.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate and based on valid assumptions and methodology; and ways to enhance the quality, utility, and clarity of the information to be collected.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the Regulatory Secretariat Division, at *GSARegSec@gsa.gov*.

Please cite OMB Control No. 3090–0250, FSS Contract Administration Information, in all correspondence.

Jeffrey A. Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2023–24433 Filed 11–3–23; 8:45 am]

BILLING CODE 6820–14–P

GENERAL SERVICES ADMINISTRATION

[Notice-MRB–2023–06; Docket No. 2023–0002; Sequence No. 37]

GSA Acquisition Policy Federal Advisory Committee; Notification of Upcoming Web-Based Public Meeting

AGENCY: Office of Government-wide Policy (OGP), General Services Administration (GSA).

ACTION: Meeting notice.

SUMMARY: GSA is providing notice of a meeting of the GSA Acquisition Policy Federal Advisory Committee (hereinafter ''the Committee'' or ''the GAP FAC'') in accordance with the requirements of the Federal Advisory Committee Act (FACA). This meeting will be open to the public, accessible via webcast. Information on attending and providing written public comment is under the **SUPPLEMENTARY INFORMATION** section.

DATES: The GAP FAC will hold an open public meeting on Tuesday, December 5, 2023, from 1 p.m. to 4:30 p.m. eastern standard time (EST).

ADDRESSES: The meeting will be accessible via webcast. Registrants will receive the webcast information before the meeting.

FOR FURTHER INFORMATION CONTACT: Boris Arratia, Designated Federal Officer, OGP, 703–795–0816, or email: *boris.arratia@gsa.gov*; or Stephanie Hardison, OGP, 202–258–6823, or email: *stephanie.hardison@gsa.gov*. Additional information about the Committee, including meeting materials and agendas, are available on-line at *https://gsa.gov/policy-regulations/policy/acquisition-policy/gsa-acquisition-policy-federal-advisory-committee*.

SUPPLEMENTARY INFORMATION:

Purpose of the Meeting

The purpose of this meeting is for each of the three subcommittees (Policy and Practice, Industry Partnerships, and Acquisition Workforce) to present recommendations to the full Committee. The Committee will, in turn, deliberate and vote on GAP FAC recommendations to be delivered to the GSA Administrator.

Meeting Agenda

- Opening Remarks
- Guest Speaker
- Acquisition Workforce Subcommittee Recommendations and Discussion
- Vote on recommendations
- Industry Partnerships Subcommittee Recommendations and Discussion
- Vote on recommendations
- Policy and Practices Subcommittee Recommendations and Discussion
- Vote on recommendations
- Closing Remarks and Adjourn

Meeting Registration

This meeting is open to the public and will be accessible by webcast. Registration information is located on the GAP FAC website: *https://www.gsa.gov/policy-regulations/policy/acquisition-policy/gsa-acquisition-policy-federal-advisory-committee*. Public attendees who want to attend virtually will need to register no later than 5 p.m. EST, on Monday, December 4, 2023 to obtain the meeting webcast information. All registrants will be asked to provide their name, affiliation, and email address. After registration, individuals will receive webcast access information details via email.

Public Comments:

Written public comments are being accepted via email at *gapfac@gsa.gov*. To submit a written public comment, please email at *gapfac.gsa.gov* and include your name, organization name (if applicable).

Jeffrey A. Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2023–24432 Filed 11–3–23; 8:45 am]

BILLING CODE 6820–RV–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–P–2536]

Determination That FORADIL (Formoterol Fumarate) Inhalation Powder, 0.012 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) has determined that FORADIL (formoterol fumarate) inhalation powder, 0.012 milligrams (mg)/inhalation (inh), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for formoterol fumarate inhalation powder, 0.012 mg/inh, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Joe Thomas, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6217, Silver Spring, MD 20993–0002, 202–815–5571, *joseph.thomas1@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved; and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all

approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

FORADIL (formoterol fumarate) inhalation powder, 0.012 mg/inh, is the subject of NDA 020831, held by Novartis Pharmaceuticals Corp., and initially approved on February 16, 2001. FORADIL is indicated for treatment of asthma in patients 5 years of age and older as an add-on to a long-term asthma control medication such as an inhaled corticosteroid; prevention of exercise-induced bronchospasm (EIB) in patients 5 years of age and older; and maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease.

In a letter dated September 30, 2015, Novartis Pharmaceuticals Corp. notified FDA that FORADIL (formoterol fumarate) inhalation powder, 0.012 mg/inh, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book. In the **Federal Register** of June 21, 2018 (83 FR 28856), FDA announced that it was withdrawing approval of NDA 020831, effective July 23, 2018.

K&L Gates LLP submitted a citizen petition dated June 21, 2023 (Docket No. FDA–2023–P–2536), under 21 CFR 10.30, requesting that the Agency determine whether FORADIL (formoterol fumarate) inhalation powder, 0.012 mg/inh, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that FORADIL (formoterol fumarate) inhalation powder, 0.012 mg/inh, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that FORADIL (formoterol fumarate) inhalation powder, 0.012 mg/inh, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of FORADIL (formoterol fumarate) inhalation powder, 0.012 mg/inh, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list FORADIL (formoterol fumarate) inhalation powder, 0.012 mg/inh, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: November 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–24506 Filed 11–3–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Revision of HHS National Environmental Policy Act Compliance Procedures To Incorporate Federal Flood Risk Management Standard Procedures

AGENCY: Assistant Secretary for Administration, U.S. Department of Health and Human Services (HHS).

ACTION: Notice; request for comments.

SUMMARY: HHS is proposing a revision to its floodplain management procedures to include climate science if an action takes place in a floodplain.

DATES: Interested parties should submit written comments to **FOR FURTHER INFORMATION CONTACT** section shown below on or before December 6, 2023 to be considered in the formation of the final procedures.

FOR FURTHER INFORMATION CONTACT: CDR Leo Angelo Gumapas, Environmental Engineering Program Chief, at 202–669–6942 or by email at *leoangelo.gumapas@psc.hhs.gov,* for clarification of content.

SUPPLEMENTARY INFORMATION:

Background

E.O. 13690 of January 30, 2015—*Establishing a Federal Flood Risk Management Standard and a Process for Further Soliciting and Considering Stakeholder Input*—was issued to improve the nation's resilience to flooding and to better prepare for the impacts of climate change. In amending and building upon E.O. 11988—*Floodplain Management*—which was issued in 1977, E.O. 13690 and the associated FFRMS reinforce the important tenets and concepts articulated in E.O. 11988, such as avoiding actions in or impacting a floodplain and minimizing potential harm if an action must be located in a floodplain. When avoiding a floodplain is not possible, E.O. 13690 calls for agencies to improve the resilience of communities and federal actions.

On August 15, 2017, E.O. 13807 was issued, which revoked E.O. 13690. Accordingly, the ''Revised Guidelines for Implementing Executive Order 11988, Floodplain Management'' and its supplementary policy were withdrawn. On May 20, 2021, E.O. 14030, reinstated E.O. 13690 and all supplementary policies.

HHS's current floodplain management procedures are published in the General Administration Manual Part 30: Environmental Protection (GAM–30) section 30–40–40 Floodplain Management, and they are based on E.O. 11988. The GAM–30 was last updated on February 25, 2000, and it is based on outdated laws and regulations. Program Support Center (PSC) √ Real Estate, Logistics, Operations (RLO) √ Real Property Management Service (RPMS) √ Real Property Policy and Strategy (RPPS) drafted HHS FFRMS procedures based on E.O. 13690 to update GAM–30 Section 30–40–40 Floodplain Management.

The Council on Environmental Quality (CEQ) reviewed HHS's FFRMS procedures and provided favorable comments on December 2022.

Procedure Revisions

Revised General Administration Manual, HHS Part 30, Environmental Protection

Part 30—Environmental Protection

30–40 Natural Asset Review
30–40–40 Floodplain Management

Purpose: Executive Order (E.O.) 13690 on Establishing a Federal Flood Risk Management Standard (FFRMS) and a Process for Further Soliciting and Considering Stakeholder Input (2015), establishes a Federal Flood Risk Management Standard to ensure each Federal agency takes actions to enhance the Nation's resilience to current and future flooding and better prepare the United States for the impacts of climate change, such as sea level rise and extreme weather events. E.O. 13690 and the associated FFRMS amended and built upon E.O. 11988 on Floodplain Management (1977), which requires agencies to take action to reduce the risk of flood loss, to minimize the impacts of floods on human safety, health, and welfare, and to restore and preserve the natural and beneficial values served by floodplains. E.O. 13690 modernizes E.O. 11988 by increasing the vertical flood elevation and expanding corresponding horizontal extent of the floodplain to consider changing flood hazards due to climate change and other processes, and by encouraging climate-conscious resilient design if there are no practicable locations outside the expanded floodplain.

Definitions

Base Flood. ''Base Flood'' means that flood which has a one percent of greater chance of occurrence in any given year.

Base Flood Elevation (BFE). ''BFE'' means the computed elevation to which the floodwater is anticipated to rise during the base flood.

Base Floodplain. ''Floodplain'' means the area subject to flooding by the base flood, the flood that has a one percent or greater chance of flooding in any given year.

Climate-Informed Science Approach (CISA). ''CISA'' means the flood hazard area (vertical flood elevation and corresponding horizontal extent) that results from using the best-available, actionable hydrologic and hydraulic data and methods that integrate current and future changes in flooding based on climate science.

Critical Action. ''Critical Action'' means any activity for which even a slight chance of flooding is too great, *e.g.,* elderly housing proposals.

Federal Flood Risk Management Standard (FFRMS). ''FFRMS'' means the floodplain determined using one of the three approaches: CISA, 0.2PFA, and FVA.

Freeboard Value Approach (FVA). ''FVA'' means the flood hazard area that results from adding an additional 2 feet to the BFE and expanding to the corresponding horizontal extent for non-critical actions, and by adding an additional 3 feet to the BFE and expanding to the corresponding horizontal extent for critical actions.

Horizontal Extent. ''Horizontal Extent'' means the horizontal land area flooded by the vertical extent (extra flood elevation beyond the BFE).

Nature-Based Approach. HHS OPDIVs/STAFFDIVs, where possible, must use natural systems, ecosystem processes, and natural features and nature-based approaches in development of alternatives for proposed action.

Vertical Extent. ''Vertical Extent'' means the additional flood height above the BFE.

0.2-Percent-Annual-Chance (500-year) Flood Approach (0.2PFA). ''0.2PFA'' means the area subject to flooding by the 0.2-percent annual chance flood.

Responsibilities: Each OPDIV/STAFFDIV has the responsibility under E.O. 13690 to act on Federally Funded Projects to reduce the risk of flood loss, to minimize the impact of floods on human safety, health, and welfare, and to restore and preserve the natural and beneficial values served by floodplains in carrying out its responsibilities for:

Acquiring, managing, and disposing of Federal lands and facilities

Providing Federally undertaken, financed, or assisted construction, substantial improvements, and substantial damages to structures and facilities

Conducting Federal activities and programs affected land use, including but not limited to, water and related land resources planning, regulating, and licensing activities.

Each OPDIV/STAFFDIV shall determine whether the site in which their action would occur could potentially be inundated by floodwaters using FFRMS and shall use this information to make an informed decision to either avoid siting in the determined flood hazard area or design the action to be more resilient to the associated flood hazard. Each OPDIV/STAFFDIV shall evaluate the potential effects of any actions it may take in a FFRMS floodplain in accordance with the floodplain assessment procedures in this section. It must also ensure that its planning programs and budget requests reflect consideration of flood hazards and floodplain management.

Integration with NEPA. OPDIVs/STAFFDIVs are to evaluate the potential effects of a proposed action in a floodplain in accordance with the procedures for National Environmental Policy Act (NEPA) review in HHS General Administration Manual Part 30–50. If an environmental assessment (EA) or environmental impact statement (EIS) is required to be prepared for the proposed action, a floodplain assessment as described Paragraph E of this section, shall be included in the EA or EIS.

Floodplain Assessment (E.O. 13690)

Determine if Proposed Action is in a FFRMS floodplain: First, determine if Federally Funded Project is a critical action, which impacts floodplain determinations for the FVA approach. Second, evaluate the vertical extent and corresponding horizontal extent to establish the FFRMS floodplain using one of the three approaches in the following is the order of preference pending data availability:

CISA
0.2PFA
FVA

Involve Public in Decision-making Process: Notify the public such as a notice in a local newspaper or posting in an accessible public space for the area where the action is under consideration. Public notifications and all supporting communications and activities should be accessible to all (*e.g.,* plain language, culturally responsive, and accommodating), including but not limited to those with disabilities or limited English proficiency. All public notifications are required to follow all guidance and regulation regarding 508 compliance, the use of plain language, and limited English proficiency. If completing an EA or EIS, then include floodplain notice in Description of Proposed Action and Alternatives or Notice of Intent, respectively.

Identify and Evaluate Practicable Alternatives to Locating in FFRMS Floodplain: OPDIVs/STAFFDIVs shall use input from public comments on practicable alternatives, including, if possible, nature-based solutions.

Identify Adverse and Beneficial Impacts: Identify adverse and beneficial impacts, including stimulating floodplain development, which may result from the project. Analyze the following factors: (1) Natural environment (water resources, hydrology, topography, habitat); (2) Social concerns (environmental justice, visual quality/aesthetics, historic and cultural values, land use patterns), (3) Economic Aspects (costs of construction, transportation, relocation, natural features, and ecosystem processes), and (4) Legal considerations (deeds, leases).

Mitigate Adverse Impacts: Minimize impacts identified and restore and preserve the beneficial values served by

floodplains. The analysis shall discuss the following: Alternatives to the proposed action that may avoid adverse effects and incompatible development in the floodplain, including the alternatives of no action or location at an alternate site. Proposed buildings and structures located in FFRMS floodplain shall be programmed and designed to latest version of the American Society of Civil Engineers ''*Flood Resistant Design and Construction*'' (ASCE/SEI 24–14) provisions to mitigate the adverse effects of the proposed action.

Senior Real Property Official Approval: No action shall take place involving HHS Federal Real Property in an FFRMS floodplain without a finding by the Senior Real Property Officer that the only practicable alternative consistent with the law and with the policy set forth in E.O. 13690 requires siting in a FFRMS floodplain. The action involving HHS Federal Real Property proposed for Senior Real Property Official approval shall be designed to minimize potential harm to or within the FFRMS floodplain. The Senior Real Property Official shall approve proposed actions requiring an EA or EIS on projects involving HHS Federal Real Property affecting FFRMS floodplains.

Re-Evaluate Alternatives: Use any new information obtained from Public Notice to determine if the proposed project is still applicable. Reissue public notice with Finding of No Significant Impact or Record of Decision if EA or EIS is drafted, respectively.

Announce and Explain Decision to the Public (Notice): Notify the public of the draft decision by publishing such as a notice in a local newspaper or posting in an accessible public space, dating the notice and the posting at removal.

For programs subject to E.O. 12372, the public notice shall be sent to the appropriate state and local reviewing agencies the geographic areas affected. A public review period of 30 days after the issuance of the public notice shall be allotted before any action is taken.

Implement the Proposed Federally Funded Project: Implement the Federally Funded Project with appropriate mitigation measures. Design and construction contracts shall include any mitigation measures are identified through the process. Ensure through independent 3rd party construction quality assurance that mitigation measures are fully implemented.

Licenses, permits, loans, or grants: Each OPDIV/STAFFDIV shall take FFRMS into account when formulating or evaluating any water and land use plans and shall require land and water resources use appropriate risk management measures to mitigate the degree of hazard involved. Adequate provision shall be made for the evaluation and consideration of flood hazards determined by FFRMS for the licenses, permits, loan, or grant-in-aid programs that an OPDIV/STAFFDIV administers. OPDIVs/STAFFDIVs shall also encourage and provide appropriate guidance to applicants to evaluate the effects of their proposal in FFRMS floodplains prior to submitting applications for Federal licenses, permits, loans, or grants.

Authorization or Appropriation Requests: OPDIVs/STAFFDIVs shall indicate in any requests for new authorizations or appropriations whether the proposed action is in accord with Executive Order 13690 if the proposed action will be in a floodplain.

Guidance: The following resources provides guidance for Implementation of FFRMS. FFRMS Floodplain Determination Job Aid.

Reducing Flood Losses through the International Codes: Coordinating Building Codes and Floodplain Management Regulations, 5th Edition, September 2019

Protecting Building Utility Systems from Flood Damage: Principles and Practices for the Design and Construction of Flood Resistant Building Utility Systems, Federal Emergency Management Agency (FEMA) P–348, Edition 2, February 2017

Cheryl R. Campbell,

Assistant Secretary for Administration.

[FR Doc. 2023–24348 Filed 11–3–23; 8:45 am]

BILLING CODE 4150–24–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Board of Scientific Counselors, National Institute Environmental Health Sciences, December 03, 2023, 07:00 p.m. to December 05, 2023, 04:45 p.m., NIEHS, Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709 which was published in the **Federal Register** on October 05, 2023, 88 FR 69209.

Meeting is being amended to reflect updated agenda.

Name of Committee: Board of Scientific Counselors, National Institute Environmental Health Sciences ESBSC December 3–5, 2023 Meeting.

Date: December 3–5, 2023.

Closed: December 03, 2023, 7:00 p.m. to 8:00 p.m.

Agenda: Discussion of BSC Reviews.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Open: December 04, 2023, 8:30 a.m. to 10:00 a.m.

Agenda: Meeting Overview and Q & A Session.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Open: December 04, 2023, 10:15 a.m. to 11:55 a.m.

Agenda: Q & A Session.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium 111 TW Alexander, Drive Research Triangle Park, NC 27709 (Hybrid Meeting).

Closed: December 04, 2023, 11:55 a.m. to 12:40 p.m.

Agenda: 1:1 Sessions with Investigators.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Closed: December 04, 2023, 12:40 p.m. to 1:30 p.m.

Agenda: Working Lunch.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Open: December 04, 2023, 1:35 p.m. to 2:25 p.m.

Agenda: Q & A Session.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Closed: December 04, 2023, 2:25 p.m. to 2:40 p.m.

Agenda: 1:1 Session with Investigator.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Open: December 04, 2023, 2:55 p.m. to 4:25 p.m.

Agenda: Poster Session.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Open: December 04, 2023, 3:30 p.m. to 4:20 p.m.

Agenda: Q & A Session.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive,

Research Triangle Park, NC 27709 (Hybrid Meeting).

Closed: December 04, 2023, 4:25 p.m. to 5:10 p.m.

Agenda: Meeting with Fellows, Staff Scientists.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Closed: December 05, 2023, 8:30 a.m. to 11:15 a.m.

Agenda: Q & A Sessions.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Closed: December 05, 2023, 11:15 a.m. to 12:00 p.m.

Agenda: 1:1 Session with Investigators.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Closed: December 05, 2023, 12:00 p.m. to 1:00 p.m.

Agenda: Working Lunch.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Closed: December 05, 2023, 1:00 p.m. to 1:50 p.m.

Agenda: Meeting with Cores/Programs; Closed BSC Discussion and Completion of Individual Review Assignments by each Member; Closed Debriefing to NIEHS/DIR Leadership.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Closed: December 05, 2023, 1:50 p.m. to 3:30 p.m.

Agenda: BSC Discussion and Completion of Individual Review Assignments by each Member.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Closed: December 05, 2023, 3:45 p.m. to 4:45 p.m.

Agenda: Debriefing to NIEHS/DIR Leadership.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

Contact Person: Darryl C. Zeldin.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has procedures at *https://www.nih.gov/about-nih/visitor-information/campus-access-security* for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: November 1, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–24507 Filed 11–3–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R4–ES–2023–N085; FXES11140400000–245–FF04E00000]

Endangered Species; Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received applications for permits to conduct activities intended to enhance the propagation or survival of endangered species under the Endangered Species Act. We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, we will take into consideration any information that we receive during the public comment period.

DATES: We must receive written data or comments on the applications by December 6, 2023.

ADDRESSES: *Reviewing Documents:* Submit requests for copies of applications and other information submitted with the applications to Karen Marlowe (see **FOR FURTHER INFORMATION CONTACT**). All requests and comments should specify the applicant name and application number (*e.g.,* Mary Smith, ESPER0001234).

Submitting Comments: If you wish to comment, you may submit comments by one of the following methods:

- *Email (preferred method): permitsR4ES@fws.gov.* Please include your name and return address in your email message. If you do not receive a confirmation from the U.S. Fish and Wildlife Service that we have received your email message, contact us directly at the telephone number listed in **FOR FURTHER INFORMATION CONTACT**.
- *U.S. mail:* U.S. Fish and Wildlife Service Regional Office, Ecological Services, 1875 Century Boulevard, Atlanta, GA 30345 (Attn: Karen Marlowe, Permit Coordinator).

FOR FURTHER INFORMATION CONTACT: Karen Marlowe, Permit Coordinator, 404–679–7097 (telephone) or *karen_marlowe@fws.gov* (email). Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service, invite review and comment from the public and local, State, Tribal, and Federal agencies on applications we have received for permits to conduct certain activities with endangered and threatened species under section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and our regulations in the Code of Federal Regulations (CFR) at 50 CFR part 17. Documents and other information submitted with the applications are available for review, subject to the requirements of the Privacy Act of 1974, as amended (5 U.S.C. 552a), and the Freedom of Information Act (5 U.S.C. 552).

Background

With some exceptions, the ESA prohibits take of listed species unless a Federal permit is issued that authorizes such take. The ESA's definition of ''take'' includes hunting, shooting, harming, wounding, or killing, and also such activities as pursuing, harassing, trapping, capturing, or collecting.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to take endangered or threatened species while engaging in activities that are conducted for scientific purposes that promote recovery of species or for enhancement of propagation or survival of species. These activities often include the capture and collection of species, which would result in prohibited take if a permit were not issued. Our regulations implementing section 10(a)(1)(A) for these permits are found at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Permit Applications Available for Review and Comment

The ESA requires that we invite public comment before issuing these permits. Accordingly, we invite local, State, Tribal, and Federal agencies, and the public to submit written data, views, or arguments with respect to these applications. The comments and recommendations that will be most useful and likely to influence agency decisions are those supported by quantitative information or studies. Proposed activities in the following permit requests are for the recovery and enhancement of propagation or survival of the species in the wild.

Permit application No.	Applicant	Species	Location	Activity	Type of take	Permit action
ES37492B–2 ..	Anthony Grow; Memphis, TN.	Mammals: Gray bat (*Myotis grisescens*), Indiana bat (*Myotis sodalis*), northern long-eared bat (*Myotis septentrionalis*), Ozark big-eared bat (*Corynorhinus townsendii ingens*), and tricolored bat (*Perimyotis subflavus*); Crustaceans: Nashville crayfish (*Orconectes shoupi*).	Alabama, Arkansas, Connecticut, Delaware, District of Columbia, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming.	Presence/probable absence surveys.	Mammals: enter hibernacula or maternity roost caves, capture with mist nets or harp traps, handle, identify, band, radio tag, and release; Crustaceans: capture, handle, identify, and release.	Renewal and amendment.
ES68773B–1 ..	Olivia Munzer; Raleigh, NC.	Indiana bat (*Myotis sodalis*), northern long-eared bat (*Myotis septentrionalis*), and tricolored bat (*Perimyotis subflavus*).	Alabama, Arkansas, Connecticut, Delaware, District of Columbia, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming.	Presence/probable absence surveys.	Capture with mist nets or harp traps, handle, identify, band, radio tag, swab, and release.	Renewal and amendment.
ES55292B–3 ..	University of Florida; Gainesville, FL.	Cape Sable seaside sparrow (*Ammodramus maritimus mirabilis*).	Florida	Demographic monitoring.	Capture, handle, identify, band, collect feathers, deploy data loggers in nests, and release.	Amendment.
ES027344–4 ...	Chattahoochee-Oconee National Forests; Eatonton, GA.	Red-cockaded woodpecker (*Picoides borealis*).	Georgia	Population monitoring.	Monitor nest cavities and construct and monitor artificial nest cavities and restrictors.	Renewal.
ES84861C–1 ..	Power South Energy Cooperative; Andalusia, AL.	Choctaw bean (*Obovaria choctawensis*), fuzzy pigtoe (*Pleurobema strodeanum*), narrow pigtoe (*Fusconaia escambia*), southern kidneyshell (*Ptychobranchus jonesi*), and southern sandshell (*Hamiota australis*).	Alabama	Presence/probable absence surveys.	Capture, handle, identify, release, and salvage relic shells.	Renewal.

Permit application No.	Applicant	Species	Location	Activity	Type of take	Permit action
ES65968A–2 ..	Richard Dickey; Niskayuna, NY.	Alabama pearlshell (*Margaritifera marrianae*), Chipola slabshell (*Elliptio chipolaensis*), Choctaw bean (*Obovaria choctawensis*), fat threeridge (*Amblema neislerii*), fuzzy pigtoe (*Pleurobema strodeanum*), Gulf moccasinshell (*Medionidus penicillatus*), narrow pigtoe (*Fusconaia escambia*), Ochlockonee moccasinshell (*Medionidus simpsonianus*), oval pigtoe (*Pleurobema pyriforme*), purple bankclimber (*Elliptoideus sloatianus*), round ebonyshell (*Fusconaia rotulata*), shinyrayed pocketbook (*Hamiota subangulata*), southern kidneyshell (*Ptychobranchus jonesi*), southern sandshell (*Hamiota australis*), Suwannee moccasinshell (*Medionidus walkeri*), and tapered pigtoe (*Fusconaia burkei*).	Alabama, Florida, and Georgia	Presence/probable absence surveys and population monitoring.	Capture, handle, identify, mark, tag, release, and salvage relic shells.	Renewal.
ES25612A–3 ..	Stephen Samoray; Nashville, TN.	Tricolored bat (*Perimyotis subflavus*).	Colorado, New Mexico, and Texas	Presence/probable absence surveys, studies to document habitat use, population monitoring, and to evaluate potential impacts of white-nose syndrome or other threats.	Enter hibernacula or maternity roost caves, capture with mist nets or harp traps, handle, identify, band, radio tag, collect hair samples, swab, and release.	Amendment.
ES56515D–2 ..	Leslie Meade; Richmond, KY.	Tricolored bat (*Perimyotis subflavus*).	Colorado, District of Columbia, Florida, New Mexico, and Texas.	Presence/probable absence surveys, studies to document habitat use, population monitoring, and to evaluate potential impacts of white-nose syndrome or other threats.	Enter hibernacula or maternity roost caves, capture with mist nets or harp traps, handle, identify, band, radio tag, collect hair samples, wing punch, swab, and release.	Amendment.
ES94849B–3 ..	Copperhead Environmental Consulting, Inc.; Paint Lick, KY.	Tricolored bat (*Perimyotis subflavus*).	Colorado, District of Columbia, and New Mexico.	Presence/probable absence surveys, studies to document habitat use, population monitoring, and to evaluate potential impacts of white-nose syndrome or other threats.	Enter hibernacula or maternity roost caves, capture with mist nets or harp traps, handle, identify, band, radio tag, collect hair samples, wing punch, swab, and release.	Amendment.
ES78383C–1 ..	Joel Casto; Crawfordville, FL.	Red-cockaded woodpecker (*Picoides borealis*).	Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, North Carolina, Oklahoma, South Carolina, Texas, and Virginia.	Population management and monitoring.	Capture, band, monitor nest cavities, construct and monitor artificial nest cavities and restrictors, release, and translocate.	Renewal.
ES67197D–2 ..	Tyler Black; Chapel Hill, NC.	Dwarf wedgemussel (*Alasmidonta heterodon*).	Connecticut, Massachusetts, New Hampshire, New York, and Vermont.	Presence/probable absence surveys.	Capture, handle, identify, tag, release, and salvage relic shells.	Amendment.

Public Availability of Comments

Written comments we receive become part of the administrative record associated with this action. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Next Steps

If we decide to issue a permit to an applicant listed in this notice, we will publish a notice in the **Federal Register**.

Authority

We publish this notice under section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Nicole Rankin,

Acting Deputy Assistant Regional Director, Ecological Services, Southeast Region.

[FR Doc. 2023–24494 Filed 11–3–23; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R7–ES–2023–0101; FXES111607MRG01–234–FF07CAMM00]

Marine Mammals; Incidental Take During Specified Activities; Proposed Incidental Harassment Authorization for Southcentral Alaska Stock of Northern Sea Otters in Cordova, Alaska; Draft Environmental Assessment

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of application; proposed incidental harassment authorization; draft environmental assessment; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, in response to a request under the Marine Mammal Protection Act of 1972, as amended, from the City of Cordova, Alaska, propose to authorize nonlethal incidental take by harassment of small numbers of the Southcentral Alaska stock of northern sea otters (*Enhydra lutris kenyoni*) for 1 year from the date of issuance of the incidental harassment authorization. The applicant has requested this authorization for take by harassment that may result from activities associated with pile driving and marine construction activities in Cordova, Alaska. We estimate that this project may result in the nonlethal incidental take by harassment of up to 82 northern sea otters from the Southcentral stock. This proposed authorization, if finalized, will be for up to 30 takes of 5 northern sea otters by Level A harassment and 790 takes of 77 northern sea otters by Level B harassment. No lethal take is requested, or expected, and no such take will be authorized.

DATES: Comments on this proposed incidental harassment authorization and the accompanying draft environmental assessment must be received by December 6, 2023.

ADDRESSES:

Document availability: You may view this proposed incidental harassment authorization, the application package, supporting information, draft environmental assessment, and the list of references cited herein at *https://www.regulations.gov* under Docket No. FWS–R7–ES–2023–0101. Alternatively, you may request these documents from the person listed under **FOR FURTHER INFORMATION CONTACT**.

Comment submission: You may submit comments on the proposed authorization by one of the following methods:

- *U.S. mail:* Public Comments Processing, Attn: Docket No. FWS–R7–ES–2023–0101, U.S. Fish and Wildlife Service, MS: PRB (JAO/3W), 5275 Leesburg Pike, Falls Church, VA 22041–3803.
- *Electronic submission: https://www.regulations.gov.* Follow the instructions for submitting comments to Docket No. FWS–R7–ES–2023–0101.

We will post all comments at *https://www.regulations.gov.* You may request that we withhold personal identifying information from public review; however, we cannot guarantee that we will be able to do so. See Request for Public Comments for more information.

FOR FURTHER INFORMATION CONTACT: Sierra Franks, by email at *R7mmmregulatory@fws.gov* or by telephone at 01–800–362–5148. U.S. Fish and Wildlife Service, MS 341, 1011 East Tudor Road, Anchorage, AK 99503. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

Background

Section 101(a)(5)(D) of the Marine Mammal Protection Act of 1972 (MMPA; 16 U.S.C. 1361 *et seq.*) authorizes the Secretary of the Interior (Secretary) to allow, upon request, the incidental, but not intentional, taking by harassment of small numbers of marine mammals in response to requests by U.S. citizens (as defined in title 50 of the Code of Federal Regulations (CFR) in part 18, at 50 CFR 18.27(c)) engaged in a specified activity (other than commercial fishing) in a specified geographic region during a period of not more than 1 year. The Secretary has delegated authority for implementation of the MMPA to the U.S. Fish and Wildlife Service (''Service'' or ''we''). According to the MMPA, the Service shall allow this incidental taking if we make findings that the total of such taking for the 1-year period:

(1) is of small numbers of marine mammals of a species or stock;

(2) will have a negligible impact on such species or stocks; and

(3) will not have an unmitigable adverse impact on the availability of these species or stocks for taking for subsistence use by Alaska Natives.

If the requisite findings are made, we issue an authorization that sets forth the following, where applicable:

(a) permissible methods of taking;

(b) means of effecting the least practicable adverse impact on the species or stock and its habitat and the availability of the species or stock for subsistence uses; and

(c) requirements for monitoring and reporting of such taking by harassment, including, in certain circumstances, requirements for the independent peer review of proposed monitoring plans or other research proposals.

The term ''take'' means to harass, hunt, capture, or kill, or to attempt to harass, hunt, capture, or kill any marine mammal. ''Harassment'' means any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (the MMPA defines this as ''Level A harassment''), or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or

sheltering (the MMPA defines this as ''Level B harassment'').

The terms ''negligible impact'' and ''unmitigable adverse impact'' are defined in 50 CFR 18.27 (*i.e.,* regulations governing small takes of marine mammals incidental to specified activities) as follows: ''Negligible impact'' is an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival. ''Unmitigable adverse impact'' means an impact resulting from the specified activity: (1) that is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by (i) causing the marine mammals to abandon or avoid hunting areas, (ii) directly displacing subsistence users, or (iii) placing physical barriers between the marine mammals and the subsistence hunters; and (2) that cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

The term ''small numbers'' is also defined in 50 CFR 18.27. However, we do not rely on that definition here as it conflates ''small numbers'' with ''negligible impacts.'' We recognize ''small numbers'' and ''negligible impacts'' as two separate and distinct considerations when reviewing requests for incidental harassment authorizations (IHA) under the MMPA (see *Natural Res. Def. Council, Inc.* v. *Evans,* 232 F. Supp. 2d 1003, 1025 (N.D. Cal. 2003)). Instead, for our small numbers determination, we estimate the likely number of takes of marine mammals and evaluate if that take is small relative to the size of the species or stock.

The term ''least practicable adverse impact'' is not defined in the MMPA or its enacting regulations. For this IHA, we ensure the least practicable adverse impact by requiring mitigation measures that are effective in reducing the impact of project activities, but they are not so restrictive as to make project activities unduly burdensome or impossible to undertake and complete.

If the requisite findings are made, we shall issue an IHA, which may set forth the following, where applicable: (i) permissible methods of taking; (ii) other means of effecting the least practicable impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock for taking for subsistence uses by coastal-dwelling Alaska Natives (if applicable); and (iii) requirements for monitoring and reporting take by harassment.

Summary of Request

On February 28, 2023, the City of Cordova (hereafter also known as ''the City'' or ''the applicant'') submitted a request to the Service for authorization to take by Level A and Level B harassment a small number of northern sea otters (*Enhydra lutris kenyoni*) (hereafter, ''sea otters'' or ''otters'' unless another species is specified) from the Southcentral Alaska stock. The Service sent requests for additional information on March 24, May 16, and May 30, 2023. We received updated versions of the request on April 27, May 18, and June 8, 2023. The Service determined the June 8, 2023, application to be adequate and complete. The applicant expects take by harassment may occur during the construction of replacements and improvements to the harbor facilities in Cordova, Alaska.

Description of Specified Activities and Specified Geographic Region

The specified activity (hereafter, ''project'') will include the installation and removal of piles and the installation of a bulkhead to rebuild the facilities of the South Harbor in Cordova, Alaska (figure 1) between September 2023 and June 2024. The City will remove 130 existing 30-centimeter (cm) (12-inch (in)) diameter timber piles and 61 existing 30-cm (12-in) diameter steel piles and will permanently install the following types of piles: 155 41-cm (16-in) diameter steel piles, 140 46-cm (18-in) diameter steel piles, 30 76-cm (30-in) diameter steel piles, and 140 steel 41-cm x 226-cm (16-in x 89-in) H piles. Construction will also include the installation and removal of 131 61-cm (24-in) diameter temporary steel piles. Components of the harbor that will be installed out of water include approximately 350 meters (m) (1,150 feet (ft)) of bulkhead wall supported by H piles; main walk floats, end floats, and stall floats; 447 slips; pedestrian gangways; other float components including bull rail, floating fenders, mooring cleats, electricity connections, potable water service, fire suppression waterlines, lighting, wireless connections, and hand rails; and an uplands service area with parking lot expansion, greenspace, and stormwater treatment capabilities. Pile-driving activities will occur over 170 non-consecutive days for approximately 434 hours over 1 year from date of issuance of the IHA. If the IHA is issued after the applicant's intended start date in September 2023, its schedule for conducting the specified activities may be adjusted accordingly. Pile installation will be done with a combination of impact, vibratory, and down-the-hole (DTH) drilling. Temporary piles will be removed with the vibratory hammer. Materials and equipment will be transported via barges, and workers will be transported to and from the barge work platform via skiff.

Additional project details may be reviewed in the application materials available as described under **ADDRESSES** or may also be requested as described under **FOR FURTHER INFORMATION CONTACT**.

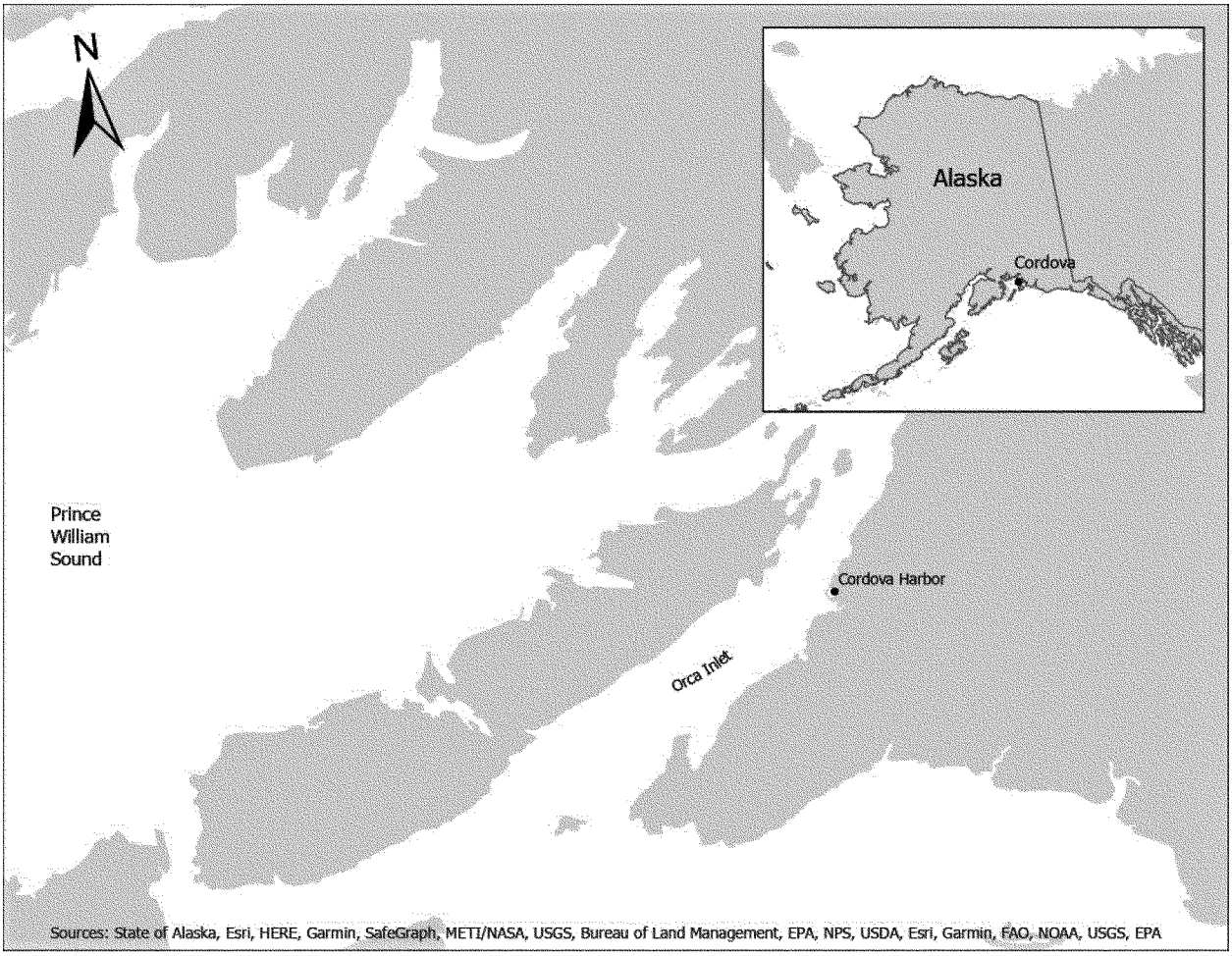

FIGURE 1—SPECIFIED GEOGRAPHIC REGION OF THE PROJECT

Description of Marine Mammals in the Specified Geographic Region

Sea Otter Biology

There are three sea otter stocks in Alaska: Southeast Alaska stock, Southcentral Alaska stock, and the Southwest Alaska stock. Only the Southcentral Alaska stock is represented in the project area. Detailed information about the biology of this stock can be found in the most recent Southcentral Alaska stock assessment report (USFWS 2023), which can be found at *https://www.regulations.gov/document/FWS-R7-ES-2022-0155-0012* and was announced in the **Federal Register** at 88 FR 53510, August 8, 2023.

Sea otters may be distributed anywhere within the specified project area other than upland areas; however, they generally occur in shallow water near the shoreline. They are most commonly observed within the 40-m (131-ft) depth contour (USFWS 2023), although they can be found in areas with deeper water. Ocean depth is generally correlated with distance to shore, and sea otters typically remain within 1 to 2 kilometers (km) (0.62 to 1.24 miles (mi)) of shore (Riedman and Estes 1990). They tend to be found closer to shore during storms, but venture farther out during good weather and calm seas (Lensink 1962, Kenyon 1969).

Sea otters are nonmigratory and generally do not disperse over long distances (Garshelis and Garshelis 1984), usually remaining within a few kilometers of their established feeding grounds (Kenyon 1981). Breeding males stay for all or part of the year in a breeding territory covering up to 1 km (0.62 mi) of coastline, while adult females maintain home ranges of approximately 8 to 16 km (5 to 10 mi), which may include one or more male territories. Juveniles move greater distances between resting and foraging areas (Lensink 1962, Kenyon 1969, Riedman and Estes 1990, Tinker and Estes 1996). Although sea otters generally remain local to an area, they are capable of long-distance travel. Sea otters in Alaska have shown daily movement distances greater than 3 km (1.9 mi) at speeds up to 5.5 km per hour (hr) (km/hr; 3.4 mi/hr) (Garshelis and Garshelis 1984).

Southcentral Alaska Sea Otter Stock

The Southcentral Alaska sea otter stock occurs in the center of the sea otter range in Alaska and extends from Cape Yakataga in the east to Cook Inlet in the west, including Prince William Sound, the eastern Kenai Peninsula coast, and Kachemak Bay (USFWS 2023). Between 2014 and 2019, aerial surveys were conducted in three regions of the Southcentral Alaska sea otter stock: (1) Eastern Cook Inlet, (2) Outer Kenai Peninsula, and (3) Prince William Sound by aerial transects flown at 91 m (298.56 ft) of altitude. The combined estimates of the three regions resulted in approximately 21,617 (SE = 2,190) sea otters and an average density of 1.96 sea otters per square kilometer (km^2) for the Southcentral Alaska stock (Esslinger et al. 2021). In aerial sea otter abundance surveys of Prince William Sound, Weitzman and Esslinger (2015) found a

density of 21.15 sea otters/km² in the Orca Inlet subregion. Multiple local sources of data (Greenwood 2022; Prince William Sound Science Center 2022; Schinella 2022, 2023; Solstice Alaska Consulting Inc. 2022) indicate a higher density within the Cordova Harbor-approximately 20 sea otters at any given time within the 0.18 km² area of the harbor, or a density of 111.11 sea otters/km². We utilized both sources of data and applied the published density for areas outside the harbor and the local data for areas within the harbor.

Potential Impacts of the Specified Activities on Marine Mammals

Effects of Noise on Sea Otters

We characterized ''noise'' as sound released into the environment from human activities that exceeds ambient levels or interferes with normal sound production or reception by sea otters. The terms ''acoustic disturbance'' or ''acoustic harassment'' are disturbances or harassment events resulting from noise exposure. Potential effects of noise exposure are likely to depend on the distance of the sea otter from the sound source, the level and intensity of sound the sea otter receives, background noise levels, noise frequency, noise duration, and whether the noise is pulsed or continuous. The actual noise level perceived by individual sea otters will also depend on whether the sea otter is above or below water and atmospheric and environmental conditions. Temporary disturbance of sea otters or localized displacement reactions are the most likely effects to occur from noise exposure.

Sea Otter Hearing

Pile driving and marine construction activities will fall within the hearing range of sea otters. Controlled sound exposure trials on southern sea otters (*Enhydra lutris nereis*) indicate that sea otters can hear frequencies between 125 hertz (Hz) and 38 kilohertz (kHz) with best sensitivity between 1.2 and 27 kHz (Ghoul and Reichmuth 2014). Aerial and underwater audiograms for a captive adult male southern sea otter in the presence of ambient noise suggest the sea otter's hearing was less sensitive to high-frequency (greater than 22 kHz) and low-frequency (less than 2 kHz) sound than terrestrial mustelids but was similar to that of a California sea lion (*Zalophus californianus*). However, the sea otter was still able to hear low-frequency sounds, and the detection thresholds for sounds between 0.125–1 kHz were between 116–101 decibels (dB), respectively. Dominant frequencies of southern sea otter vocalizations are between 3 and 8 kHz, with some energy extending above 60 kHz (McShane et al. 1995, Ghoul and Reichmuth 2012).

Exposure to high levels of sound may cause changes in behavior, masking of communications, temporary or permanent changes in hearing sensitivity, discomfort, and injury to marine mammals. Unlike other marine mammals, sea otters do not rely on sound to orient themselves, locate prey, or communicate under water; therefore, masking of communications by anthropogenic sound is less of a concern than for other marine mammals. However, sea otters, especially mothers and pups, do use sound for communication in air (McShane et al. 1995), and sea otters may monitor underwater sound to avoid predators (Davis et al. 1987).

Exposure Thresholds

Underwater Sounds

Noise exposure criteria for identifying underwater noise levels capable of causing Level A harassment to marine mammal species, including sea otters, have been established using the same methods as those used by the National Marine Fisheries Service (NMFS) (Southall et al. 2019). These criteria are based on estimated levels of sound exposure capable of causing a permanent shift in sensitivity of hearing (*i.e.,* a permanent threshold shift (PTS) (NMFS 2018)). PTS occurs when noise exposure causes hairs within the inner ear system to die (Ketten 2012). Although the effects of PTS are, by definition, permanent, PTS does not equate to total hearing loss.

Sound exposure thresholds incorporate two metrics of exposure: the peak level of instantaneous exposure likely to cause PTS and the cumulative sound exposure level (SEL_{CUM}) during a 24-hour period. They also include weighting adjustments for the sensitivity of different species to varying frequencies. PTS-based injury criteria were developed from theoretical extrapolation of observations of temporary threshold shifts (TTS) detected in lab settings during sound exposure trials (Finneran 2015). Southall and colleagues (2019) predict PTS for sea otters, which are included in the ''other marine carnivores'' category, will occur at 232 dB peak or 203 dB SEL_{CUM} (db SEL) for impulsive underwater sound and 219 dB SEL for nonimpulsive (continuous) underwater sound.

Thresholds based on TTS have been used as a proxy for Level B harassment (*i.e.,* 70 FR 1871, January 11, 2005; 71 FR 3260, January 20, 2006; 73 FR 41318, July 18, 2008). Southall et al. (2007) derived TTS thresholds for pinnipeds based on 212 dB peak and 171 dB SEL. Exposures resulting in TTS in pinnipeds were found to range from 152 to 174 dB (183 to 206 dB SEL) (Kastak et al. 2005), with a persistent TTS, if not a PTS, after 60 seconds of 184 dB SEL (Kastak et al. 2008). Kastelein et al. (2012) found small but statistically significant TTSs at approximately 170 dB SEL (136 dB, 60 minutes (min)) and 178 dB SEL (148 dB, 15 min). Based on these findings, Southall et al. (2019) developed TTS thresholds for sea otters, which are included in the ''other marine carnivores'' category, of 188 dB SEL for impulsive sounds and 199 dB SEL for nonimpulsive sounds.

The NMFS (2018) criteria do not identify thresholds for avoidance of Level B harassment. For pinnipeds (seals and sea lions), NMFS has adopted a 160-dB threshold for Level B harassment from exposure to impulsive noise and a 120-dB threshold for continuous noise (NMFS 1998, HESS 1999, NMFS 2018). These thresholds were developed from observations of mysticete (baleen) whales responding to airgun operations (*e.g.,* Malme et al. 1983; Malme and Miles 1983; Richardson et al. 1986, 1995) and from equating Level B harassment with noise levels capable of causing TTS in lab settings. Southall et al. (2007, 2019) assessed behavioral response studies and found considerable variability among pinnipeds. The authors determined that exposures between approximately 90 to 140 dB generally do not appear to induce strong behavioral responses from pinnipeds in water. However, they found behavioral effects, including avoidance, become more likely in the range between 120 to 160 dB, and most marine mammals showed some, albeit variable, responses to sound between 140 to 180 dB. Wood et al. (2012) adapted the approach identified in Southall et al. (2007) to develop a probabilistic scale for marine mammal taxa at which 10 percent, 50 percent, and 90 percent of individuals exposed are assumed to produce a behavioral response. For many marine mammals, including pinnipeds, these response rates were set at sound pressure levels of 140, 160, and 180 dB, respectively.

We have evaluated these thresholds and determined that the Level B threshold of 120 dB for nonimpulsive noise is not applicable to sea otters. The 120-dB threshold is based on studies in which gray whales (*Eschrichtius robustus*) were exposed to experimental playbacks of industrial noise (Malme et

al. 1983, Malme and Miles 1983). During these playback studies, southern sea otter responses to industrial noise were also monitored (Riedman 1983, 1984). Gray whales exhibited avoidance to industrial noise at the 120-dB threshold; however, there was no evidence of disturbance reactions or avoidance in southern sea otters. Thus, given the different range of frequencies to which sea otters and gray whales are sensitive, the NMFS 120-dB threshold based on gray whale behavior is not appropriate for predicting sea otter behavioral responses, particularly for low-frequency sound.

Based on the lack of sea otter disturbance response or any other reaction to the playback studies from the 1980s, as well as the absence of a clear pattern of disturbance or avoidance behaviors attributable to underwater sound levels up to about 160 dB resulting from low-frequency broadband noise, we assume 120 dB is not an appropriate behavioral response threshold for sea otters exposed to continuous underwater noise.

Based on the best available scientific information about sea otters, and closely related marine mammals when sea otter data are limited, the Service has set 160 dB of received underwater sound as a threshold for Level B harassment by disturbance for sea otters for this proposed IHA. Exposure to unmitigated in-water noise levels between 125 Hz and 38 kHz that are greater than 160 dB-for both impulsive and nonimpulsive sound sources-will be considered by the Service as Level B harassment. Thresholds for Level A harassment (which entails the potential for injury) will be 232 dB peak or 203 dB SEL for impulsive sounds and 219 dB SEL for continuous sounds (table 1).

Airborne Sounds

The NMFS (2018) guidance neither addresses thresholds for preventing injury or disturbance from airborne noise, nor provides thresholds for avoidance of Level B harassment. Conveyance of underwater noise into the air is of little concern since the effects of pressure release and interference at the water's surface reduce underwater noise transmission into the air. For activities that create both in-air and underwater sounds, we will estimate take based on parameters for underwater noise transmission. Considering sound energy travels more efficiently through water than through air, this estimation will also account for exposures to sea otters at the surface.

Southall et al. (2019) have developed TTS and PTS thresholds for other marine carnivores, which include sea otters, for airborne impulsive and non-impulsive sounds (table 1). For project activities that create only airborne sounds, such as pile driving on land, the sound levels are significantly below the TTS thresholds developed by Southall et al. 2019. NMFS has previously used ''a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment'' (April 10, 2019, 84 FR 14314). NMFS predicts that all other pinniped species that are not harbor seals will be behaviorally harassed when exposed to airborne sounds above 100 dB re 20 micropascal (μPa) (84 FR 14314). Since otariid pinnipeds are the closest available physiological and anatomical proxy for sea otters, we used the NMFS criteria for pinniped harassment from exposure to airborne sound to estimate take by Level B harassment from pile driving on shore.

TABLE 1—TEMPORARY THRESHOLD SHIFT (TTS) AND PERMANENT THRESHOLD SHIFT (PTS) THRESHOLDS ESTABLISHED BY SOUTHALL ET AL. (2019) THROUGH MODELING AND EXTRAPOLATION FOR ''OTHER MARINE CARNIVORES,'' WHICH INCLUDE SEA OTTERS

[Values are weighted for other marine carnivores' hearing thresholds and given in cumulative sound exposure level (SEL_{CUM} dB re (20 μPa) in air and SEL_{CUM} dB re (1 μPa) in water) for impulsive and nonimpulsive sounds and unweighted peak sound pressure level (SPL) in air (dB re 20 μPa) and water (dB 1μPa) (impulsive sounds only).]

	TTS			PTS		
	nonimpulsive	impulsive		nonimpulsive	impulsive	
	SEL_{CUM}	SEL_{CUM}	Peak SPL	SEL_{CUM}	SEL_{CUM}	Peak SPL
Air	157	146	170	177	161	176
Water	199	188	226	219	203	232

Evidence From Sea Otter Studies

Sea otters may be more resistant to the effects of sound disturbance and human activities than other marine mammals. For example, observers have noted no changes from southern sea otters in regard to their presence, density, or behavior in response to underwater sounds from industrial noise recordings at 110 dB and a frequency range of 50 Hz to 20 kHz and airguns, even at the closest distance of 0.5 nautical miles (<1 km or 0.6 mi) (Riedman 1983). Southern sea otters did not respond noticeably to noise from a single 1,638 cubic centimeters (cm^3) (100 cubic inches [in^3]) airgun, and no sea otter disturbance reactions were evident when a 67,006 cm^3 (4,089 in^3) airgun array was as close as 0.9 km (0.6 mi) to sea otters (Riedman 1983, 1984). However, southern sea otters displayed slight reactions to airborne engine noise (Riedman 1983). Northern sea otters were observed to exhibit a limited response to a variety of airborne and underwater sounds, including a warble tone, sea otter pup calls, calls from killer whales (*Orcinus orca*) (which are predators to sea otters), air horns, and an underwater noise harassment system designed to drive marine mammals away from crude oil spills (Davis et al. 1988). These sounds elicited reactions from northern sea otters, including startle responses and movement away from noise sources. However, these reactions were observed only when northern sea otters were within 100 to 200 m (328 to 656 ft) of noise sources. Further, northern sea otters appeared to become habituated to the noises within 2 hours or, at most, 3–4 days (Davis et al. 1988).

Noise exposure may be influenced by the amount of time sea otters spend at the water's surface. Noise at the water's surface can be attenuated by turbulence from wind and waves more quickly compared to deeper water, reducing potential noise exposure (Greene and Richardson 1988, Richardson et al. 1995). Additionally, turbulence at the water's surface limits the transference of sound from water to air. A sea otter with its head above water will be exposed to only a small fraction of the sound energy traveling through the water beneath it. The average amount of time that sea otters spend above the water

each day while resting and grooming varies between males and females and across seasons (Esslinger et al. 2014, Zellmer et al. 2021). For example, female sea otters foraged for an average of 8.78 hours per day compared to male sea otters, which foraged for an average of 7.85 hours per day during the summer months (Esslinger et al. 2014). Male and female sea otters spend an average of 63 to 67 percent of their day at the surface resting and grooming during the summer months (Esslinger et al. 2014). Few studies have evaluated foraging times during the winter months. Garshelis et al. (1986) found that foraging times increased from 5.1 hours per day to 16.6 hours per day in the winter; however, Gelatt et al. (2002) did not find a significant difference in seasonal foraging times. It is likely that seasonal variation is determined by seasonal differences in energetic demand and the quality and availability of prey sources (Esslinger et al. 2014). These findings suggest that the large portion of the day sea otters spend at the surface may help limit sea otters' exposure during noise-generating operations.

Sea otter sensitivity to industrial activities may be influenced by the overall level of human activity within the sea otter population's range. In locations that lack frequent human activity, sea otters appear to have a lower threshold for disturbance. Sea otters in Alaska exhibited escape behaviors in response to the presence and approach of vessels (Udevitz et al. 1995). Behaviors included diving or actively swimming away from a vessel, entering the water from haulouts, and disbanding groups with sea otters swimming in multiple different directions (Udevitz et al. 1995). Sea otters in Alaska were also observed to avoid areas with heavy boat traffic in the summer and return to these areas during seasons with less vessel traffic (Garshelis and Garshelis 1984). In Cook Inlet, sea otters drifting on a tide trajectory that would have taken them within 500 m (0.3 mi) of an active offshore drilling rig were observed to swim in order to avoid a close approach of the drilling rig despite near-ambient noise levels (BlueCrest 2013).

Individual sea otters in Orca Inlet will likely show a range of responses to noise from pile-driving activities. Some sea otters will likely dive, show startle responses, change direction of travel, or prematurely surface. Sea otters reacting to pile-driving activities may divert time and attention from biologically important behaviors, such as feeding and nursing pups. Sea otter responses to disturbance can result in energetic costs, which increases the amount of prey required by sea otters (Barrett 2019). This increased prey consumption may impact sea otter prey availability and cause sea otters to spend more time foraging and less time resting (Barrett 2019). Some sea otters may abandon the project area and return when the disturbance has ceased. Based on the observed movement patterns of sea otters (*i.e.,* Lensink 1962; Kenyon 1969, 1981; Garshelis and Garshelis 1984; Riedman and Estes 1990; Tinker and Estes 1996), we expect some individuals will respond to pile-driving activities by dispersing to nearby areas of suitable habitat; however, other sea otters, especially territorial adult males, are less likely to be displaced.

Consequences of Disturbance

The reactions of wildlife to disturbance can range from short-term behavioral changes to long-term impacts that affect survival and reproduction. When disturbed by noise, animals may respond behaviorally (*e.g.,* escape response) or physiologically (*e.g.,* increased heart rate, hormonal response) (Harms et al. 1997, Tempel and Gutiérrez 2003). Theoretically, the energy expense and associated physiological effects from repeated disturbance could ultimately lead to reduced survival and reproduction (Gill and Sutherland 2000, Frid and Dill 2002). For example, South American sea lions (*Otaria byronia*) visited by tourists exhibited an increase in the state of alertness and a decrease in maternal attendance and resting time on land, thereby potentially reducing population size (Pavez et al. 2015). In another example, killer whales that lost feeding opportunities due to boat traffic faced a substantial (18 percent) estimated decrease in energy intake (Williams et al. 2006). In severe cases, such disturbance effects could have population-level consequences. For example, increased disturbance by tourism vessels has been associated with a decline in abundance of bottlenose dolphins (*Tursiops* spp.) (Bejder et al. 2006, Lusseau et al. 2006). However, these examples evaluated sources of disturbance that were longer term and more consistent than the temporary and intermittent nature of the specified project activities.

These examples illustrate direct effects on survival and reproductive success, but disturbances can also have indirect effects. Response to noise disturbance is considered a nonlethal stimulus that is similar to an antipredator response (Frid and Dill 2002). Sea otters are susceptible to predation, particularly from killer whales and eagles, and have a well-developed antipredator response to perceived threats. For example, the presence of a harbor seal (*Phoca vitulina*) did not appear to disturb southern sea otters, but they demonstrated a fear response in the presence of a California sea lion by actively looking above and beneath the water (Limbaugh 1961).

Although an increase in vigilance or a flight response is nonlethal, a tradeoff occurs between risk avoidance and energy conservation. An animal's reactions to noise disturbance may cause stress and direct an animal's energy away from fitness-enhancing activities such as feeding and mating (Frid and Dill 2002, Goudie and Jones 2004). For example, southern sea otters in areas with heavy recreational boat traffic demonstrated changes in behavioral time budgeting, showing decreased time resting and changes in haulout patterns and distribution (Benham 2006, Maldini et al. 2012). Chronic stress can also lead to weakened reflexes, lowered learning responses (Welch and Welch 1970, van Polanen Petel et al. 2006), compromised immune function, decreased body weight, and abnormal thyroid function (Selye 1979).

Changes in behavior resulting from anthropogenic disturbance can include increased agonistic interactions between individuals or temporary or permanent abandonment of an area (Barton et al. 1998). Additionally, the extent of previous exposure to humans (Holcomb et al. 2009), the type of disturbance (Andersen et al. 2012), and the age or sex of the individuals (Shaughnessy et al. 2008, Holcomb et al. 2009) may influence the type and extent of response in individual sea otters.

Vessel Activities

Vessel collisions with marine mammals can result in death or serious injury. Wounds resulting from vessel strike may include massive trauma, hemorrhaging, broken bones, or propeller lacerations (Knowlton and Kraus 2001). An animal may be harmed by a vessel when the vessel runs over the animal at the surface, the animal hits the bottom of a vessel while the animal is surfacing, or the animal is cut by a vessel's propeller.

Vessel strike has been documented as a cause of death across all three stocks of northern sea otters in Alaska. Since 2002, the Service has conducted 1,433 sea otter necropsies to determine cause of death, disease incidence, and the general health status of sea otters in Alaska. Vessel strike or blunt trauma was identified as a definitive or

presumptive cause of death in 65 cases (4 percent) (USFWS 2020). In most of these cases, trauma was determined to be the ultimate cause of death; however, there was a contributing factor, such as disease or biotoxin exposure, which incapacitated the sea otter and made it more vulnerable to vessel strike (USFWS 2023).

Vessel speed influences the likelihood of vessel strikes involving sea otters. The probability of death or serious injury to a marine mammal increases as vessel speed increases (Laist et al. 2001, Vanderlaan and Taggart 2007). Sea otters spend a considerable portion of their time at the water's surface (Esslinger et al. 2014). They are typically visually aware of approaching vessels and can move away if a vessel is not traveling too quickly. Mitigation measures to be applied to vessel operations to prevent collisions or interactions are included below in the proposed authorization portion of this document under *Avoidance and Minimization.*

Sea otters exhibit behavioral flexibility in response to vessels, and their responses may be influenced by the intensity and duration of the vessel's activity. As noted above, sea otter populations in Alaska were observed to avoid areas with heavy vessel traffic but return to those same areas during seasons with less vessel traffic (Garshelis and Garshelis 1984). Sea otters have also shown signs of disturbance or escape behaviors in response to the presence and approach of survey vessels, including sea otters diving and/or actively swimming away from a vessel, sea otters on haulouts entering the water, and groups of sea otters disbanding and swimming in multiple different directions (Udevitz et al. 1995).

Additionally, sea otter responses to vessels may be influenced by the sea otter's previous experience with vessels. Groups of southern sea otters in two locations in California showed markedly different responses to kayakers approaching to within specific distances, suggesting a different level of tolerance between the groups (Gunvalson 2011). Benham (2006) found evidence that the sea otters exposed to high levels of recreational activity may have become more tolerant than individuals in less disturbed areas. Sea otters off the California coast showed only mild interest in vessels passing within hundreds of meters and appeared to have habituated to vessel traffic (Riedman 1983, Curland 1997). These findings indicate that sea otters may adjust their responses to vessel activities depending on the level of activity. Vessel activity during the project includes the transit of two barges for materials and construction, both of which will remain on site, mostly stationary, to support the work; additionally, a skiff will be used during the project for transporting workers short distances to support construction activities. Vessels will not be used extensively or over a long duration during the planned work; therefore, we do not anticipate that sea otters will experience changes in behavior indicative of tolerance or habituation.

Effects on Sea Otter Habitat and Prey

Physical and biological features of habitat essential to the conservation of sea otters include the benthic invertebrates that sea otters eat and the shallow rocky areas and kelp beds that provide cover from predators. Sea otter habitat in the project area includes coastal areas within the 40-m (131-ft) depth contour where high densities of sea otters have been detected.

Industrial activities, such as pile driving, may generate in-water noise at levels that can temporarily displace sea otters from important habitat and impact sea otter prey species. The primary prey species for sea otters are sea urchins (*Strongylocentrotus* spp. and *Mesocentrotus* spp.), abalone (*Haliotis* spp.), clams (*e.g., Clinocardium nuttallii, Leukoma staminea,* and *Saxidomus gigantea*), mussels (*Mytilus* spp.), crabs (*e.g., Metacarcinus magister, Pugettia* spp*., Telemessus cheiragonus,* and *Cancer* spp.), and squid (*Loligo* spp.) (Tinker and Estes 1996, LaRoche et al. 2021). When preferred prey are scarce, sea otters will also eat kelp, slow-moving benthic fishes, sea cucumbers (*e.g., Apostichopus californicus*), egg cases of rays, turban snails (*Tegula* spp.), octopuses (*e.g., Octopus* spp.), barnacles (*Balanus* spp.), sea stars (*e.g., Pycnopodia helianthoides),* scallops (*e.g., Patinopecten caurinus),* rock oysters (*Saccostrea* spp.), worms (*e.g., Eudistylia* spp.), and chitons (*e.g., Mopalia* spp.) (Riedman and Estes 1990, Davis and Bodkin 2021).

Several studies have addressed the effects of noise on invertebrates (Tidau and Briffa 2016, Carroll et al. 2017). Behavioral changes, such as an increase in lobster (*Homarus americanus*) feeding levels (Payne et al. 2007), an increase in avoidance behavior by wild-caught captive reef squid (*Sepioteuthis australis*) (Fewtrell and McCauley 2012), and deeper digging by razor clams (*Sinonovacula constricta*) (Peng et al. 2016) have been observed following experimental exposures to sound. Physical changes have also been observed in response to increased sound levels, including changes in serum biochemistry and hepatopancreatic cells in lobsters (Payne et al. 2007) and long-term damage to the statocysts required for hearing in several cephalopod species (André et al. 2011, Solé et al. 2013). De Soto et al. (2013) found impaired embryonic development in scallop (*Pecten novaezelandiae*) larvae when exposed to 160 dB. Christian et al. (2003) noted a reduction in the speed of egg development of bottom-dwelling crabs following exposure to noise; however, the sound level (221 dB at 2 m or 6.6 ft) was far higher than the planned project activities will produce. Industrial noise can also impact larval settlement by masking the natural acoustic settlement cues for crustaceans and fish (Pine et al. 2012, Simpson et al. 2016, Tidau and Briffa 2016).

While these studies provide evidence of deleterious effects to invertebrates as a result of increased sound levels, Carroll et al. (2017) caution that there is a wide disparity between results obtained in field and laboratory settings. In experimental settings, changes were observed only when animals were housed in enclosed tanks, and many were exposed to prolonged bouts of continuous, pure tones. We would not expect similar results in open marine conditions. It is unlikely that noises generated by project activities will have any lasting effect on sea otter prey given the short-term duration of sounds produced by each component of the planned work.

Noise-generating activities that interact with the seabed can produce vibrations, resulting in the disturbance of sediment and increased turbidity in the water. Although turbidity is likely to have little impact on sea otters and prey species (Todd et al. 2015), there may be some impacts from vibrations and increased sedimentation. For example, mussels (*Mytilus edulis*) exhibited changes in valve gape and oxygen demand, and hermit crabs (*Pagurus bernhardus*) exhibited limited behavioral changes in response to vibrations caused by pile driving (Roberts et al. 2016). Increased sedimentation is likely to reduce sea otter visibility, which may result in reduced foraging efficiency and a potential shift to less-preferred prey species. These outcomes may cause sea otters to spend more energy on foraging or processing the prey items; however, the impacts of a change in energy expenditure are not likely seen at the population level (Newsome et al. 2015). Additionally, the benthic invertebrates may be impacted by increased sedimentation, resulting in higher

abundances of opportunistic species that recover quickly from industrial activities that increase sedimentation (Kotta et al. 2009). Although sea otter foraging could be impacted by industrial activities that cause vibrations and increased sedimentation, it is more likely that sea otters would be temporarily displaced from the project area due to impacts from noise rather than vibrations and sedimentation.

Potential Impacts of the Specified Activities on Subsistence Uses

The planned specified activities will occur near marine subsistence harvest areas used by Alaska Natives from Cordova and the surrounding areas. Since 2013, there have been 914 sea otters harvested by hunters from the Cordova area, and most of those were taken prior to 2016. From 2018 through 2022, 236 sea otters were harvested from the Cordova area.

The planned project would occur within the Cordova city limits, where firearm use is prohibited. The area potentially affected by the planned project does not significantly overlap with current subsistence harvest areas. Construction activities will not preclude access to hunting areas or interfere in any way with individuals wishing to hunt. Despite no conflict with subsistence use being anticipated, the Service will notify potentially affected communities and stakeholders of the public comment period on this proposed IHA so they have an opportunity to share any questions, concerns, or potential conflicts regarding subsistence use in those areas. If any conflicts are identified in the future, the applicant will develop a plan of cooperation specifying the steps necessary to minimize any effects the project may have on subsistence harvest.

Estimated Take

Definitions of Incidental Take Under the Marine Mammal Protection Act

Below we provide definitions of three potential types of take of sea otters. The Service does not anticipate and is not authorizing lethal take as a part of this proposed IHA; however, the definitions of these take types are provided for context and background:

Lethal Take—Human activity may result in biologically significant impacts to sea otters. In the most serious interactions, human actions can result in mortality of sea otters.

Level A Harassment—Human activity may result in the injury of sea otters. Level A harassment, for nonmilitary readiness activities, is defined as any act of pursuit, torment, or annoyance that has the potential to injure a marine mammal or marine mammal stock in the wild.

Level B Harassment—Level B Harassment for nonmilitary readiness activities means any act of pursuit, torment, or annoyance that has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, feeding, or sheltering. Changes in behavior that disrupt biologically significant behaviors or activities for the affected animal are indicative of take by Level B harassment under the MMPA.

The Service has identified the following sea otter behaviors as indicative of possible Level B harassment:

- Swimming away at a fast pace on belly (*i.e.,* porpoising);
- Repeatedly raising the head vertically above the water to get a better view (spyhopping) while apparently agitated or while swimming away;
- In the case of a pup, repeatedly spyhopping while hiding behind and holding onto its mother's head;
- Abandoning prey or feeding area;
- Ceasing to nurse and/or rest (applies to dependent pups);
- Ceasing to rest (applies to independent animals);
- Ceasing to use movement corridors;
- Ceasing mating behaviors;
- Shifting/jostling/agitation in a raft so that the raft disperses;
- Sudden diving of an entire raft; or
- Flushing animals off a haulout.

This list is not meant to encompass all possible behaviors; other behavioral responses may equate to take by Level B harassment. Relatively minor changes in behavior such as increased vigilance or a short-term change in direction of travel are not likely to disrupt biologically important behavioral patterns, and the Service does not view such minor changes in behavior as indicative of a take by Level B harassment.

Calculating Take

We assumed all animals exposed to underwater sound levels that meet the acoustic exposure criteria defined above in Exposure Thresholds will experience take by Level A or Level B harassment due to exposure to underwater noise. Likewise, we assumed that all animals exposed to airborne sound levels that meet the acoustic exposure criteria in Exposure Thresholds will experience take by Level B harassment due to exposure to in-air noise. Spatially explicit zones of ensonification were established around the planned construction location to estimate the number of otters that may be exposed to these sound levels. We determined the number of otters present in the ensonification zones using density information generated by Weitzman and Esslinger (2015), as well as local sources of data that indicated a higher density of sea otters within the harbor (Greenwood 2022; Prince William Sound Science Center 2022; Schinella 2022, 2023; Solstice Alaska Consulting Inc. 2022).

The project can be divided into five major components: DTH pile driving, vibratory pile driving, impact pile driving, skiff use to support construction, and pile driving on land. Each of these components will generate a different type of noise. Vibratory pile driving and the use of skiffs will produce nonimpulsive or continuous noise; impact pile driving will produce impulsive noise; and DTH pile driving is considered to produce both impulsive and continuous noise (NMFS 2020).

The level of sound anticipated from each project component was established using recorded data from several sources listed in tables 2 through 7. We used the NMFS Technical Guidance and User Spreadsheet (NMFS 2018, 2020) to determine the distance at which sound levels would attenuate to Level A harassment thresholds, and empirical data from the proxy projects were used to determine the distance at which sound levels would attenuate to Level B harassment thresholds (table 1). The weighting factor adjustment included in the NMFS user spreadsheet accounts for sounds created in portions of an organism's hearing range where they have less sensitivity. We used the weighting factor adjustment for otariid pinnipeds as they are the closest available physiological and anatomical proxy for sea otters. The spreadsheet also incorporates a transmission loss coefficient, which accounts for the reduction in sound level outward from a sound source. We used the NMFS-recommended transmission loss coefficient of 15 for coastal pile-driving activities to indicate practical spread (NMFS 2020) to determine the distance at which sound levels attenuate to 160 dB re 1 µPa. Due to limited data of underwater sound pressure levels from DTH pile driving as well as differences in how PTS and TTS thresholds are calculated, the resultant Level A isopleths for DTH pile driving are larger than the Level B isopleths.

TABLE 2—SUMMARY OF SOUND LEVEL, TIMING OF SOUND PRODUCTION, DISTANCE FROM SOUND SOURCE TO BELOW LEVEL A HARASSMENT AND LEVEL B HARASSMENT THRESHOLDS, DAYS OF IMPACT, SEA OTTERS IN LEVEL A AND LEVEL B HARASSMENT ENSONIFICATION AREA, AND TOTAL OTTERS EXPECTED TO BE HARASSED THROUGH BEHAVIORAL DISTURBANCE BY VIBRATORY PILE DRIVING

Pile size	30 to 61-cm (12-in to 24-in) existing timber pile removal	30 to 61-cm (12-in to 24-in) existing steel pile removal	61-cm (24-inch) template installation	61-cm (24-inch) template removal	41-cm (16-in) permanent pile installation	46-cm (18-in) permanent pile installation	76-cm (30-in) permanent pile installation
Total number of piles	130	61	61	61	155	70	30.
Sound level	162 dB re 1 μPa at 10 m (RMS).	161 dB re 1 μPa at 10 m (RMS)					161.9 dB re 1 μPa at 10 m (RMS).
Source	NMFS 2023	NAVFAC[a] 2013, 2015					Denes et al. 2016.
Timing per pile	10 minutes/pile	10 minutes/pile.	10 minutes/pile.	10 minutes/pile.	15 minutes/pile.	20 minutes/pile.	30 minutes/pile.
Maximum number of piles per day.	25	25	6	10	10	10	6.
Maximum number of days of activity.	6	3	11	7	16	7	5.
Sea otter density	111.11 sea otters/km^2						
Distance to below Level A harassment threshold.	0.9 meters	0.8 meters	0.4 meters	0.4 meters	0.5 meters	0.7 meters	0.7 meters.
Level A area (km^2)	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000.
Potential sea otters affected by Level A sound per day.	0	0	0	0	0	0	0.
Potential sea otters affected by Level A sound per day (rounded).	0	0	0	0	0	0	0.
Total potential Level A harassment events.	0	0	0	0	0	0	0.
Distance to below Level B harassment threshold.	14 meters	12 meters	12 meters	12 meters	12 meters	12 meters	13 meters.
Level B area (km^2)	0.0003	0.0002	0.0002	0.0002	0.0002	0.0002	0.0002.
Potential sea otters affected by Level B sound per day.	0.0333	0.0222	0.0222	0.0222	0.0222	0.0222	0.0222.
Potential sea otters affected by Level B sound per day (rounded).	1	1	1	1	1	1	1.
Total potential Level B harassment events.	6	3	11	7	16	7	5.

[a] Naval Facilities Engineering Command.

TABLE 3—SUMMARY OF SOUND LEVEL, TIMING OF SOUND PRODUCTION, DISTANCE FROM SOUND SOURCE TO BELOW LEVEL A HARASSMENT THRESHOLDS, DAYS OF IMPACT, SEA OTTERS IN LEVEL A HARASSMENT ENSONIFICATION AREA, AND TOTAL OTTERS EXPECTED TO BE TAKEN BY LEVEL A HARASSMENT BY IMPACT PILE DRIVING

Pile size	41-cm (16-in) permanent pile installation	46-cm (18-in) permanent pile installation	76-cm (30-in) permanent pile installation
Total number of piles	73	35	20.
Sound level	168.3 dB (SEL)/181.1 dB (RMS)/192.8 dB (peak) re 1 μPa at 10 m.	168.3 dB (SEL)/181.1 dB (RMS)/192.8 dB (peak) re 1 μPa at 10 m.	177 dB (SEL)/190 dB (RMS)/210 dB (peak) re 1 μPa at 10 m.
Source	Denes et al. 2016		NMFS 2023.
Timing per pile	20 minutes/pile; 240 strikes/pile	20 minutes/pile; 240 strikes/pile	20 minutes/pile; 360 strikes/pile.
Maximum number piles per day	6	6	6.
Maximum number of days of activity	13	6	4.
Sea otter density	111.11 sea otters/km^2		
Distance to below Level A harassment threshold.	5.2 meters	5.2 meters	25.9 meters.
Total Level A area (km^2)	0.0001	0.0001	0.0021.
Level A area (km^2) after excluding 10-m shutdown zone (0.0003 km^2).	0	0	0.0018.
Potential sea otters affected by Level A sound per day.	0	0	0.2000.
Potential sea otters affected by Level A sound per day (rounded).	0	0	1.
Total potential Level A harassment events.	0	0	4.

TABLE 4—SUMMARY OF SOUND LEVEL, TIMING OF SOUND PRODUCTION, DISTANCE FROM SOUND SOURCE TO BELOW LEVEL B HARASSMENT THRESHOLDS, DAYS OF IMPACT, SEA OTTERS IN LEVEL B ENSONIFICATION AREA, AND TOTAL OTTERS EXPECTED TO BE TAKEN BY LEVEL B HARASSMENT BY IMPACT PILE DRIVING

Pile size	41-cm (16-in) permanent pile installation	46-cm (18-in) permanent pile installation	76-cm (30-in) permanent pile installation
Total number of piles	73	35	20.
Sound level	168.3 dB (SEL)/181.1 dB (RMS)/192.8 dB (peak) re 1 μPa at 10 m.	168.3 dB (SEL)/181.1 dB (RMS)/192.8 dB (peak) re 1 μPa at 10 m.	177 dB (SEL)/190 dB (RMS)/210 dB (peak) re 1 μPa at 10 m.
Source	Denes et al. 2016		NMFS 2023.
Timing per pile	20 minutes/pile; 240 strikes/pile	20 minutes/pile; 240 strikes/pile	20 minutes/pile; 360 strikes/pile.
Maximum number piles per day	6	6	6.
Maximum number of days of activity	13	6	4.
Distance to below Level B harassment threshold [a].	255 meters	255 meters	1,000 meters.
Total Level B area (km^2)	0.2038	0.2038	0.3137.
Level B area (km^2) within harbor	0.18	0.18	0.18.
Sea otter density inside harbor	111.11 sea otters/km^2		
Potential sea otters affected by Level B sound per day within harbor.	19.9998	19.9998	19.9998.
Potential sea otters affected by Level B sound per day within harbor (rounded).	20	20	20.
Potential Level B harassment events within harbor.	260	120	80.
Level B area (km^2) outside harbor	0.0238	0.0238	0.1337.
Sea otter density outside harbor	21.15 sea otters/km^2		
Potential sea otters affected by Level B sound per day outside harbor.	0.5034	0.5034	2.8278.
Potential sea otters affected by Level B sound per day outside harbor (rounded).	1	1	3.
Potential Level B harassment events outside harbor.	13	6	12.
Total potential Level B harassment events.	273	126	92.

TABLE 5—SUMMARY OF SOUND LEVEL, TIMING OF SOUND PRODUCTION, DISTANCE FROM SOUND SOURCE TO BELOW LEVEL A HARASSMENT AND LEVEL B HARASSMENT THRESHOLDS, DAYS OF IMPACT, SEA OTTERS IN LEVEL A AND LEVEL B HARASSMENT ENSONIFICATION AREA, AND TOTAL OTTERS EXPECTED TO BE HARASSED THROUGH BEHAVIORAL DISTURBANCE BY DOWN-THE-HOLE PILE DRIVING

Pile size	41-cm (16-in) permanent pile installation	46-cm (18-in) permanent pile installation	76-cm (30-in) permanent pile installation
Total number of piles	50	20	16.
Sound level	159 dB (SEL)/167 dB (RMS) re 1 μPa at 10 m		164 dB (SEL)/174 dB (RMS) re 1 μPa at 10 m.
Source	Heyvaert and Reyff 2021		Reyff and Heyvaert 2019, Reyff 2020, Denes et al. 2019.
Timing per pile	75 minutes/pile	75 minutes/pile	75 minutes/pile.
Maximum number piles per day	4	4	4.
Maximum number of days of activity	13	5	4.
Sea otter density	111.11 sea otters/km^2		
Distance to below Level A harassment threshold.	35.2 meters	35.2 meters	67.1 meters.
Total Level A area (km^2)	0.0039	0.0039	0.0141.
Level A area (km^2) after excluding 10-m shutdown zone (0.0003 km^2).	0.0036	0.0036	0.0138.
Potential sea otters affected by Level A sound per day.	0.4000	0.4000	1.5333.
Potential sea otters affected by Level A sound per day (rounded).	1	1	2.
Total potential Level A harassment events	13	5	8.
Distance to below Level B harassment threshold [a].	29 meters	29 meters	86 meters.
Level B area (km^2)	0	0	0.0091.
Potential sea otters affected by Level B sound per day.	0	0	1.0111.
Potential sea otters affected by Level B sound per day (rounded).	0	0	2.

TABLE 5—SUMMARY OF SOUND LEVEL, TIMING OF SOUND PRODUCTION, DISTANCE FROM SOUND SOURCE TO BELOW LEVEL A HARASSMENT AND LEVEL B HARASSMENT THRESHOLDS, DAYS OF IMPACT, SEA OTTERS IN LEVEL A AND LEVEL B HARASSMENT ENSONIFICATION AREA, AND TOTAL OTTERS EXPECTED TO BE HARASSED THROUGH BEHAVIORAL DISTURBANCE BY DOWN-THE-HOLE PILE DRIVING—Continued

Pile size	41-cm (16-in) permanent pile installation	46-cm (18-in) permanent pile installation	76-cm (30-in) permanent pile installation
Total potential Level B harassment events	0	0	8.

[a] Due to differences in how PTS and TTS thresholds are calculated, the Level A isopleths are larger than the Level B isopleths.

TABLE 6—SUMMARY OF SOUND LEVEL, TIMING OF SOUND PRODUCTION, DISTANCE FROM SOUND SOURCE TO BELOW LEVEL A HARASSMENT AND LEVEL B HARASSMENT THRESHOLDS, DAYS OF IMPACT, SEA OTTERS IN LEVEL A AND LEVEL B HARASSMENT ENSONIFICATION AREA, AND TOTAL OTTERS EXPECTED TO BE HARASSED THROUGH BEHAVIORAL DISTURBANCE BY USE OF A SKIFF

Sound source	Worker transit skiff
Sound level	182 dB (RMS) re 1 μPa at 0.9 m.
Source	Kipple and Gabriele 2007.
Number of days of vessel use	170.
Sea otter density	111.11 sea otters/km^2.
Distance to below Level A harassment threshold	0 meters.
Level A area (km^2)	0.
Potential sea otters affected by Level A sound per day	0.
Potential sea otters affected by Level A sound per day (rounded)	0.
Total potential Level A harassment events	0.
Distance to below Level B harassment threshold	26.4 meters.
Total Level B area (km^2)	0.007.
Level B area after excluding 10-m shutdown zone (0.0003 km^2)	0.0067.
Potential sea otters affected by Level B sound per day	0.7444.
Potential sea otters affected by Level B sound per day (rounded)	1.
Total potential Level B harassment events	170.

TABLE 7—SUMMARY OF SOUND LEVEL, TIMING OF SOUND PRODUCTION, DISTANCE FROM SOUND SOURCE TO BELOW LEVEL B HARASSMENT THRESHOLDS, DAYS OF IMPACT, SEA OTTERS IN LEVEL B HARASSMENT ENSONIFICATION AREA, AND TOTAL OTTERS EXPECTED TO BE HARASSED THROUGH BEHAVIORAL DISTURBANCE BY IN-AIR SOUND

Sound source	Vibratory pile driving on shore	Impact pile driving on shore
Sound level	103.2 dB re 20 μPa at 15 m (RMS)	101 dB 20 μPa at 15 m (RMS).
Source	Laughlin 2010	Ghebreghzabiher 2017.
Maximum number of days of activity	45	21.
Sea otter density	111.11 sea otters/km.^{2}	
Distance to below Level B harassment threshold	22 meters	17 meters.
Total Level B area (km^2)	0.0015	0.0009.
Level B area after excluding 10-m shutdown zone (0.0003 km^2)	0.0012	0.0006.
Potential sea otters affected by Level B sound per day	0.1333	0.0667.
Potential sea otters affected by Level B sound per day (rounded)	1	1.
Total potential Level B harassment events	45	21.

Sound levels for all underwater sound sources are unweighted and given in dB re 1 μPa; sound levels for airborne sound sources are unweighted and given in dB re 20 μPa. Nonimpulsive sounds are in the form of mean maximum root mean square (RMS) sound pressure level (SPL) as it is more conservative than cumulative sound exposure level (SEL) or peak SPL for these activities. Impulsive sound sources are in the form of SEL for a single strike.

To determine the number of sea otters that may experience in-water sounds >160 dB re 1μPa due to pile driving, we multiplied the area ensonified to >160 dB re 1μPa outside Cordova Harbor by the density of animals (21.15 sea otters/km^2) derived from surveys conducted of Orca Inlet (Weitzman and Esslinger 2015), whereas the area ensonified to >160 dB re 1μPa within Cordova Harbor was multiplied by the density derived from local knowledge (111.11 sea otters/km^2; Greenwood 2022; Prince William Sound Science Center 2022; Schinella 2022, 2023; Solstice Alaska Consulting Inc. 2022). We applied the same methodology to determine the number of sea otters that may experience sounds capable of causing PTS. Similarly, to determine the number of sea otters that may experience airborne construction sounds >100 dB re 20 μPa due to pile driving, we multiplied the area ensonified to >100 dB re 20 μPa by the density of sea otters within the harbor (111.11 sea otters/km^2; Greenwood 2022; Prince William Sound Science Center 2022; Schinella 2022, 2023; Solstice Alaska Consulting Inc. 2022). The number of sea otters expected to be exposed to such sound levels can be found in tables 2 through 7. To calculate the underwater area ensonified for most types of pile-driving activity, we used πr^2. Given the numerous harbor floats and the number of piles being removed and installed, it was not feasible to calculate the actual area of water

ensonified for most activities, so the area of a circle was used for a conservative estimate for pile driving activities where the ensonified area is entirely within the harbor. Likewise, to calculate the area ensonified by pile-driving activities on shore, we used πr^2. For the Level B underwater area ensonified by impact pile driving 76-cm (30-in) piles, we used ArcGIS Pro to map the zones and calculate the area of the water ensonified, since it is the largest zone and extends beyond the harbor. The applicant proposed a universal 10-m (33-ft) shutdown zone for all project activities so that area was subtracted from all calculated areas when estimating take.

The area ensonified by the worker transit skiff was estimated by multiplying the vessel's anticipated daily track length by twice the 160 dB radius plus πr^2 to account for the rounded ends of the track line. It was estimated that the distance of each trip would be no more than 91.44 m (300 ft).

We assumed that the different types of activities would occur sequentially and that the total number of days of work would equal the sum of the number of days required to complete each type of activity. While it is possible that on some days more than one type of activity will take place, which would reduce the number of days of exposure within a year, we cannot know this information in advance. As such, the estimated number of days and, therefore, exposures per year is the maximum possible for the planned work. Where the number of exposures expected per day was zero to three or more decimal places (*i.e.,* <0.00X), the number of exposures per day was assumed to be zero.

In order to minimize exposure of sea otters to sounds above Level A harassment thresholds, the applicant will implement shutdown zones ranging from 10 to 100 m (33 to 328 ft), based on the pile size and type of pile driving or construction activity, where operations will cease should a sea otter enter or approach the specified zone. Soft-start and zone clearance prior to startup will also limit the exposure of sea otters to sound levels that could cause PTS. However, the City of Cordova has requested, and the Service proposes to authorize, small numbers of take by Level A harassment during impact pile driving and DTH drilling.

Critical Assumptions

We estimate that 790 takes of 77 sea otters by Level B harassment and 30 takes of 5 sea otters by Level A harassment may occur due to the City's planned harbor construction activities. In order to conduct this analysis and estimate the potential amount of take by harassment, several critical assumptions were made.

Level B harassment is equated herein with behavioral responses that indicate harassment or disturbance. There is likely a portion of animals that respond in ways that indicate some level of disturbance but do not experience significant biological consequences.

We used the sea otter density for Orca Inlet from surveys and analyses conducted by Weitzman and Esslinger (2015) for areas ensonified outside Cordova Harbor. Methods and assumptions for these surveys can be found in the original publication.

Multiple local sources (Greenwood 2022; Prince William Sound Science Center 2022; Schinella 2022, 2023; Solstice Alaska Consulting Inc. 2022) indicated a higher density within the Cordova Harbor—approximately 20 sea otters at any given time within the 0.18 km^2 area of the harbor, or a density of 111.11 sea otters/km^2. We used this density to estimate take for areas ensonified within the harbor.

We used sound source verification from recent pile-driving activities in a number of locations within and beyond Alaska to generate sound level estimates for construction activities. Environmental conditions in these locations, including water depth, substrate, and ambient sound levels, are similar to those in the project location, but not identical. Further, estimation of underwater ensonification zones were based on sound attenuation models using a practical spreading loss model; estimation of in-air ensonification zones were based on sound attenuation models using a spherical spreading loss model. These factors may lead to actual sound values differing slightly from those estimated here.

Finally, the in-water pile-driving activities described here will also create in-air noise. Because sea otters spend over half of their day with their heads above water (Esslinger et al. 2014), they will be exposed to increased in-air noise from construction equipment. However, we have calculated Level B harassment with the assumption that an individual may be harassed only one time per 24-hour period, and underwater sound levels will be more disturbing and extend farther than in-air noise. Thus, while sea otters may be disturbed by noise both in air and underwater, we have relied on the more conservative underwater estimates.

Sum of Harassment From All Sources

The applicant plans to conduct pile driving and marine construction activities in Cordova, Alaska, over the course of a year from the date of issuance of the IHA. A summary of total estimated take during the project, by source, is provided in table 8.

TABLE 8—TOTAL ESTIMATED TAKES BY SOURCE OF LEVEL A AND LEVEL B HARASSMENT OF SEA OTTERS

Source	Number of days of activity	Sea otters exposed per day to Level A harassment	Total takes of sea otters by Level A harassment	Sea otters exposed per day to Level B harassment	Total takes of sea otters by Level B harassment
Vibratory drilling:					
30-to-61-cm (12-in-to-24-in) existing timber pile removal	6	0	0	1	6
30-to-61-cm (12-in-to-24-in) existing steel pile removal	3	0	0	1	3
61-cm (24-in) template installation	11	0	0	1	11
61-cm (24-in) template removal	7	0	0	1	7
41-cm (16-in) permanent pile installation	16	0	0	1	16
46-cm (18-in) permanent pile installation	7	0	0	1	7
76-cm (30-in) permanent pile installation	5	0	0	1	5
Impact drilling:					
41-cm (16-in) permanent pile installation	13	0	0	21	273
46-cm (18-in) permanent pile installation	6	0	0	21	126
76-cm (30-in) permanent pile installation	4	1	4	23	92
Down-the-hole drilling:					
41-cm (16-in) permanent pile installation	13	1	13	0	0
46-cm (18-in) permanent pile installation	5	1	5	0	0
76-cm (30-in) permanent pile installation	4	2	8	2	8
Skiff use:					
Worker transit skiff	170	0	0	1	170

TABLE 8—TOTAL ESTIMATED TAKES BY SOURCE OF LEVEL A AND LEVEL B HARASSMENT OF SEA OTTERS—Continued

Source	Number of days of activity	Sea otters exposed per day to Level A harassment	Total takes of sea otters by Level A harassment	Sea otters exposed per day to Level B harassment	Total takes of sea otters by Level B harassment
In-air Sound:					
Vibratory pile driving on shore	45	0	0	1	45
Impact pile driving on shore	21	0	0	1	21
Totals	336	5	30	77	790

Over the course of the project, we estimate 790 instances of take by Level B harassment of 77 northern sea otters from the Southcentral Alaska stock due to behavioral responses of TTS associated with noise exposure. Although multiple instances of Level B harassment of individual sea otters are possible, these events are unlikely to have significant consequences for the health, reproduction, or survival of affected animals, and therefore would not rise to the level of an injury or Level A harassment.

The use of soft-start procedures, zone clearance prior to startup, and shutdown zones is likely to decrease both the number of sea otters exposed to sounds above Level A harassment thresholds and the exposure time of any sea otters venturing into a Level A harassment zone. This reduces the likelihood of losses of hearing sensitivity that might impact the health, reproduction, or survival of affected animals. Despite the implementation of mitigation measures, it is anticipated that some sea otters will experience Level A harassment via exposure to underwater sounds above threshold criteria during impact and DTH pile-driving activities. Due to sea otters' small body size and low profile in the water, as well as the relatively large size of the Level A harassment zone associated with these activities, we anticipate that sea otters will at times avoid detection before entering Level A harassment zones for those activities. We anticipate that protected species observers (PSOs) will be able to reliably detect and prevent take by Level A harassment of sea otters up to 10 m (33 ft) away; conversely, we anticipate that at distances greater than 10 m, sea otters will at times avoid detection. Throughout the project, we estimate 30 instances of take by Level A harassment of 5 sea otters.

Determinations and Findings

Sea otters exposed to sound from the specified activities are likely to respond with temporary behavioral modification or displacement. The specified activities could temporarily interrupt the feeding, resting, and movement of sea otters. Because activities will occur during a limited amount of time and in a localized region, the impacts associated with the project are likewise temporary and localized. The anticipated effects are short-term behavioral reactions and displacement of sea otters near active operations.

Sea otters that encounter the specified activity may exert more energy than they would otherwise, due to temporary cessation of feeding, increased vigilance, and retreating from the project area. We expect that affected sea otters will tolerate this exertion without measurable effects on health or reproduction. Most of the anticipated takes will be due to short-term Level B harassment in the form of TTS, startle reactions, or temporary displacement. While mitigation measures incorporated into the applicant's request will reduce occurrences of Level A harassment to the extent practicable, a small number of takes by Level A harassment would be authorized for impact and DTH pile-driving activities, which have Level A harassment zone radii ranging in size from 5.2 to 67.1 m (17 to 220 ft).

With the adoption of the mitigation measures incorporated in the applicant's request and required by this proposed IHA, anticipated take was reduced. Those mitigation measures are further described below.

Small Numbers

To assess whether the authorized incidental taking would be limited to ''small numbers'' of marine mammals, the Service uses a proportional approach that considers whether the estimated number of marine mammals to be subjected to incidental take is small relative to the population size of the species or stock. Here, predicted levels of take were determined based on the estimated density of sea otters in the project area and ensonification zones developed using empirical evidence from similar geographic areas.

We estimate that the City's specified activities in the specified geographic region will result in no more than 790 takes of 77 sea otters by Level B harassment and 30 takes of 5 sea otters by Level A harassment during the 1-year period of this proposed IHA (see *Sum of Harassment from All Sources*). Take of 82 animals is 0.4 percent of the best available estimate of the current Southcentral Alaska stock size of 21,617 animals (Esslinger et al. 2021) ($(82 \div 21{,}617) \times 100 \approx 0.4$) and represents a ''small number'' of sea otters of that stock.

Negligible Impact

We propose a finding that any incidental take by harassment resulting from the specified activities cannot be reasonably expected to, and is not reasonably likely to, adversely affect the sea otter through effects on annual rates of recruitment or survival and will, therefore, have no more than a negligible impact on the Southcentral Alaska stock of northern sea otters. In making this finding, we considered the best available scientific information, including the biological and behavioral characteristics of the species, the most recent information on species distribution and abundance within the area of the specified activities, the current and expected future status of the stock (including existing and foreseeable human and natural stressors), the potential sources of disturbance caused by the project, and the potential responses of marine mammals to this disturbance. In addition, we reviewed applicant-provided materials, information in our files and datasets, published reference materials, and species experts.

Sea otters are likely to respond to planned activities with temporary behavioral modification or temporary displacement. These reactions are not anticipated to have consequences for the long-term health, reproduction, or survival of affected animals. Most animals will respond to disturbance by moving away from the source, which may cause temporary interruption of foraging, resting, or other natural behaviors. Affected animals are expected to resume normal behaviors soon after exposure, with no lasting consequences. Each sea otter is estimated to be exposed to construction noise for between 3 and 170 days per year, resulting in repeated exposures.

However, injuries (*i.e.,* Level A harassment or PTS) due to chronic sound exposure are estimated to occur over a longer time scale (Southall et al. 2019). The area that will experience noise greater than Level B thresholds due to pile driving is small (less than 0.0141 km^2), and an animal that may be disturbed could escape the noise by moving to nearby quiet areas. Further, sea otters spend over half of their time above the surface during the summer months (Esslinger et al. 2014), and likely no more than 70 percent of their time foraging during winter months (Gelatt et al. 2002); thus, their ears will not be exposed to continuous noise, and the amount of time it may take for permanent injury is considerably longer than that of mammals primarily under water. Some animals may exhibit some of the stronger responses typical of Level B harassment, such as fleeing, interruption of feeding, or flushing from a haulout. These responses could have temporary biological impacts for affected individuals, but are not anticipated to result in measurable changes in survival or reproduction.

The total number of animals affected and severity of impact are not sufficient to change the current population dynamics at the stock scale. Although the specified activities may result in approximately 820 incidental takes of 82 sea otters from the Southcentral Alaska stock, we do not expect this level of harassment to affect annual rates of recruitment or survival or result in adverse effects on the stock.

Our proposed finding of negligible impact applies to incidental take associated with the specified activities as mitigated by the avoidance and minimization measures identified in the applicant's mitigation and monitoring plan. These mitigation measures are designed to minimize interactions with and impacts to sea otters. These measures and the monitoring and reporting procedures are required for the validity of our finding and are a necessary component of the proposed IHA. For these reasons, we propose a finding that the specified project will have a negligible impact on the Southcentral Alaska stock of northern sea otters.

Least Practicable Adverse Impacts

We find that the mitigation measures required by this proposed IHA will affect the least practicable adverse impacts on the stocks from any incidental take likely to occur in association with the specified activities. In making this finding, we considered the biological characteristics of sea otters, the nature of the specified activities, the potential effects of the activities on sea otters, the documented impacts of similar activities on sea otters, and alternative mitigation measures.

In evaluating what mitigation measures are appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses, we considered the manner and degree to which the successful implementation of the measures are expected to achieve this goal. We considered the nature of the potential adverse impact being mitigated (likelihood, scope, range), the likelihood that the measures will be effective if implemented, and the likelihood of effective implementation. We also considered the practicability of the measures for applicant implementation (*e.g.,* cost, impact on operations). We assessed whether any additional practicable requirements could be implemented to further reduce effects, but did not identify any.

To reduce the potential for disturbance from acoustic stimuli associated with the activities, the City of Cordova will implement mitigation measures, including the following:

- Using a project design that incorporates the smallest diameter piles and footprint practicable while minimizing the overall number of piles and area;
- Using a project design that does not include dredging or excavating below the high tide line;
- Using a project design that does not include blasting;
- Using pile driving equipment with muffler systems to reduce in-air noise generation;
- Using a vibratory hammer equipped with a suppressor to reduce rattling;
- Using dampeners to eliminate steel-on-steel in-air noise;
- Employing a sediment curtain during all DTH pile driving to contain drill spoils and to minimize turbidity;
- Development of a marine mammal monitoring and mitigation plan;
- Establishment of shutdown and monitoring zones;
- Visual mitigation monitoring by designated protected species observers (PSO);
- Site clearance before startup;
- Soft-start procedures; and
- Shutdown procedures.

The Service has not identified any additional (*i.e.,* not already incorporated into the applicant's request) mitigation or monitoring measures that are practicable and would further reduce potential impacts to sea otters and their habitat.

Impact on Subsistence Use

The project will not preclude access to harvest areas or interfere with the availability of sea otters for harvest. Additionally, the construction activities take place within the Cordova Harbor, where firearm use is prohibited. We therefore propose a finding that the applicant's anticipated harassment will not have an unmitigable adverse impact on the availability of any stock of northern sea otters for taking for subsistence uses. In making this finding, we considered the timing and location of the planned activities and the timing and location of subsistence harvest activities in the project area.

Monitoring and Reporting

The purposes of the monitoring requirements are to document and provide data for assessing the effects of specified activities on sea otters; to ensure that take is consistent with that anticipated in the small numbers, negligible impact, and subsistence use analyses; and to detect any unanticipated effects on the species. Monitoring plans include steps to document when and how sea otters are encountered and their numbers and behaviors during these encounters. This information allows the Service to measure encounter rates and trends and to estimate numbers of animals potentially affected. To the extent possible, monitors will record group size, age, sex, reaction, duration of interaction, and closest approach to the project activity.

As proposed, monitoring activities will be summarized and reported in formal reports. The applicant must submit monthly reports for all months during which noise-generating work takes place as well as a final monitoring report that must submitted no later than 90 days after the expiration of the IHA. We will require an approved plan for monitoring and reporting the effects of pile driving and marine construction activities on sea otters prior to issuance of an IHA. We will require approval of the monitoring results for continued operation under the IHA.

We find that these proposed monitoring and reporting requirements to evaluate the potential impacts of planned activities will ensure that the effects of the activities remain consistent with the rest of the findings.

Required Determinations

National Environmental Policy Act (NEPA)

We have prepared a draft environmental assessment in accordance with the NEPA (42 U.S.C.

4321 *et seq.*). We have preliminarily concluded that authorizing the nonlethal, incidental, unintentional take by Level B harassment of up to 790 takes of 77 sea otters and by Level A harassment of up to 30 takes of 5 sea otters from the Southcentral Alaska stock in the specified geographic region during the specified activities during the regulatory period would not significantly affect the quality of the human environment and, thus, preparation of an environmental impact statement for this proposed IHA is not required by section 102(2) of NEPA or its implementing regulations. We are accepting comments on the draft environmental assessment as specified above in **DATES** and **ADDRESSES**.

Government-to-Government Consultation

It is our responsibility to communicate and work directly on a Government-to-Government basis with federally recognized Alaska Native Tribes in developing programs for healthy ecosystems. We seek their full and meaningful participation in evaluating and addressing conservation concerns for protected species. It is our goal to remain sensitive to Alaska Native culture, and to make information available to Alaska Tribal organizations and communities. Our efforts are guided by the following policies and directives:

(1) *The Native American Policy of the Service* (January 20, 2016);

(2) *The Alaska Native Relations Policy* (currently in draft form);

(3) Executive Order 13175 (January 9, 2000);

(4) Department of the Interior Secretary's Orders 3206 (June 5, 1997), 3225 (January 19, 2001), 3317 (December 1, 2011), and 3342 (October 21, 2016);

(5) *The Alaska Government-to-Government Policy* (a departmental memorandum issued January 18, 2001); and

(6) The Department of the Interior's policies on consultation with Alaska Native Tribes and organizations.

We have evaluated possible effects of the specified activities on federally recognized Alaska Native Tribes and organizations. The Service has determined that, due to this project's locations and activities, the Tribal organizations and communities near Cordova, Alaska, as well as relevant Alaska Native Claims Settlement Act corporations, will not be impacted by this project. Regardless, we will be reaching out to them to inform them of the availability of this proposed IHA and offer them the opportunity to consult.

We invite continued discussion, either about the project and its impacts or about our coordination and information exchange throughout the IHA process.

Proposed Authorization

We propose to authorize the nonlethal incidental take by Level A and Level B harassment of 820 takes of 82 sea otters from the Southcentral Alaska stock. Authorized take may be caused by pile driving and marine construction activities conducted by the City of Cordova in Cordova, Alaska, over the course of a year from the date of issuance of the IHA. We do not anticipate or authorize any lethal take to sea otters resulting from these activities.

A. General Conditions for the Incidental Harassment Authorization (IHA)

(1) Activities must be conducted in the manner described in the request from the City of Cordova for an IHA and in accordance with all applicable conditions and mitigation measures. The taking of sea otters whenever the required conditions, mitigation, monitoring, and reporting measures are not fully implemented as required by the IHA is prohibited. Failure to follow the measures specified both in the request and within this proposed authorization may result in the modification, suspension, or revocation of the IHA.

(2) If project activities cause unauthorized take (*i.e.,* greater than 820 takes of 82 of the Southcentral Alaska stock of northern sea otters, a form of take other than Level A or Level B harassment, or take of one or more sea otters through methods not described in the IHA), the City of Cordova must take the following actions:

(i) cease its activities immediately (or reduce activities to the minimum level necessary to maintain safety);

(ii) report the details of the incident to the Service within 48 hours; and

(iii) suspend further activities until the Service has reviewed the circumstances and determined whether additional mitigation measures are necessary to avoid further unauthorized taking.

(3) All operations managers, vehicle operators, and machine operators must receive a copy of this IHA and maintain access to it for reference at all times during project work. These personnel must understand, be fully aware of, and be capable of implementing the conditions of the IHA at all times during project work.

(4) This IHA will apply to activities associated with the specified project as described in this document and in the City of Cordova's request. Changes to the specified project without prior authorization may invalidate the IHA.

(5) The City of Cordova's request is approved and fully incorporated into this IHA unless exceptions are specifically noted herein. The request includes:

(i) The City of Cordova's original request for an IHA, dated February 28, 2023;

(ii) Revised requests, dated April 27, May 18, and June 8, 2023;

(iii) Marine Mammal Mitigation and Monitoring Plan; and

(iv) Google Earth package;

(6) Operators will allow Service personnel or the Service's designated representative to visit project worksites to monitor for impacts to sea otters and subsistence uses of sea otters at any time throughout project activities, so long as it is safe to do so. ''Operators'' are all personnel operating under the City of Cordova's authority, including all contractors and subcontractors.

B. Avoidance and Minimization

(7) Construction activities must be conducted using equipment that generates the lowest practicable levels of underwater sound within the range of frequencies audible to sea otters.

(8) During all pile-installation activities, regardless of predicted sound levels, a physical interaction shutdown zone of 10 m (33 ft) must be enforced. If a sea otter enters the shutdown zone, in-water activities must be delayed until either the animal has been visually observed outside the shutdown zone, or 15 minutes have elapsed since the last observation time without redetection of the animal.

(9) If the impact driver has been idled for more than 30 minutes, an initial set of three strikes from the impact driver must be delivered at reduced energy, followed by a 1-minute waiting period, before full powered proofing strikes.

(10) In-water activity must be conducted in daylight. If environmental conditions prevent visual detection of sea otters within the shutdown zone, in-water activities must be stopped until visibility is regained.

(11) All in-water work along the shoreline must be conducted during low tide when the site is dewatered to the maximum extent practicable.

C. Mitigation Measures for Vessel Operations

Vessel operators must take every precaution to avoid harassment of sea otters when a vessel is operating near these animals. The applicant must carry out the following measures:

(12) Vessels must remain at least 500 m (0.3 mi) from rafts of sea otters, unless

safety is a factor. Vessels must reduce speed and maintain a distance of 100 m (328 ft) from all sea otters, unless safety is a factor.

(13) Vessels must not be operated in such a way as to separate members of a group of sea otters from other members of the group, and must avoid alongshore travel in shallow water (<20 m (66 ft)) whenever practicable.

(14) When weather conditions require, such as when visibility drops, vessels must adjust speed accordingly to avoid the likelihood of injury to sea otters.

(15) Vessel operators must be provided written guidance for avoiding collisions and minimizing disturbances to sea otters. Guidance will include measures identified in paragraphs (C)(12) through (15) of this section.

D. Monitoring

(16) Operators shall work with protected species observers (PSO) to apply mitigation measures and shall recognize the authority of PSOs up to and including stopping work, except where doing so poses a significant safety risk to personnel.

(17) Duties of the PSOs include watching for and identifying sea otters, recording observation details, documenting presence in any applicable monitoring zone, identifying and documenting potential harassment, and working with operators to implement all appropriate mitigation measures.

(18) A sufficient number of PSOs will be available to meet the following criteria: 100 percent monitoring of exclusion zones during all daytime periods of underwater noise-generating work; a maximum of 4 consecutive hours on watch per PSO; a maximum of approximately 12 hours on watch per day per PSO.

(19) All PSOs will complete a training course designed to familiarize individuals with monitoring and data collection procedures. A field crew leader with prior experience as a sea otter observer will supervise the PSO team. Initially, new or inexperienced PSOs will be paired with experienced PSOs so that the quality of marine mammal observations and data recording is kept consistent. Resumes for candidate PSOs will be made available for the Service to review.

(20) Observers will be provided with reticule binoculars (7×50 or better), big-eye binoculars or spotting scopes (30×), inclinometers, and range finders. Field guides, instructional handbooks, maps, and a contact list will also be made available.

(21) Observers will collect data using the following procedures:

(i) All data will be recorded onto a field form or database.

(ii) Global positioning system data, sea state, wind force, and weather will be collected at the beginning and end of a monitoring period, every hour in between, at the change of an observer, and upon sightings of sea otters.

(iii) Observation records of sea otters will include date; time; the observer's locations, heading, and speed (if moving); weather; visibility; number of animals; group size and composition (adults/juveniles); and the location of the animals (or distance and direction from the observer).

(iv) Observation records will also include initial behaviors of the sea otters, descriptions of project activities and underwater sound levels being generated, the position of sea otters relative to applicable monitoring and mitigation zones, any mitigation measures applied, and any apparent reactions to the project activities before and after mitigation.

(v) For all sea otters in or near a mitigation zone, observers will record the distance from the sound source to the sea otter upon initial observation, the duration of the encounter, and the distance at last observation in order to monitor cumulative sound exposures.

(vi) Observers will note any instances of animals lingering close to or traveling with vessels for prolonged periods of time.

(22) Monitoring of the shutdown zone must continue for 30 minutes following completion of pile installation.

E. Measures To Reduce Impacts to Subsistence Users

(23) Prior to conducting the work, the City of Cordova will take the following steps to reduce potential effects on subsistence harvest of sea otters:

(i) Avoid work in areas of known sea otter subsistence harvest;

(ii) If any concerns remain, develop a plan of cooperation in consultation with the Service and subsistence stakeholders to address these concerns.

F. Reporting Requirements

(24) The City of Cordova must notify the Service at least 48 hours prior to commencement of activities.

(25) Monthly reports will be submitted to the Service's Marine Mammal Management office (MMM) for all months during which noise-generating work takes place. The monthly report will contain and summarize the following information: dates, times, weather, and sea conditions (including the Beaufort Scale sea state and wind force conditions) when sea otters were sighted; the number, location, distance from the sound source, and behavior of the sea otters; the associated project activities; and a description of the implementation and effectiveness of mitigation measures with a discussion of any specific behaviors the sea otters exhibited in response to mitigation.

(26) A final report will be submitted to the Service's MMM within 90 days after completion of work or expiration of the IHA. The report will include:

(i) A summary of monitoring efforts (hours of monitoring, activities monitored, number of PSOs, and, if requested by the Service, the daily monitoring logs).

(ii) A description of all project activities, along with any additional work yet to be done. Factors influencing visibility and detectability of marine mammals (*e.g.,* sea state, number of observers, and fog and glare) will be discussed.

(iii) A description of the factors affecting the presence and distribution of sea otters (*e.g.,* weather, sea state, and project activities). An estimate will be included of the number of sea otters exposed to noise at received levels greater than or equal to 160 dB (based on visual observation).

(iv) A description of changes in sea otter behavior resulting from project activities and any specific behaviors of interest.

(v) A discussion of the mitigation measures implemented during project activities and their observed effectiveness for minimizing impacts to sea otters. Sea otter observation records will be provided to the Service in the form of electronic database or spreadsheet files.

(27) Injured, dead, or distressed sea otters that are not associated with project activities (*e.g.,* animals known to be from outside the project area, previously wounded animals, or carcasses with moderate to advanced decomposition or scavenger damage) must be reported to the Service within 24 hours of the discovery to either the Service's MMM (1–800–362–5148, business hours), the Alaska SeaLife Center in Seward (1–888–774–7325, 24 hours a day), or both. Photographs, video, location information, or any other available documentation must be provided to the Service.

(28) All reports shall be submitted by email to *fw7_mmm_reports@fws.gov.*

(29) The City of Cordova must notify the Service upon project completion or end of the work season.

Request for Public Comments

If you wish to comment on this proposed authorization, the associated

draft environmental assessment, or both documents, you may submit your comments by either of the methods described in **ADDRESSES**. Please identify whether you are commenting on the proposed authorization, draft environmental assessment, or both, make your comments as specific as possible, confine them to issues pertinent to the proposed authorization, and explain the reason for any changes you recommend. Where possible, your comments should reference the specific section or paragraph that you are addressing. The Service will consider all comments that are received before the close of the comment period (see **DATES**). The Service does not anticipate extending the public comment period beyond the 30 days required under section 101(a)(5)(D)(iii) of the MMPA.

Comments, including names and street addresses of respondents, will become part of the administrative record for this proposal. Before including your address, telephone number, email address, or other personal identifying information in your comment, be advised that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comments to withhold from public review your personal identifying information, we cannot guarantee that we will be able to do so.

Peter Fasbender,

Assistant Regional Director Fisheries and Ecological Services, Alaska Region.

[FR Doc. 2023–24428 Filed 11–3–23; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2023–0207; FXIA16710900000–234–FF09A30000]

Foreign Endangered Species; Receipt of Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on applications to conduct certain activities with foreign species that are listed as endangered under the Endangered Species Act (ESA). With some exceptions, the ESA prohibits activities with listed species unless Federal authorization is issued that allows such activities. The ESA also requires that we invite public comment before issuing permits for any activity otherwise prohibited by the ESA with respect to any endangered species.

DATES: We must receive comments by December 6, 2023.

ADDRESSES:

Obtaining Documents: The applications, application supporting materials, and any comments and other materials that we receive will be available for public inspection at *https://www.regulations.gov* in Docket No. FWS–HQ–IA–2023–0207.

Submitting Comments: When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. You may submit comments by one of the following methods:

- *Internet: https://www.regulations.gov.* Search for and submit comments on Docket No. FWS–HQ–IA–2023–0207.
- *U.S. mail:* Public Comments Processing, Attn: Docket No. FWS–HQ–IA–2023–0207; U.S. Fish and Wildlife Service Headquarters, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

For more information, see Public Comment Procedures under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, by phone at 703–358–2185 or via email at *DMAFR@fws.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I comment on submitted applications?

We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits/, we will take into consideration any information that we receive during the public comment period.

You may submit your comments and materials by one of the methods in **ADDRESSES**. We will not consider comments sent by email or to an address not in **ADDRESSES**. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**).

When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. Provide sufficient information to allow us to authenticate any scientific or commercial data you include. The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) those that include citations to, and analyses of, the applicable laws and regulations.

B. May I review comments submitted by others?

You may view and comment on others' public comments at *https://www.regulations.gov* unless our allowing so would violate the Privacy Act (5 U.S.C. 552a) or Freedom of Information Act (5 U.S.C. 552).

C. Who will see my comments?

If you submit a comment at *https://www.regulations.gov,* your entire comment, including any personal identifying information, will be posted on the website. If you submit a hardcopy comment that includes personal identifying information, such as your address, phone number, or email address, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(c) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), we invite public comments on permit applications before final action is taken. With some exceptions, the ESA prohibits certain activities with listed species unless Federal authorization is issued that allows such activities. Permits issued under section 10(a)(1)(A) of the ESA allow otherwise prohibited activities for scientific purposes or to enhance the propagation or survival of the affected species. Service regulations regarding prohibited activities with endangered species, captive-bred wildlife registrations, and permits for any activity otherwise prohibited by the ESA with respect to any endangered species are available in title 50 of the Code of Federal Regulations in part 17.

III. Permit Applications

We invite comments on the following applications.

Applicant: University of California-Santa Cruz, Santa Cruz, CA; Permit No. PER4073903

The applicant requests authorization to export biological samples collected from individual animals of cetacean and pinniped species (except walrus) for the purpose of scientific research. Samples are collected from live wild and captive individuals or salvaged from dead wild and captive individuals. This notification covers activities conducted by the applicant over a 5-year period.

Applicant: University of California Santa Cruz, Santa Cruz, CA; Permit No. PER4871061

The applicant requests authorization to import biological samples collected from individual animals of cetacean and pinniped species (except walrus) for the purpose of scientific research. Samples are collected from live wild and captive individuals or salvaged from dead wild and captive individuals. This notification covers activities conducted by the applicant over a 5-year period.

Applicant: Mario Gutierrez, San Antonio, TX; Permit No. PER3979790

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for radiated tortoise (*Astrochelys radiata*), to enhance the propagation or survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: National Marine Fisheries Service, Southwest Fisheries Science Center (NMFS), La Jolla, CA; Permit No. PER4479189

The applicant requests renewal of a permit to import biological samples collected from wild and captive-bred animals of Kemp's ridley turtle (*Lepidochelys kempii*), hawksbill sea turtle (*Eretmochelys imbricata*), leatherback sea turtle (*Dermochelys coriacea*), green sea turtle (*Chelonia mydas*), loggerhead sea turtle (*Caretta caretta*), and olive ridley sea turtle (*Lepidochelys olivacea*) for the purpose of scientific research. Samples are collected from live or salvaged specimens. This notification covers activities conducted by the applicant over a 5-year period.

Applicant: World Bird Sanctuary, Valley Park, MO; Permit No. PER5047417

The applicant requests a permit to import an Andean condor (*Vultur gryphus*), to enhance the propagation or survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Shawn Dooley, Belle Plaine, KS; Permit No. PER4621221

The applicant requests a permit to import a sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancing the propagation or survival of the species.

IV. Next Steps

After the comment period closes, we will make decisions regarding permit issuance. If we issue permits to any of the applicants listed in this notice, we will publish a notice in the **Federal Register**. You may locate the notice announcing the permit issuance by searching *https://www.regulations.gov* for the permit number listed above in this document. For example, to find information about the potential issuance of Permit No. 12345A, you would go to *regulations.gov* and search for ''12345A''.

V. Authority

We issue this notice under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and its implementing regulations.

Brenda Tapia,

Supervisory Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2023–24458 Filed 11–3–23; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2023–0183; FXIA16710900000–234–FF09A30000]

Wild Bird Conservation Act; Receipt of Permit Application

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit application; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), invite the public to comment on a permit application regarding a foreign bird species for which the Service has jurisdiction under the Wild Bird Conservation Act (WBCA). With some exceptions, the WBCA prohibits activities with listed species unless Federal authorization is issued that allows such activities. The WBCA also requires that we invite public comment before issuing permits for any activity it otherwise prohibits.

DATES: We must receive comments by December 6, 2023.

ADDRESSES: *Obtaining Documents:* The application, application supporting materials, and any comments and other materials that we receive will be available for public inspection at *https://www.regulations.gov* in Docket No. FWS–HQ–IA–2023–0183.

Submitting Comments: When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. You may submit comments by one of the following methods:

- *internet: https://www.regulations.gov.* Search for and submit comments on Docket No. FWS–HQ–IA–2023–0183.
- *U.S. mail:* Public Comments Processing, Attn: Docket No. FWS–HQ–IA–2023–0183; U.S. Fish and Wildlife Service Headquarters, MS: PRB/3W; 5275 Leesburg Pike; Falls Church, VA 22041–3803.

For more information, see Public Comment Procedures under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, by phone at 703–358–2185 or via email at *DMAFR@fws.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I comment on submitted applications?

We invite the public and local, State, Tribal, and Federal agencies to comment on this application. Before issuing any requested permit, we will take into consideration any information that we receive during the public comment period.

You may submit your comments and materials by one of the methods in **ADDRESSES**. We will not consider comments sent by email, or to an address not in **ADDRESSES**. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**).

When submitting comments, please specify the name of the applicant and

the permit number at the beginning of your comment. Provide sufficient information to allow us to authenticate any scientific or commercial data you include. The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) those that include citations to, and analyses of, the applicable laws and regulations.

B. May I review comments submitted by others?

You may view and comment on others' public comments at *https://www.regulations.gov* unless our allowing so would violate the Privacy Act (5 U.S.C. 552a) or Freedom of Information Act (5 U.S.C. 552).

C. Who will see my comments?

If you submit a comment at *https://www.regulations.gov,* your entire comment, including any personal identifying information, will be posted on the website. If you submit a hardcopy comment that includes personal identifying information, such as your address, phone number, or email address, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 112(4) of the Wild Bird Conservation Act of 1992 (WBCA; 16 U.S.C. 4901–4916), we invite public comments on permit applications before final action is taken. With some exceptions, the WBCA prohibits certain activities with listed species unless Federal authorization is issued that allows such activities. Service regulations regarding permits for any activity otherwise prohibited by the WBCA with respect to any wild birds are available in title 50 of the Code of Federal Regulations in part 15.

III. Permit Applications

We invite comments on the following application.

Applicant: Gerald Bobak c/o David Garcia, Homestead, FL; Permit No. PER0051912

The applicant, along with member Laurella Desborough, and the oversight committee, the Organization of Professional Aviculturists (OPA), wishes to establish a Cooperative Breeding Program covering the eclectus parrot (*Eclectus roratus*).

IV. Next Steps

After the comment period closes, we will make decisions regarding permit issuance. If we issue permits to any of the applicants listed in this notice, we will publish a notice in the **Federal Register**. You may locate the notice announcing the permit issuance by searching *https://www.regulations.gov* for the permit number listed above in this document. For example, to find information about the potential issuance of Permit No. 12345A, you would go to *https://www.regulations.gov* and search for ''12345A''.

V. Authority

We issue this notice under the authority of the Wild Bird Conservation Act of 1992 (16 U.S.C. 4901–4916). This notice is provided pursuant to section 112(4) of the Wild Bird Conservation Act of 1992, 50 CFR 15.26(c).

Brenda Tapia,

Supervisory Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2023–24449 Filed 11–3–23; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R4–ES–2023–0199; FXES11140400000–245–FF04EF4000]

Receipt of Incidental Take Permit Application and Proposed Habitat Conservation Plan for the Sand Skink; Lake County, FL; Categorical Exclusion

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the Fish and Wildlife Service (Service), announce receipt of an application from PMF Leesburg Michigan, LLC (Michigan Property) (applicant) for an incidental take permit (ITP) under the Endangered Species Act. The applicant requests the ITP to take the federally listed sand skink (*Neoseps reynoldsi*) incidental to the construction of a multi-family development in Lake County, Florida. We request public comment on the application, which includes the applicant's proposed habitat conservation plan (HCP), and on the Service's preliminary determination that the proposed permitting action may be eligible for a categorical exclusion pursuant to the Council on Environmental Quality's National Environmental Policy Act (NEPA) regulations, the Department of the Interior's (DOI) NEPA regulations, and the DOI Departmental Manual. To make this preliminary determination, we prepared a draft environmental action statement and low-effect screening form, both of which are also available for public review. We invite comment from the public and local, State, Tribal, and Federal agencies.

DATES: We must receive your written comments on or before December 6, 2023.

ADDRESSES:

Obtaining Documents: You may obtain copies of the documents online in Docket No. FWS–R4–ES–2023–0199 at *https://www.regulations.gov.*

Submitting Comments: If you wish to submit comments on any of the documents, you may do so in writing by one of the following methods:

- *Online: https://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–R4–ES–2023–0199.
- *U.S. mail:* Public Comments Processing, Attn: Docket No. FWS–R4–ES–2023–0199; U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

FOR FURTHER INFORMATION CONTACT: Erin Gawera, by U.S. mail (see **ADDRESSES**), by telephone at 904–731–3121 or via email at *erin_gawera@fws.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: We, the Fish and Wildlife Service (Service), announce receipt of an application from PMF Leesburg Michigan, LLC (Michigan Property) (applicant) 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 federally listed sand skinks (*Neoseps reynoldsi*) (skink) incidental to the construction and operation of a multi-family development

in Lake County, Florida. We request public comment on the application, which includes the applicant's habitat conservation plan (HCP), and on the Service's preliminary determination that this proposed ITP qualifies as low effect, and may qualify for a categorical exclusion pursuant to the Council on Environmental Quality's National Environmental Policy Act (NEPA) regulations (40 CFR 1501.4), the Department of the Interior's (DOI) NEPA regulations (43 CFR 46), and the DOI's Departmental Manual (516 DM 8.5(C)(2)). To make this preliminary determination, we prepared a draft environmental action statement and low-effect screening form, both of which are also available for public review.

Proposed Project

The applicant requests a 5-year ITP to take skinks via the conversion of approximately 1.42 acres (ac) of occupied nesting, foraging, and sheltering skink habitat incidental to the construction and operation of a multi-family development on 7.78 ac on Parcels 15–19–24–0605–001–00000 and 15–19–24–0605–003–00100 in Sections 14 and 15, Township 19 South, Range 24 East, Lake County, Florida. The applicant proposes to mitigate for take of the skinks by purchasing credits equivalent to 2.84 ac of skink-occupied habitat within the Lake Wales Ridge Conservation Bank or another Service-approved conservation bank. The Service would require the applicant to purchase the credits prior to engaging in any phase of the project.

Our Preliminary Determination

The Service has made a preliminary determination that the applicant's proposed project, including the construction of the buildings and associated infrastructure (*e.g.,* electric, water, and sewer lines), would individually and cumulatively have a minor effect on the sand skinks and the environment. Therefore, we have preliminarily determined that the proposed ESA section 10(a)(1)(B) permit would be a low-effect ITP that individually or cumulatively would have a minor effect on the sand skink and may qualify for application of a categorical exclusion pursuant to the Council on Environmental Quality's NEPA regulations, DOI's NEPA regulations, and the DOI Departmental Manual. A low-effect incidental take permit is one that would result in (1) minor or nonsignificant effects on species covered in the HCP; (2) nonsignificant effects on the human environment; and (3) impacts that, when added together with the impacts of other past, present, and reasonably foreseeable actions, would not result in significant cumulative effects to the human environment.

Next Steps

The Service will evaluate the application and the comments 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 and other matters, 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 PER1345003 to PMF Leesburg Michigan, LLC (Michigan Property).

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.

Authority

The Service provides this notice under section 10(c) of the Endangered Species Act (16 U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR 17.32) and the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations (40 CFR 1500–1508 and 43 CFR 46).

Robert L. Carey,

Manager, Division of Environmental Review, Florida Ecological Services Field Office.

[FR Doc. 2023–24493 Filed 11–3–23; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R8–ES–2023–0190; FXES11140800000–234–FF08ECAR00]

Receipt of Incidental Take Permit Application and Proposed Habitat Conservation Plan, City of Santee, California; Categorical Exclusion

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the Fish and Wildlife Service (Service), announce receipt of an application from Mr. Louis Jutras (applicant) for an incidental take permit (ITP) under the Endangered Species Act (ESA). The applicant requests the ITP to take the federally threatened coastal California gnatcatcher (*Polioptila californica californica*) incidental to construction of the Jutras residential home project, in the City of Santee, San Diego County, California. We request public comment on the application, which includes the applicant's proposed habitat conservation plan (HCP), and the Service's preliminary determination that the proposed permitting action may be eligible for a categorical exclusion pursuant to the Council on Environmental Quality's National Environmental Policy Act (NEPA) regulations, the Department of the Interior's (DOI) NEPA regulations, and the DOI Departmental Manual. To make this preliminary determination, we prepared a draft environmental action statement and low-effect screening form, both of which are also available for public review. We invite comment from the public and local, State, Tribal, and Federal agencies.

DATES: We must receive your written comments on or before December 6, 2023.

ADDRESSES:

Obtaining Documents: You may obtain copies of the documents this notice announces, along with any comments and other materials that we receive, online in Docket No. FWS–R8–ES–2023–0190 at *https://www.regulations.gov.*

Submitting Comments: If you wish to submit comments, you may do so in writing by one of the following methods:

- *Online: https://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–R8–ES–2023–0190.
- *U.S. mail:* Public Comments Processing, Attn: Docket No. FWS–R8–ES–2023–0190; U.S. Fish and Wildlife Service, MS: PRB/3W; 5275 Leesburg Pike; Falls Church, VA 22041–3803.:

FOR FURTHER INFORMATION CONTACT: Mr. Jonathan Snyder, Assistant Field Supervisor, Carlsbad Fish and Wildlife Office, 760–431–9440 (telephone). Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service (Service), have received an application from Mr.

Louis Jutras (applicant) for a 3-year incidental take permit (ITP) for one covered species pursuant to section 10(a)(1)(B) of the Endangered Species Act of 1973 (ESA), as amended (16 U.S.C. 1531 *et seq.*). The application addresses the potential ''take'' of the threatened coastal California gnatcatcher (*Polioptila californica californica*) in the course of activities associated with the construction of the Jutras residential home project, in the City of Santee, San Diego County, California. We request public comment on the application, which includes the applicant's habitat conservation plan (HCP), and on the Service's preliminary determination that this proposed ITP qualifies as ''low effect, '' and may qualify for a categorical exclusion pursuant to the Council on Environmental Quality's National Environmental Policy Act (NEPA) regulations (40 CFR 1501.4), the Department of the Interior's (DOI) NEPA regulations (43 CFR 46), and the DOI's Departmental Manual (516 DM 8.5(C)(2)). To make this preliminary determination, we prepared a draft environmental action statement and low-effect screening form, both of which are also available for public review.

Proposed Project

A conservation program to avoid, minimize, and mitigate for project activities would be implemented as described in the proposed Habitat Conservation Plan (HCP) by the applicant.

The applicant requests a 3-year ITP under section 10(a)(1)(B) of the ESA. If we approve the permit, the applicant anticipates taking coastal California gnatcatcher (*Polioptila californica californica*) as a result of permanent impacts to 0.662 acres (ac) of habitat the species uses for breeding, feeding, and sheltering. The take would be incidental to the applicant's activities associated with the construction of the Jutras residential project in the City of Santee, California, and includes preservation of 0.329 ac on site and funding for management of preserved land in the City of Santee.

The Jutras residential project proposes to construct a single-family residence on a 1.015-ac parcel in the City of Santee. The project will permanently impact 0.662 ac of coastal California gnatcatcher occupied habitat and 0.032 ac of disturbed land as a result of clearing and grading activities. The remaining 0.277 ac of coastal California gnatcatcher-occupied Diegan coastal sage scrub (DCSS) and 0.052 ac of disturbed land would not be impacted.

To minimize take of coastal California gnatcatcher by the Jutras residential development project and offset impacts to its habitat, the applicant proposes to mitigate for permanent impacts to 0.662 ac of occupied coastal California gnatcatcher habitat through the contribution of $54,580 for management of preserved land within the City of Santee. The long-term management will be carried out by the Endangered Habitat Conservancy and will be funded by a lump-sum initial contribution by the applicant. The applicant's proposed HCP also contains measures to minimize the effects of construction activities on the coastal California gnatcatcher. The clearing of DCSS will not take place during the gnatcatcher breeding season (defined as February 15 through August 31) when active gnatcatcher nests are present in the DCSS. In the event it is not feasible to clear outside of the gnatcatcher breeding season, pre-construction surveys for nesting birds will be conducted within the week prior to initiating grading activities to ensure construction activities do not occur within 300 feet of an active gnatcatcher nest. A U.S. Fish and Wildlife Service-approved biologist will conduct a training session for the grading contractor and will be present on site during the initial clearing and grubbing activities to ensure that the direct impacts are limited to the project footprint.

Proposed Action and Alternatives

The proposed action consists of the issuance of an incidental take permit and implementation of the proposed HCP, which includes measures to avoid, minimize, and mitigate impacts to covered species. To comply with the requirements for an HCP under ESA section 10(a), alternatives to the project and the incidental take of coastal California gnatcatcher were evaluated. Under the No Action Alternative, the project would not be constructed, and no ITP would be issued. The applicant would have no use of their private property. With implementation of the project, the single-family home would be situated in the northwestern corner of the project site, as close as feasible to the existing home to the north and to the adjacent parcel with approved TM 08–04 to the west. Previous iterations of the project design with the home sited in the middle of the project site were considered; however, the impacts to Diegan coastal sage scrub were greater than under the current project design and would not avoid incidental take of the coastal California gnatcatcher. Therefore, the project is the most biologically conservative feasible configuration for development of a single-family residence on the project site.

Our Preliminary Determination

The Service has made a preliminary determination that the applicant's proposed project would individually and cumulatively have a minor effect on the California gnatcatcher and the human environment. Therefore, we have preliminarily determined that the proposed ESA section 10(a)(1)(B) ITP would be a ''low-effect'' ITP that individually or cumulatively would have a minor effect on the species and may qualify for application of a categorical exclusion pursuant to the Council on Environmental Quality's NEPA regulations, DOI's NEPA regulations, and the DOI Departmental Manual. A ''low-effect'' ITP is one that would result in (1) minor or nonsignificant effects on species covered in the HCP; (2) nonsignificant effects on the human environment; and (3) impacts that, when added together with the impacts of other past, present, and reasonable foreseeable actions, would not result in significant cumulative effects to the human environment.

Next Steps

The Service will evaluate the application and the comments received to determine whether to issue the requested ITP. 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 and other matters, 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 the permit to the applicant for incidental take of coastal California gnatcatcher.

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 may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority

We provide this notice under section 10 of the ESA (16 U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR 17.22 and 17.32) and the National Environmental Policy Act (42 U.S.C.

4321 *et seq.*) and its implementing regulations (40 CFR 1500–1508 and 43 CFR 46).

Scott A. Sobiech,

Field Supervisor, Carlsbad Fish and Wildlife Office, Carlsbad, California.

[FR Doc. 2023–24404 Filed 11–3–23; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–PPFL–36595; PPWOPPFLF0–PMO00AD05.Y00000; 23XP103905]

Notice of Availability and Request for Comments on Draft Director's Order #36 Concerning National Park Service Policies and Procedures Governing Housing Management

AGENCY: National Park Service, Interior.

ACTION: Notice of availability.

SUMMARY: The National Park Service (NPS) has prepared Director's Order #36 to set forth its policies and procedures to manage Government-furnished housing (GFH), units owned or leased by the Government for which the Government serves as landlord, or lease holder. Once adopted, the policies and procedures in Director's Order #36 and the accompanying Reference Manual 36 will supersede and replace the policies and procedures issued in Director's Order #36: Housing Management, dated August 5, 2009.

DATES: Written comments will be accepted until December 6, 2023.

ADDRESSES: Draft Director's Order #36 is available online at *https://www.nps.gov/subjects/policy/new.htm* where readers may submit comments electronically.

FOR FURTHER INFORMATION CONTACT: Alicia Overby, Housing Management Program Manager, National Park Service, at *housing_management_program@nps.gov,* or by telephone at 202–513–7014.

SUPPLEMENTARY INFORMATION: The NPS is updating its current system of internal written instructions. When these documents contain new policy or procedural requirements that may affect parties outside the NPS, they are first made available for public review and comment before being adopted. Director's Order #36 and a reference manual (subsequent to the Director's Order) will be issued. The draft Director's Order provides direction to NPS managers and employees who are responsible for GFH programs; guidance of consistent application and adherence to laws, regulations, and Department of the Interior policies; and requirements and procedures for providing and maintaining GFH.

Public Disclosure of Comments: Before including your address, telephone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 54 U.S.C. 100101(a) *et seq.*)

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2023–24466 Filed 11–3–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[DOI–2023–0016; S1D1S SS08011000 SX064A000 234S180110]

Privacy Act of 1974; System of Records

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of a modified system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, as amended, the Department of the Interior (DOI, Department) is issuing a public notice of its intent to modify the Office of Surface Mining Reclamation and Enforcement (OSMRE) Privacy Act system of records, INTERIOR/OSM–12, Blaster Certification. The OSMRE is revising this system of records notice (SORN) to update the bureau designation in the system number to reflect the entirety of the bureau name, update all sections of the notice, and provide general and administrative updates to accurately reflect the modified system. This modified system will be included in DOI's inventory of record systems.

DATES: This modified system will be effective upon publication. New or modified routine uses will be effective December 6, 2023. Submit comments on or before December 6, 2023.

ADDRESSES: You may submit comments, identified by docket number [DOI–2023–0016], by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: DOI_Privacy@ios.doi.gov.* Include docket number [DOI–2023–0016] in the subject line of the message.
- *U.S. Mail or Hand-Delivery:* Teri Barnett, Departmental Privacy Officer, U.S. Department of the Interior, 1849 C Street NW, Room 7112, Washington, DC 20240.

Instructions: All submissions received must include the agency name and docket number [DOI–2023–0016]. All comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Patrick Dege, Associate Privacy Officer, Information Resource Office, Office of Surface Mining Reclamation and Enforcement, 1849 C Street NW, Mail Stop 1200 West Corridor, Washington, DC 20240, *OSMRE_Privacy@osmre.gov* or (202) 208–3549.

SUPPLEMENTARY INFORMATION:

I. Background

The OSMRE maintains the INTERIOR/OSM–12, Blaster Certification, system of records to manage the certifications of blasters in Federal Program States and on Indian Lands in compliance with the provisions of the Surface Mining Control and Reclamation Act of 1977. The OSMRE Blaster Certification system of records serves as a tool for OSMRE to grant blaster applicants' certificates for issuance, renewal, reissuance and reciprocity status, administration, and notification procedures, as well as to provide an adequate record-keeping system for compliance with a Federal program and enable OSMRE as the regulatory authority to effectively monitor its program requirements.

OSMRE is publishing this revised notice to update the bureau designation in the SORN number from ''OSM–12'' to ''OSMRE–12'' in order to reflect the bureau's full title of Office of Surface Mining Reclamation and Enforcement; update the system location and system manager and address; update legal authorities; propose new and modified routine uses; update the categories of records to provide additional information on the types of data maintained in the records; update the records retention schedule; update the sections for record access, notification, and contesting record procedures to clarify how individuals may submit Privacy Act requests; and provide general and administrative updates to

remaining sections to accurately reflect the management and scope of the system in accordance with the Office of Management and Budget (OMB) Circular A–108, *Federal Agency Responsibilities for Review, Reporting, and Publication under the Privacy Act.*

OSMRE is updating its routine uses from a numerical to alphabetical listing and is proposing to modify existing routine uses to provide clarity and transparency and reflect updates consistent with standard Departmental routine uses. Routine uses A, B, D, J, and O have been modified to provide additional clarification regarding external organizations and circumstances where disclosures are proper and necessary to facilitate the management of blaster certifications. Routine use A was modified to further clarify disclosures to the Department of Justice or other Federal agencies, when necessary, in relation to litigation or judicial proceedings. Routine use B was modified to clarify disclosures to a congressional office responding to or resolving an individual's request made to that office. Routine use D was modified to clarify the sharing of information with appropriate Federal, State, local, foreign agencies, or other public authority agencies responsible for investigating or prosecuting violations of, or for enforcing, or implementing, a statute, rule, regulation, order, or license. Modified routine use J would allow the Department to share information with appropriate Federal agencies or entities when reasonably necessary to respond to a breach of personally identifiable information and to prevent, minimize, or remedy the risk of harm to individuals or the Federal Government resulting from a breach in accordance with OMB Memorandum M–17–12, *Preparing for and Responding to a Breach of Personally Identifiable Information.* Routine use O was modified to include Federal and Tribal officials who may have responsibility for obtaining information relevant to a Federal blaster.

OSMRE is proposing new routine uses to facilitate the sharing of information with agencies and organizations to ensure the efficient and effective management of the Blaster Certification system of records or to carry out a Departmental or other Federal Government statutory responsibility. Proposed routine use C would facilitate the sharing of information with the Executive Office of the President to respond to an inquiry by the individual to whom that record pertains or a third party on the individual's behalf. Proposed routine use E facilitates sharing of information with an official of another Federal agency to assist in reconciling or reconstructing data files or to enable that agency to respond to an inquiry by the individual to whom the information pertains. Proposed routine use F would allow OSMRE to share information with agencies when relevant for hiring and retention or issuance of a security clearance, license, contract, grant, or benefit. Proposed routine use G would allow OSMRE to share information with the National Archives and Records Administration (NARA) to conduct records management inspections. Proposed routine use H would allow OSMRE to share information with external entities, such as State, Tribal, territorial, and local governments, and Tribal organizations, in response to court orders and/or for discovery purposes related to litigation. Proposed routine use I allows OSMRE to share information with organizations that perform services on the Department's behalf to carry out the purposes of the Blaster Certification system of records. Proposed routine use L would allow OSMRE to share information with the OMB during the coordination and clearance process in connection with legislative affairs. Proposed routine use M would allow OSMRE to share information with the Department of the Treasury to recover debts owed to the United States. Proposed routine use N would allow OSMRE to share information with the news media and the public if there is a legitimate public interest in the disclosure of the information.

II. Privacy Act

The Privacy Act of 1974, as amended, embodies fair information practice principles in a statutory framework governing the means by which 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 the Department by complying with Departmental 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 INTERIOR/OSMRE–12, Blaster Certification, system of records notice is published in its entirety below. 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.

III. Public Participation

You should be aware that your entire comment, including any personally identifiable information, such as your address, phone number, email address, or any other personal information, may be made publicly available at any time. While you may request that your personally identifiable information be withheld from public review, we cannot guarantee that it will be able to do so.

SYSTEM NAME AND NUMBER:

INTERIOR/OSMRE–12, Blaster Certification.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Office of Surface Mining Reclamation and Enforcement, U.S. Department of the Interior, Three Parkway Center, Pittsburgh, PA 15220. Records are also located at OSMRE offices in Alton, Illinois; Lakewood, Colorado; Knoxville, Tennessee; Tulsa, Oklahoma; and Casper, Wyoming. To obtain specific addresses for the offices listed, contact the System Manager at the address given below.

SYSTEM MANAGER(S):

OSMRE Blaster Certification Coordinator, Office of Surface Mining Reclamation and Enforcement, U.S. Department of the Interior, Three Parkway Center, Pittsburgh, PA 15220.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Surface Mining Control and Reclamation Act of 1977 (SMCRA), 30 U.S.C. 1201–1328; Safe Explosives Act, Title XI, Subtitle C of the Homeland Security Act of 2002, Public Law 107–296; 18 U.S.C. 842–843; 30 CFR Chapter VII, Subchapter E—Indian Lands Program, Section 750.19; 30 CFR Chapter VII, Subchapter G—Surface Coal Mining and Reclamation Operations Permits and Coal Exploration Systems Under Regulatory Programs; 30 CFR Chapter VII, Subchapter K—Permanent Program

Performance Standards, Sections, 816.61 and 817.61; 30 CFR Chapter VII, Subchapter M—Training, Examination, and Certification of Blasters; 30 CFR Chapter VII, Subchapter T—Programs for the Conduct of Surface Mining Operations Within Each State, Part 900, Part 910, Part 912, Part 921, Part 922, Part 933, Part 937, Part 939, Part 941, Part 942, Part 947, Part 955; and Executive Order 9397, Numbering System for Federal Accounts Relating to Individual Persons, as amended by Executive Order 13478.

PURPOSE(S) OF THE SYSTEM:

The primary purpose of the system is to enable OSMRE to effectively issue blaster certificates and manage blaster certifications issued to individuals (blasters) to conduct blasting operations in any Federal Program State or on Indian Lands under Federal jurisdiction while meeting the regulatory performance standards of SMCRA.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individual members of the public who apply to OSMRE for certification as blasters in Federal Program States and on Indian Lands.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records in the system include Applications for OSMRE Blaster Certificates (OSMRE–74 form), application status updates, including issuance, renewal, reissuance, replacement, or reciprocity, records of denials, revocation or suspension, and reports on the status of blaster certifications as follows:

(1) Application information submitted by candidates containing the following: name, Social Security number (voluntary), address, phone number, birthdate, email address and other contact information, gender, height and weight, hair and eye color, employment history, blasting experience, education, blaster training, examination dates, blaster certification history, and personal affirmation of application information;

(2) Summary reports of Federal blaster certificates alphabetically, numerically, by status or certificate type;

(3) Certification Status reports that contain listings of active, expired, revoked, or suspended certificates along with the performance history of each blaster; and

(4) Records of approval as an ''Employee Possessor'' or ''Responsible Party'' issued by the Department of Justice, Bureau of Alcohol, Tobacco, Firearms and Explosives. Approval letters are provided by the applicant and must be renewed triennially.

RECORD SOURCE CATEGORIES:

Records in the system are obtained from applicants for certification as blasters in Federal Program States and on Indian Lands. Information related to verification of applications is obtained from Federal agencies, States, Tribes, mining companies, and law enforcement organizations.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND 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 DOI as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To the Department of Justice (DOJ), including Offices of the U.S. Attorneys, or other Federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body, when it is relevant or necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

(1) DOI or any component of DOI;

(2) Any other Federal agency appearing before the Office of Hearings and Appeals;

(3) Any DOI employee or former employee acting in his or her official capacity;

(4) Any DOI employee or former employee acting in his or her individual capacity when DOI or DOJ has agreed to represent that employee or pay for private representation of the employee; or

(5) The United States Government or any agency thereof, when DOJ determines that DOI is likely to be affected by the proceeding.

B. To a congressional office when requesting information on behalf of, and at the request of, the individual who is the subject of the record.

C. To the Executive Office of the President in response to an inquiry from that office made at the request of the subject of a record or a third party on that person's behalf, or for a purpose compatible with the reason for which the records are collected or maintained.

D. To any criminal, civil, or regulatory law enforcement authority (whether Federal, State, territorial, local, Tribal, or foreign) when a record, either alone or in conjunction with other information, indicates a violation or potential violation of law—criminal, civil, or regulatory in nature, and the disclosure is compatible with the purpose for which the records were compiled.

E. To an official of another Federal agency to provide information needed in the performance of official duties related to reconciling or reconstructing data files or to enable that agency to respond to an inquiry by the individual to whom the record pertains.

F. To Federal, State, territorial, local, Tribal, or foreign agencies that have requested information relevant or necessary to the hiring, firing or retention of an employee or contractor, or the issuance of a security clearance, license, contract, grant or other benefit, when the disclosure is compatible with the purpose for which the records were compiled.

G. To representatives of the National Archives and Records Administration (NARA) to conduct records management inspections under the authority of 44 U.S.C. 2904 and 2906.

H. To State, territorial, and local governments and Tribal organizations to provide information needed in response to court order and/or discovery purposes related to litigation, when the disclosure is compatible with the purpose for which the records were compiled.

I. To an expert, consultant, grantee, shared service provider, or contractor (including employees of the contractor) of DOI that performs services requiring access to these records on DOI's behalf to carry out the purposes of the system.

J. To appropriate agencies, entities, and persons when:

(1) DOI suspects or has confirmed that there has been a breach of the system of records;

(2) DOI has determined that, as a result of the suspected or confirmed breach, there is a risk of harm to individuals, DOI (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 DOI's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

K. To another Federal agency or Federal entity, when DOI 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.

L. To the Office of Management and Budget (OMB) during the coordination and clearance process in connection with legislative affairs as mandated by OMB Circular A–19.

M. To the Department of the Treasury to recover debts owed to the United States.

N. To the news media and the public, with the approval of the Public Affairs Officer in consultation with counsel and the Senior Agency Official for Privacy, where there exists a legitimate public interest in the disclosure of the information, except to the extent it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

O. To Federal, State, Tribal, or mining company officials to verify whether an individual is a certified blaster under the OSMRE Blaster Certification Program.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Blaster certification applications (OSMRE–74 forms), related records and information are maintained in hard copy format such as file folders, and in digital format on servers, computers, electronic databases, and other appropriate electronic storage media.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by OSMRE Blaster Certificate number and last name filed alphabetically by applicant or candidate.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records in this system are maintained and disposed of in accordance with OSMRE Records Schedule N1–471–89–1, Item 201–13—Blaster Certification Files. The disposition for these records is temporary and the records are cut-off upon expiration of certification. Records are destroyed two years after cut-off.

Approved destruction methods for temporary records that have met their retention period include shredding or pulping of paper records and erasing or degaussing electronic records in accordance with Departmental policy and NARA guidelines.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

The records contained in this system are safeguarded in accordance with 43 CFR 2.226 and other applicable security and privacy rules and policies. Records are accessible only by authorized OSMRE employees. During normal hours of operation, paper records are maintained in locked file cabinets under the control of authorized personnel. Computer servers on which electronic records are stored are in secured Department-controlled facilities with physical, technical, and administrative levels of security to prevent unauthorized access to the Department's network and information assets. Access granted to authorized personnel is based on muti-factor authentication and each person granted access to the system must be individually authorized to use the system. A Privacy Act Warning Notice appears on computer monitor screens when records containing information on individuals are first displayed. Data exchanged between the servers and the system is encrypted. Backup tapes are encrypted and stored in a locked and controlled room in a secure, off-site location. A Privacy Impact Assessment was conducted to ensure that Privacy Act requirements are met and appropriate privacy controls were implemented to safeguard the personally identifiable information contained in the system.

RECORD ACCESS PROCEDURES:

An individual requesting access to their records should send a signed, written inquiry to the applicable System Manager identified above. DOI forms and instructions for submitting a Privacy Act request may be obtained from the DOI Privacy Act Requests website at *https://www.doi.gov/privacy/privacy-act-requests.* The request must include a general description of the records sought and the requester's full name, current address, and sufficient identifying information such as date of birth or other information required for verification of the requester's identity. The request must be signed and dated and be either notarized or submitted under penalty of perjury in accordance with 28 U.S.C. 1746. Requests submitted by mail must be clearly marked ''PRIVACY ACT REQUEST FOR ACCESS'' on both the envelope and letter. A request for access must meet the requirements of 43 CFR 2.238.

CONTESTING RECORD PROCEDURES:

An individual requesting amendment of their records should send a written request to the applicable System Manager as identified above. DOI instructions for submitting a request for amendment of records are available on the DOI Privacy Act Requests website at *https://www.doi.gov/privacy/privacy-act-requests.* The request must clearly identify the records for which amendment is being sought, the reasons for requesting the amendment, and the proposed amendment to the record. The request must include the requester's full name, current address, and sufficient identifying information such as date of birth or other information required for verification of the requester's identity. The request must be signed and dated and be either notarized or submitted under penalty of perjury in accordance with 28 U.S.C. 1746. Requests submitted by mail must be clearly marked ''PRIVACY ACT REQUEST FOR AMENDMENT'' on both the envelope and letter. A request for amendment must meet the requirements of 43 CFR 2.246.

NOTIFICATION PROCEDURES:

An individual requesting notification of the existence of records about them should send a written inquiry to the applicable System Manager as identified above. DOI instructions for submitting a request for notification are available on the DOI Privacy Act Requests website at *https://www.doi.gov/privacy/privacy-act-requests.* The request must include a general description of the records and the requester's full name, current address, and sufficient identifying information such as date of birth or other information required for verification of the requester's identity. The request must be signed and dated and be either notarized or submitted under penalty of perjury in accordance with 28 U.S.C. 1746. Requests submitted by mail must be clearly marked ''PRIVACY ACT INQUIRY'' on both the envelope and letter. A request for notification must meet the requirements of 43 CFR 2.235.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

64 FR 17413 (April 9, 1999); modification published at 73 FR 45244 (August 4, 2008) and 86 FR 50156 (September 7, 2021).

Teri Barnett,

Departmental Privacy Officer, Department of the Interior.

[FR Doc. 2023–24382 Filed 11–3–23; 8:45 am]

BILLING CODE 4310–05–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint *Certain Video Capable Electronic Devices, Including Computers, Streaming Devices, Televisions, Cameras, and Components and Modules Thereof, DN 3705;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.*

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.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: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Nokia Technologies Oy and Nokia Corporation on October 31, 2023. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain video capable electronic devices, including computers, streaming devices, televisions, cameras, and components and modules thereof. The complaint names as respondents: HP, Inc. of Palo Alto, CA; *Amazon.com,* Inc. of Seattle, WA; and Amazon.com Services LLC of Seattle, WA. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders, and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due, notwithstanding § 201.14(a) of the Commission's Rules of Practice and Procedure. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3705'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures).[1] Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. 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,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: November 1, 2023.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2023–24452 Filed 11–3–23; 8:45 am]

BILLING CODE 7020–02–P

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint *Certain Video Capable Electronic Devices, Including Computers, Streaming Devices, Televisions, and Components and Modules Thereof, DN 3706;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.*

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Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due, notwithstanding § 201.14(a) of the Commission's Rules of Practice and Procedure. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3706'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures).[1] Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. 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,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: November 1, 2023.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2023–24498 Filed 11–3–23; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint *Certain Organic Light-Emitting Diode Display Modules and Components Thereof, DN 3704;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.*

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov* . The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.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: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Samsung Display Co., Ltd. on October 31, 2023. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain organic light-emitting diode display modules and components thereof. The complaint names as respondents: BOE Technology Group Co., Ltd. of China; Mianyang BOE Optoelectronics Technology Co., Ltd. of China; Ordos Yuansheng Optoelectronics Co., Ltd. of China; Chengdu BOE Optoeletronics Technology Co., Ltd. of China; Chongqing BOE Optoeletronics Technology Co., Ltd. of China; Wuhan BOE Optoeletronics Technology Co., Ltd. of China; BMOT f/k/a Kunming BOE Display Technology of China; and BOE Technology America Inc. of China. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders, and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due, notwithstanding § 201.14(a) of the Commission's Rules of Practice and Procedure. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3704'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [1]). Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*)

No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. 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

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

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,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: October 31, 2023.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2023–24409 Filed 11–3–23; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

[Exemption Application No. L–11954]

Proposed Exemption for Certain Prohibited Transaction Restrictions: Fedeli Group, Inc. Employee Benefits Plan Located in Cleveland, OH

AGENCY: Employee Benefits Security Administration, Labor.

ACTION: Notice of proposed exemption.

SUMMARY: This document provides notice of the pendency before the Department of Labor (the Department) of a proposed individual exemption from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (ERISA or the Act). This proposed exemption would permit the Fedeli Group, Inc. Employee Benefits Plan (the Benefit Plan) sponsored by Fedeli Group, Inc. (Fedeli Group or the Applicant) to enter into an insurance contract with THP Insurance Company, Inc. (THP), an unrelated insurance company, and THP will, in turn, enter a reinsurance arrangement with Risk Specialists LLC (Risk Specialists), a captive reinsurance company affiliated with Fedeli Group.

DATES:

Comments due: Written comments and requests for a public hearing on the proposed exemption should be submitted to the Department by December 21, 2023.

Exemption date: If granted, this proposed exemption will be in effect on the date that the grant notice is published in the **Federal Register**.

ADDRESSES: All written comments and requests for a hearing should be submitted to the Employee Benefits Security Administration (EBSA), Office of Exemption Determinations, Attention: Application No. L–11954 via email to *e-OED@dol.gov* or online through *https://www.regulations.gov.* Any such comments or requests should be sent by the end of the scheduled comment period. The application 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.

FOR FURTHER INFORMATION CONTACT: Blessed Chuksorji-Keefe of the Department, telephone (202) 693–8567. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

Comments: 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 how the person would be adversely affected by the exemption, if granted. Any person who may be adversely affected by an exemption can request a hearing on the 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 if: (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 *https://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 a 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 *https://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 *https://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.

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). If the exemption is granted, the Fedeli Group, Inc. Employee Benefits Plan (the Benefit Plan) sponsored by Fedeli Group, Inc. (Fedeli Group or the Applicant) will enter into an insurance contract with THP Insurance Company, Inc. (THP), an unrelated insurance company, and THP will, in turn, enter a reinsurance arrangement with Risk Specialists LLC (Risk Specialists), a captive reinsurance company affiliated with Fedeli Group. Under the reinsurance arrangement, Risk Specialists will reinsure the insurance risks associated with the Benefit Plan. The reinsurance arrangement would result in an indirect transfer of premium payments from the Benefit Plan to Risk Specialists, LLC. This exemption requires, among other things, annual reports to be prepared by a qualified, independent fiduciary and submitted to the Department of Labor confirming whether Fedeli and its

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov*

affiliates have met the exemption's terms and conditions.[1]

Summary of Facts and Representations[2]

1. *The Plan Sponsor.* Fedeli Group is an S corporation based in Cleveland, Ohio. Fedeli Group provides insurance products and risk management services. Fedeli Group is 51% owned by the Umberto P. Fedeli Amended and Restated Revocable Trust (dated July 16, 2016), 29% by the Umberto P. Fedeli 2012 Discretionary Trust (dated November 28, 2012) and 20% by the Umberto P. Fedeli 2009 Discretionary Trust (dated December 23, 2009).

2. *The Plan.* The Fedeli Group sponsors and administers the Benefit Plan, which is a self-funded employee welfare benefit plan covering medical and hospital expenses for eligible Fedeli Group employees. The Benefit Plan currently covers approximately 64 participants.

3. *The Captive Reinsurer.* Risk Specialists is a licensed property and casualty captive insurance company that operates under applicable Tennessee law. Risk Specialists is 100% owned by Risk Specialists Captive Holdings, LLC (Risk Specialists Captive Holdings LLC), a limited liability company formed in Ohio on the same date as Risk Specialists. Risk Specialists Captive Holdings is 51% owned by the Fedeli Revocable Trust, 29% owned by the Fedeli 2012 Trust, and 20% owned by the Fedeli 2009 Trust. Risk Specialists serves as the reinsurer with respect to 13 different lines of insurance coverages provided to Fedeli Group and unrelated third parties.

4. *The Third-Party Insurer.* THP Insurance Company, Inc. (THP) is a domestic stock insurance company domiciled in West Virginia and licensed in both Ohio and West Virginia. THP is unrelated to all Fedeli Group-related entities and is currently rated ''A+'' by A.M. Best Company.

5. *Transitioning the Benefit Plan to the Third-Party Insurer Using the Captive Reinsurer.* Fedeli Group seeks to use its captive insurance company, Risk Specialists, to reinsure the Benefit Plan's claims. If this proposed exemption is granted, the Plan will enter into a Master Group Policy with THP, pursuant to which THP will provide group health insurance coverage to eligible participants under the Benefit Plan. THP will enter into a reinsurance agreement (the Reinsurance Agreement) with Risk Specialists. Under this arrangement, Risk Specialists will be responsible for the Benefit Plan's insurance claims under the Master Group Policy with THP, and Risk Specialists will indirectly receive the Benefit Plan's premium payments to THP. The Reinsurance Agreement between THP and Risk Specialists will be ''indemnity only,'' which means that THP will be responsible for Benefit Plan claims under the Master Group Policy to the extent Risk Specialists does not satisfy those claims under the Reinsurance Agreement.

6. *Exemptive Relief Requested.* The proposed reinsurance arrangement would violate certain prohibited transaction provisions of ERISA for the following reasons:

- Fedeli Group is a party in interest with respect to the Benefit Plan pursuant to ERISA section 3(14)(C), because it is an employer whose employees are covered by the Benefit Plan;
- The Trusts are parties in interest with respect to the Benefit Plan under ERISA section 3(14)(E) because they collectively own 100% of Fedeli Group, the Benefit Plan sponsor.
- Risk Specialists, the captive reinsurer, is a party in interest with respect to the Benefit Plan under ERISA section 3(14)(G) because it is 100% owned by the Trusts.

7. ERISA section 406(a) prohibits a wide range of transactions between plans and parties in interest with respect to those plans. As relevant here, ERISA section 406(a)(l)(D) prohibits a plan fiduciary from engaging in a transaction if the fiduciary knows or should know the transaction constitutes a direct or indirect transfer any plan assets for the use or benefit of a party in interest. The reinsurance arrangement would result in an indirect transfer of Benefit Plan premium payments to Risk Specialists, which is a party in interest with respect to the Benefit Plan.

8. ERISA section 406(b)(1) of ERISA prohibits a fiduciary from dealing with plan assets for the fiduciary's own interest or own account. The fiduciaries of the Benefit Plan would violate ERISA section 406(b)(1) by causing the Benefit Plan to pay premiums to THP, with the knowledge that the premiums will ultimately be directed to Risk Specialists, the captive reinsurer.

9. *Benefits to the ERISA-Covered Plan.* The Department has the authority under ERISA section 408(a) to exempt transactions from the prohibitions of ERISA section 406. Specifically, ERISA section 408(a) provides that the Department may not grant an exemption unless it finds that the exemption is administratively feasible, in the interests of the plan and the plan's participants and beneficiaries, and protective of the rights of the plan's participants and beneficiaries.

10. The Department has tentatively determined that the proposed reinsurance arrangement would be in the interest of the Benefit Plan and its participants and beneficiaries. As described in further detail below, a qualified, independent fiduciary has concluded that the reinsurance arrangement will reduce each Benefit Plan participant's share of the Benefit Plan premium paid to THP by at least $2,023.20[3] per participant per year for the duration of the exemption relative to the contribution the participant would otherwise have made under a non-captive arrangement with a competitive third party insurer receiving no more than reasonable compensation within the meaning of ERISA section 408(b)(2). Historically, Benefit Plan participants contributed approximately 25% towards the cost of the Benefit Plan. Under the proposal, all the savings from the Captive Approach will be used to reduce Benefit Plan participants' share of the Benefit Plan's premiums, and Benefit Plan participants will contribute no more than 17.38% of the Benefit Plan's costs throughout the duration of the exemption.

11. The Department requested that the Applicant provide a complete and accurate accounting of all benefits the Fedeli Group expects to derive from the captive reinsurance arrangement, including tax and non-tax benefits. In addition, the Department requested that the Applicant provide a full explanation of the ''economic substance of the proposed transaction,'' that is, the economic impact or outcome that the exemption would have on the Fedeli Group, Fedeli-related parties and the Benefit Plan's participants and beneficiaries. Both the accounting of

[1] The Department notes that the independent fiduciary's annual written report is essential to the Department's tentative finding that this proposed exemption is and will continue to be, in the interest and protective of the Plan and its participants and beneficiaries. Each report must demonstrate that the independent fiduciary has clearly, prudently, and loyally determined whether Fedeli and its affiliates have complied with each term and condition of the exemption. The exemption's relief is conditioned on the independent fiduciary's compliance with this requirement.

[2] The Department notes that availability of this exemption is subject to the express condition that the material facts and representations contained in Application L–11954 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 to the covered transactions as of the date of such change.

[3] The independent fiduciary's determination of the $2,023.20 amount is described below in more detail.

expected benefits and the explanation of the expected economic substance of the proposed transaction were reviewed and confirmed by the independent fiduciary.

Applicant's Response: The Applicant represents that the only benefits Fedeli Group expects to receive from the proposed Captive Approach relative to the Plan's current self-funding arrangement are the incidental benefits that would result from more predictability and better control over its benefit funding obligations. Under Fedeli Group's current self-funded arrangement, Fedeli's benefit funding obligations are dependent on the timing and amount of participant claims. In contrast, under the Captive Approach, the Fedeli Group will only make one annual premium payment. According to the Applicant, this initial funding obligation will represent an estimate of the anticipated claims Benefit Plan participants and beneficiaries will incur during the year. The ability to budget for one up-front annual premium payment instead of multiple weekly or monthly claims payments would provide Fedeli Group with predictability for Fedeli Group's benefit obligations.[4]

In addition, the Applicant represents that the Captive Approach grants financial control to the Fedeli Group over insurance spending by managing risks and underwriting ''Fedeli specific'' risks rather than paying risk premiums to third-party insurers or self-insuring. By underwriting its own risks, the Fedeli Group gains greater transparency and improved data on its actual benefit claims cost and utilization. Fedeli also benefits from flexibility in underwriting and funding depending on the Fedeli Group's specific employee demographics and plan design that it could not receive by purchasing commercial insurance.

Furthermore, the Captive Approach will result in reduced overall plan costs because benefit expenses are paid based on actual experience, as opposed to a third-party insurance carrier (the Third-Party Approach) requiring a fixed payment at a premium charged by an insurance carrier where the premium amount does not change regardless of the amount of claims that are incurred. Moreover, the Fedeli Group will not bear the sole payment obligation that it does under its current self-insurance arrangement. These reduced costs will redound to the Benefit Plan in the form of lower cost of health care coverage.

The Department's Note: This exemption is being proposed based on the Applicant's representations and the exemption's requirement, that no Fedeli Group-related entity will receive a direct or indirect profit, tax benefit, investment gain or other remunerative benefit through the Captive Approach. The Department notes that if a Fedeli Group-related entity ultimately receives such a profit, benefit or gain, the Fedeli Group must further enhance the Benefit Plan in an amount greater than the $2,023.20 per participant per year contribution reduction in a manner consistent with the terms and conditions of this proposed exemption. Additionally, the Department notes that this proposed exemption prohibits Fedeli Group or a related entity from using any participant-related data or information generated by, or derived from, the Captive Approach in a manner that benefits the Fedeli Group or related entity.

As described below, this exemption, if granted, requires a qualified, independent fiduciary to review all relevant financial information of Risk Specialists and any other Fedeli-related entity as is necessary to ensure that this and the other terms and conditions described in this proposal are met and to annually certify in a written report submitted to the Department that all requirements of the proposed exemption have been met.

Applicant's Analyses

12. The Applicant represents to the Department that it evaluated two different insurance-based approaches to provide the benefits payable under the Benefit Plan and the effects on the costs from each, based on the 2023 plan year information for the Benefit Plan. The Applicant's first insurance-based approach contemplates a Third-Party Approach, while the second insurance-based approach takes into account Risk Specialists as the captive reinsurer (the Captive Approach).

13. The Applicant states that, based on actual values from the Benefit Plan's 2023 financial statement, the annual premium under the Third-Party Approach would have been $2,254,314, compared to the $2,124,829 annual premium under the Captive Approach. Therefore, the Applicant calculated the total annual cost savings under the Captive Approach would be $129,485 for the 2023 Plan Year.

14. The cost savings under the Captive Approach will be passed on to Benefit Plan participants on a pro-rata basis, by reducing employees' Benefit Plan contribution obligations. As of September 19, 2023, the Benefit Plan covered 64 participants, the $129,485 in total annual cost savings under the Captive Approach will be directly applied to Benefit Plan participants as a reduction in their contribution obligations.

15. The Applicant calculated the monthly $161.60 contribution reduction per Benefit Plan participant ($129,485.00/12 months = $10,790.42/64 participants = $168.60). The Applicant states that this monthly reduction in contribution obligations will result in annual savings per participant of $2,023.20 ($168.60 × 12 months) with no reduction in medical, health, or other plan benefits. Further, the Applicant states that these cost savings for Benefit Plan participants will be implemented simultaneously with the establishment of the Captive Approach.

16. The Applicant represents that, historically, contributions to the Benefit Plan by Benefit Plan participants have been targeted at 25% of Benefit Plan costs. By implementing the proposed Captive Approach and lowering annual Benefit Plan costs by $129,485, there will be a cost savings to the Benefit Plan of 7.62% per year. Based on the Applicant's assertions that the Captive Approach will result in participants' savings of 7.62% per year, the Department is including an exemption condition that requires participant contributions to comprise no more than 17.38% (*i.e.,* 25% − 7.62%) of the Benefit Plan's premiums on a going-forward annual basis.

The Independent Fiduciary

17. George J. Stadtlander, President and majority owner of Consoliplex L.L.C. (Consoliplex), a health plan service organization located in Cleveland, Ohio, will serve as the Benefit Plan's qualified independent fiduciary (the Independent Fiduciary) with respect to the proposed transactions. Mr. Stadtlander states that he is qualified to serve as the Independent Fiduciary for the Benefit Plan because he: (a) is not employed by Fedeli Group or its affiliates; (b) has more than thirty years of experience in the field of health benefits, including serving as an officer and executive vice president for Medical Mutual, a local health insurance company with over $2 billion in annual premiums; (c) currently owns an organization that serves as a plan manager for five multiple employer welfare arrangements; and (d) has managed the actuarial department, the underwriting department, network contracting, utilization management and sales departments, in his capacity with the local health local health insurance company, which has provided him with

[4] Under the current arrangement, the funding obligation is less predictable because benefits are paid out as claims are incurred.

the experience and background for forming the opinions expressed in his Independent Fiduciary report. Mr. Stadtlander was chosen to act as Independent Fiduciary by David M. Deroma, the plan fiduciary responsible for selecting the independent fiduciary. Mr. Deroma represents that Mr. Standtlander's selection was based solely on his qualifications to serve as an independent fiduciary after a prudent process without regard to whether Mr. Standtlander's views were likely to favor the interests of the Fedeli Group or related parties.

18. Mr. Stadtlander represents that he understands his duties, responsibilities, and liabilities under ERISA as the Independent Fiduciary on behalf of the Benefit Plan participants and their beneficiaries, and that, as Independent Fiduciary of the Benefit Plan, he does not act on behalf of the Benefit Plan sponsor or take its interests into account. Mr. Stadtlander also represents that neither he nor Consoliplex have received, nor will they receive, more than 1% of their annual income from Fedeli Group and its related parties. In addition, Mr. Stadtlander represents that neither he nor any related parties, including Consoliplex: have performed any work in connection with the Captive Approach on behalf of the Fedeli Group or its related parties; have any financial interest with respect to his work as an independent fiduciary or the Captive Approach apart from his express fees for his work as an independent fiduciary for the Benefit Plan; or have received any other compensation or entered into any financial or compensation arrangements with the Fedeli Group and related parties. Fedeli Group and its related parties have not, and will not, indemnify the Independent Fiduciary, in whole or in part, for any violations of state or federal law that may be attributable to the Independent Fiduciary in performing its duties under the captive reinsurance arrangement. In addition, no contract or instrument purports to waive any liability under state or federal law for any such violations.

19. As the Independent Fiduciary, Mr. Stadtlander prepared an initial report dated February 26, 2018 (the February 2018 Independent Fiduciary Report), which he has updated with supplemental reports on July 30, 2019 (the July 2019 Independent Fiduciary Report), and December 5, 2019 (the December 2019 Independent Fiduciary Report), at the Department's request.

20. *February 2018 Independent Fiduciary Report.* Mr. Stadtlander represents that he reviewed the Applicant's rationale as to why the Captive Approach would directly Benefit Plan participants and beneficiaries. Mr. Stadtlander represents that the Applicant's factual assumptions and related analysis were accurate and reasonable, and that his access to the Fedeli Group's books and records will allow him to ensure that the use of the Benefit Plan's assets comply with the requirements of ERISA.

21. Mr. Stadtlander represents that he is authorized to take all appropriate actions to safeguard the interests of the Benefit Plan and its participants and beneficiaries, including but not limited to monitoring the proposed transactions to ensure the transactions remain in the interests of the Benefit Plan and its participants and beneficiaries, and that he can take appropriate actions available under the circumstances with respect to the proposed transactions, including but not limited to enforcing compliance with all contractual conditions and obligations imposed on any party dealing with the Benefit Plan.

22. *July 2019 Independent Fiduciary Report.* In the July 30, 2019 Independent Fiduciary Report, Mr. Stadtlander certified that the proposed captive reinsurance arrangement would: (a) primarily Benefit Plan participants and beneficiaries and only provide non-monetary benefits to the Fedeli Group; (b) create real and substantial additional benefits for the Plan and Plan participants; (c) not be offset by reduction in benefits/salaries elsewhere; and (d) otherwise be consistent with ERISA (including the prudence and loyalty provisions) and the law.

23. *December 2019 Independent Fiduciary Report.* At the Department's request, Mr. Stadtlander provided additional responses and clarifications related to the proposed transactions. Mr. Stadtlander: (a) reviewed the Applicant's representations that the Fedeli Group and/or its related parties would not receive a monetary benefit (tax or non-tax, including a profit) from the proposed captive reinsurance arrangement, and certified that the Applicant's representations were accurate; [5] (b) determined that the proposed captive reinsurance arrangement would: (i) primarily Benefit Plan participants inasmuch as the financial benefits to Benefit Plan participants would exceed the amount of any non-monetary incidental benefit to the Fedeli Group and related parties; [6] (ii) create real and substantial additional benefits for the Benefit Plan and for Benefit Plan participants; (iii) not be offset by reduction in benefits/salaries elsewhere; and (iv) be otherwise consistent with ERISA (including prudence/loyalty provisions) and the law; (d) certified, within the context of the captive, that the savings from the Captive Approach would inure to the benefit of the participants through a combination of some or all improved benefits or reduced contributions; (e) confirmed that, as the Independent Fiduciary, he had the requisite knowledge regarding captive reinsurance arrangements to fulfill his duties under ERISA section 404 as a prudent plan fiduciary; (f) confirmed that he, as the Independent Fiduciary, would monitor the reinsurance arrangement throughout the duration of the exemption, if granted by the Department; (g) confirmed that the proposed captive reinsurance arrangement is consistent with the prudence and loyalty provisions of ERISA section 40 and other applicable laws; and (h) provided analyses to support all representations it made to the Department.

24. In addition, Mr. Stadtlander stated that he would annually determine whether the terms and conditions of the exemption, if granted, had been met in the prior year. Specifically, the terms of the proposed exemption, if granted, provide that Mr. Stadtlander must file annual certified reports with the Department that confirm whether all terms and conditions of the exemption have been met under penalty of perjury. Under the terms of the proposed exemption, each report must be completed within six months from the end of the 12-month period to which it relates (the first 12-month period beginning on the effective date of the exemption, if granted, and submitted to the Department within six months thereafter).

25. Finally, Mr. Stadtlander attached his supporting analysis to the Independent Fiduciary Report. Stadtlander's analysis confirmed the Fedeli Group's calculations of the final saving value and annual cost savings. As stated above, the Applicant calculated a savings of $168.60 per Benefit Plan participant per month using the Captive Approach based on an

[5] In this regard, Mr. Stadtlander stated that he received full disclosure of all benefits the Applicant expected to derive from the proposed transactions. Among other things, Mr. Stadtlander reviewed internal analyses of the economic benefits to the Applicant prepared by consultants and the Applicant itself, and he received full access to all data necessary to evaluate the transactions, including submissions made by the Applicant to state insurance departments.

[6] As described above, Fedeli Group represents that it would benefit by an increased predictability and greater control over its benefit funding obligations.

overall annual cost savings to the Benefit Plan of $129,485.00.

The Department's Findings

26. The Department has the authority under ERISA section 408(a) to grant an exemption from the prohibition transaction provisions of ERISA section 406 if the Department finds that the transaction is in the interest and protective of the rights of the affected plan and its participants and beneficiaries, and is administratively feasible.[7] The Department's findings required under ERISA section 408(a) with respect to the proposed captive reinsurance arrangement are discussed below.

27. *The Proposed Exemption is ''Administratively Feasible.''* The Department has tentatively determined that the proposed exemption would be administratively feasible, because the proposed captive reinsurance arrangement is subject to robust annual reviews by Mr. Stadtlander and included in a report he must file with the Department's Office of Exemption Determinations.

28. *The Proposed Exemption is ''Protective of the Plan.''* The Department has tentatively determined that the proposed exemption is protective of the rights of the Benefit Plan's participants and beneficiaries because, among other things, a the exemption contains a number of additional conditions in addition to the requirement discussed above, including the following: (a) no commissions will be paid by the Benefit Plan with respect to the direct sale of any third party insurance contract and/or any reinsurance contract; and (b) the Fedeli Group will only contract on behalf of the Benefit Plan with insurers having a financial strength rating of ''A'' or better from A.M. Best Company or the equivalent rating from another rating company. In addition, for each taxable year of Risk Specialists, the gross premiums received in that taxable year by Risk Specialists for benefit insurance provided to Fedeli Group and its employees with respect to which Risk Specialists is a party in interest by reason of the relationship to Fedeli Group as described in ERISA section 3(14)(E) or (G), will not exceed 50% of the gross premiums received for all lines of insurance (*i.e.,* benefit insurance and non-benefit insurance) in that taxable year by Risk Specialists.

29. Further, the interests of the Benefit Plan and its participants and beneficiaries are represented in the covered transactions by an Independent Fiduciary that is obligated, among other things, to: (a) monitor the transactions described in the exemption on behalf of the Benefit Plan, on a continuing basis, to ensure the transactions remain in the interest of the Benefit Plan; (b) take all appropriate actions to safeguard the interests of the Benefit Plan; and (c) enforce compliance with all conditions of the exemption and all conditions and obligations imposed on any party dealing with the Benefit Plan. In connection with the provision to participants in the Benefit Plan of the insurance coverage provided by THP or its successor, which is reinsured by the Risk Specialists, the Independent Fiduciary will review all contracts (and any renewal of such contracts) of the reinsurance of risks and the receipt of premiums therefrom and ensure that the requirements of this exemption, and the terms of the increased benefits continue to be satisfied.

30. *The Proposed Exemption is ''In the Interests of the Plan.''* The Department has tentatively determined that the proposed exemption would be in the interest of the Benefit Plan because, among other things, all of the cost savings from the Captive Approach (relative to the reasonable cost the Benefit Plan would otherwise have paid for comparable benefits pursuant to a non-captive arrangement with an unrelated, third-party insurer) will be used to reduce the amount that each Benefit Plan participant is required to contribute toward the premium the Benefit Plan pays to THP or another fronting insurer. Specifically, based on calculations confirmed by the Independent Fiduciary, the captive reinsurance arrangement will reduce the monthly contribution of each Benefit Plan participant by approximately $168.60. This monthly reduction in contribution obligations will result in annual savings per participant of $2,023.20 ($168.60 × 12 months). Significantly, Benefit Plan participants will contribute no more than 17.38% of the premium paid by the Benefit Plan to THP or another fronting insurer in any Benefit Plan year, which is less than the 25% the participants previously contributed to Benefit Plan premiums.

In addition, the proposed exemption conditions require contributions of Benefit Plan participants to be further reduced by any net benefit received by any Fedeli Group entity, including Risk Specialists, that is generated by the Captive Approach over each five-year period, the first year of which would begin on the date this exemption is granted. Net benefits may include, but are not limited to, increased earned income, increased savings, a tax reduction or a profit or any benefit arising from a further diversification of Risk Specialist's risks in connection with adding Plan-related insurance risks to Risk Specialist's other risks. Participants' contributions will be reduced by the amount of the net benefit (plus interest) on a pro rata basis in the year following the five-year period to which the net benefit relates.

Summary

31. Based on Fedeli Group, Inc. satisfying the conditions described above and the representations made in its exemption allocation and communications with the Department, the Department has tentatively determined that the relief sought by the Applicant satisfies the statutory requirements for an exemption under ERISA section 408(a).

Notice to Interested Persons

Notice of the proposed exemption will be provided by the Applicant to all Interested Persons within 15 days of the publication of the notice of proposed exemption in the **Federal Register**, by first class U.S. mail to the last known address of all such individuals. Such notice 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 the pending exemption. Written comments are due within 45 days of the publication of the notice of 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 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.

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 ERISA section 408(a) does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions of ERISA and/or the Code, including any prohibited transaction

[7] ERISA section 408(a).

provisions to which the exemption does not apply and the general fiduciary responsibility provisions of ERISA section 404, which, among other things, require a fiduciary to discharge their duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with ERISA section 404(a)(1)(B); nor does it affect the requirement of Code Section 401(a) 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 ERISA section 408(a), 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 exemption would be supplemental to, and not in derogation of, any other provisions of ERISA 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 exemption would be subject to the express condition that the material facts and representations contained in the application are true and complete at all times and that the application accurately describes all material terms of the transactions which are the subject of the exemption.

Proposed Exemption

Section I. Proposed Transactions

If the proposed exemption is granted, the restrictions of ERISA sections 406(a)(1)(D)and 406(b)(1) shall not apply to the reinsurance of risks and the receipt of premiums therefrom by Risk Specialists Insurance Company, Inc. (Risk Specialists), in connection with insurance contracts sold by THP Insurance Company, Inc. (THP) or any successor insurance company to THP, which is unrelated to the Fedeli Group, Inc., including any entity related to Fedeli Group Inc. (collectively, Fedeli Group), to provide medical and hospital coverage to participants in the Fedeli Group Inc. Employee Benefit Plan (the Benefit Plan) provided that the conditions set forth in Section II are met.

Section II. Conditions

(a) All of the savings from the captive reinsurance arrangement will be used to reduce the amount that each Benefit Plan participant is required to contribute toward the premium the Benefit Plan pays to THP or another fronting insurer. The cost savings must be determined relative to the reasonable cost the Benefit Plan would otherwise have paid for comparable benefits pursuant to a non-captive arrangement with an unrelated, third-party insurer. In no year will the reduction in Benefit Plan participant contributions be less than $2,023.20 per participant per year. The premium reduction must benefit all Plan participants equally and must be verified by the Independent Fiduciary as described below.

(b) Benefit Plan participant contributions will be further reduced by an amount equal to any net benefit (the Extra Benefit) any Fedeli Group entity received that is directly or indirectly generated by the Captive Approach over each five-year period, the first of which begins on the grant date this exemption is granted. Extra Benefits include, but are not limited to, increased earned income, increased savings, a tax reduction or a profit or any benefit arising from a further diversification of Risk Specialist's risks in connection with adding Plan-related insurance risks to Risk Specialist's other risks. The reduction must be received by Benefit Plan participants on a pro rata basis in the year following the five-year period to which the Extra Benefit relates; plus, an additional interest payment on the amount of the Extra Benefit at the Internal Revenue Code's federal underpayment rate established in Code section 6621(b). The interest on the Extra Benefit must be calculated for the period from the end of the Benefit Plan year the Extra Benefit was earned through the start of the Benefit Plan year in which the Extra Benefit is applied to reduce Benefit Plan participants' contributions.

(c) Benefit Plan participants contribute no more than 17.38% of the premium paid by the Benefit Plan to THP or another fronting insurer;

(d) Risk Specialists:

(1) Is a party in interest with respect to the Benefit Plan by reason of a stock affiliation with Fedeli Group that is described in ERISA section 3(14)(E) or (G);

(2) Is licensed to sell insurance or conduct reinsurance operations in the state of Tennessee;

(3) Has obtained a Certificate of Authority from the insurance commissioner of the State of Tennessee to transact the business of a captive insurance company, which has neither been revoked nor suspended, and has undergone a financial examination (within the meaning of the law of its domiciliary State, Tennessee) by the Insurance Commissioner of the State of Tennessee within five years before the end of the year preceding the year in which the reinsurance transaction occurred;

(4) Has undergone and shall continue to undergo an examination by an independent certified public accountant for its last completed taxable year immediately prior to the taxable year of the reinsurance transaction covered by this exemption; and

(5) Is licensed to conduct reinsurance transactions by a state whose law requires that an actuarial review of reserves be conducted annually by an independent firm of actuaries and reported to the appropriate regulatory authority;

(e) The Benefit Plan pays no more than adequate consideration with respect to insurance that is part of the captive reinsurance arrangement covered by the exemption;

(f) No commissions are paid by the Benefit Plan with respect to the direct sale of such contracts or the reinsurance thereof;

(g) In the initial year of any contract involving Risk Specialists and THP or any successor insurer, the Benefit Plan's participants and beneficiaries receive an immediate and objectively determined benefit in the form of decreased participant contributions, and such benefits will continue in all subsequent years of each contract and in every renewal of each contract;

(h) In the initial year and in subsequent years of coverage provided by THP or another fronting insurer (either, a Fronting Insurer), the formulae used by the Fronting Insurer to calculate premiums must be similar to formulae used by other insurers providing comparable life insurance coverage under similar programs that are not captive reinsured. Furthermore, the premium charges calculated in accordance with the formulae must be reasonable and must be comparable to the premiums charged by the Fronting Insurer and its competitors with the same or a better financial strength rating providing the same coverage under comparable programs that are not captive reinsured;

(i) Fedeli Group only contracts with insurers with a financial strength rating of ''A'' or better from A.M. Best Company. The reinsurance arrangement between any fronting insurer and Risk Specialists will be indemnity insurance only, such that the fronting insurer will not be relieved of any liability to the Benefit Plan should Risk Specialists be unable or unwilling to cover any

liability arising from the reinsurance arrangement;

(j) Participants and beneficiaries in the Benefit Plan must receive no less than the immediate and objectively determined increased benefits the participant and beneficiary received in the initial year of each such contract involving Risk Specialists and THP in subsequent years of every contract of reinsurance involving Risk Specialists and THP;

(k) For each taxable year of Risk Specialists, the gross premiums received in that taxable year by Risk Specialists for benefit insurance provided to Fedeli Group and its employees with respect to which Risk Specialists is a party in interest by reason of the relationship to Fedeli Group as described in ERISA section 3(14)(E) or (G), will not exceed 50% of the gross premiums received for all lines of insurance (*i.e.,* benefit insurance and non-benefit insurance) in that taxable year by Risk Specialists;

(l) The Benefit Plan retains a qualified independent fiduciary (the Independent Fiduciary) to analyze the transactions covered by the exemption and render an opinion that the terms and conditions of this exemption have been satisfied;

(m) The Independent Fiduciary will:

(1) Monitor the transactions described here on behalf of the Benefit Plan on a continuing basis to ensure such transactions remain in the interest of the Benefit Plan;

(2) Take all appropriate actions to safeguard the interests of the Benefit Plan; and

(3) Enforce compliance with all conditions of this exemption and all conditions and obligations imposed on any party dealing with the Benefit Plan;

(4) Review all contracts, and any renewals of such contracts, pertaining to the captive reinsurance arrangement, to determine whether the requirements of this exemption, and the terms of the increased benefits continue to be satisfied; and

(5) Provide an annual, certified report to the Department, under penalty of perjury, indicating whether the terms and conditions of the exemption continue to be satisfied. Each report must be completed within six months after the end of the twelve-month period to which it relates (the first twelve-month period begins on the first day of the implementation of the captive reinsurance arrangement covered by this exemption), and be submitted to the Department within 60 days thereafter. The relevant report must include all the objective data necessary to demonstrate that the Primary Benefit Test has been met; and

(n) The Benefit Plan, Fedeli Group and its related parties have not, and will not, indemnify the Independent Fiduciary, in whole or in part, for negligence and/or for any violations of state or federal law that may be attributable to the Independent Fiduciary in performing its duties under the captive reinsurance arrangement. In addition, no contract or instrument will purport to waive any liability under state or federal law for any such violations. In the event a successor Independent Fiduciary is appointed to represent the interests of the Plan with respect to the subject transaction, no time shall elapse between the resignation or termination of the former Independent Fiduciary and the appointment of the successor Independent Fiduciary.

(o) No Fedeli Group entity or related entity may use participant-related data or information generated by or derived from the proposed arrangement in a manner that benefits the Fedeli Group or related entity;

(p) No amount of THP's reserves that are attributable to the Plan participants' contributions may be transferred to Fedeli Group or a related party;

(q) Fedeli Group will not evade the conditions in this exemption by offsetting or reducing any benefits provided to Fedeli Group employees to defray the costs, expenses, or obligations of complying with this exemption;

(r) All expenses associated with the exemption and the exemption application, including any payment to the Independent Fiduciary, must be paid by Fedeli Group and not the Plan;

and

(s) All the material facts and representations set forth in the Summary of Facts and Representation are true and accurate at all times.

Effective Date: The proposed exemption will be in effect as of the date the grant notice is published in the **Federal Register**.

Signed at Washington, DC.

George Christopher Cosby,

Director, Office of Exemption Determinations, Employee Benefits Security Administration, U.S. Department of Labor.

[FR Doc. 2023–24401 Filed 11–3–23; 8:45 am]

BILLING CODE 4510–29–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[NOTICE: 23–111]

Name of Information Collection: NASA Complaint of Discrimination Form 1355

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of information collection.

SUMMARY: The National Aeronautics and Space Administration, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections.

DATES: Comments are due by December 6, 2023.

ADDRESSES: Written comments and recommendations for this information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.*

Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Bill Edwards-Bodmer, NASA Clearance Officer, NASA Headquarters, 300 E Street SW, JF0000, Washington, DC 20546, 757–864–7998, or *b.edwards-bodmer@nasa.gov*.

SUPPLEMENTARY INFORMATION:

I. Abstract

Federal agencies are required by statute not to engage in discrimination on the bases of race, color, religion, sex, national origin, age, disability, genetic information, or retaliation. A federal employee, former employee, or job applicant who believes s/he was discriminated against has a right to file a complaint with the agency's office responsible for its Equal Employment Opportunity (EEO) programs. Federal agencies must offer pre-complaint counseling or EEO alternative dispute resolution (EEO ADR) to individuals who allege that they were discriminated against by the agency. If pre-complaint counseling or EEO ADR does not resolve the dispute(s), the individual can file a formal discrimination complaint with the agency's EEO office.

II. Methods of Collection

Title 29 of the Code of Federal Regulations (CFR) part 1614 section 104 requires agencies to establish

procedures for processing individual and class complaints of discrimination that include the provisions contained in 29 CFR 1614.105 through 1614.110 and in § 1614.204, which are consistent with all other applicable Federal EEO regulations and complaint processing requirements contained in the Equal Employment Opportunity Commission (EEOC) Management Directives (MD).

When an individual decides to pursue the formal discrimination complaint process, EEOC MD 110 requires that the formal complaint must be:

- In writing;
- Specific with regard to the claim(s) that the individual raised in pre-complaint counseling and that the person wishes to pursue;
- Must be signed by the individual and/or his or her representative; and
- Must be filed within fifteen (15) calendar days from the date s/he receives the Notice of Right to File a Discrimination Complaint.

Consequently, NASA established NF–1355P form to ensure the individual who wishes to utilize the EEO process complies with the requirements listed above.

III. Data

Title: Formal Discrimination Complaint Form.

OMB Number: 2700–0163.

Type of review: Reinstatement of Information Collection.

Affected Public: Individuals who wish to file a formal discrimination complaint against NASA.

Estimated Annual Number of Activities: 60.

Estimated Number of Respondents per Activity: 1.

Annual Responses: 60.

Estimated Time per Response: 30 minutes.

Estimated Total Annual Burden Hours: 30 hours.

IV. Request for Comments

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of NASA, including whether the information collected has practical utility; (2) the accuracy of NASA's estimate of the burden (including hours and cost) 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 respondents, including automated collection techniques or the use of other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of this information collection. They will also become a matter of public record.

William Edwards-Bodmer,

NASA PRA Clearance Officer.

[FR Doc. 2023–24505 Filed 11–3–23; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Institute of Museum and Library Services

Submission for OMB Review, Comment Request, Proposed Collection: Native American Library Services Enhancement Grants Notice of Funding Opportunity

AGENCY: Institute of Museum and Library Services, National Foundation on the Arts and the Humanities.

ACTION: Submission for OMB Review, request for comments, collection of information.

SUMMARY: The Institute of Museum and Library Services announces that the following information collection has been submitted to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. This Notice proposes the renewal of the clearance of the Notice of Funding Opportunity for the Native American Library Services Enhancement Grants Program. A copy of the proposed information collection request can be obtained by contacting the individual listed below in the **FOR FURTHER INFORMATION CONTACT** section of this Notice.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section below on or before December 3, 2023.

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 particular information collection request by selecting ''Institute of Museum and Library Services'' under ''Currently Under Review;'' then check ''Only Show ICR for Public Comment'' checkbox. Once you have found this information collection request, select ''Comment,'' and enter or upload your comment and information. Alternatively, please mail your written comments to Office of Information and Regulatory Affairs, Attn.: OMB Desk Officer for Education, Office of Management and Budget, Room 10235, Washington, DC 20503, or call (202) 395–7316.

OMB is particularly interested in comments that help the agency to:

- 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).

FOR FURTHER INFORMATION CONTACT: Jennifer Himmelreich, Senior Program Officer, Office of Library Services, Institute of Museum and Library Services, 955 L'Enfant Plaza North SW, Suite 4000, Washington, DC 20024–2135. Ms. Himmelreich can be reached by telephone at 202–653–4797, or by email at *jhimmelreich@imls.gov.* Persons who are deaf or hard of hearing (TTY users) can contact IMLS at 202–207–7858 via 711 for TTY-Based Telecommunications Relay Service.

SUPPLEMENTARY INFORMATION: The Institute of Museum and Library Services is the primary source of federal support for the nation's libraries and museums. We advance, support, and empower America's museums, libraries, and related organizations through grant-making, research, and policy development. To learn more, visit *www.imls.gov.*

Current Actions: This Notice proposes the renewal of the clearance of the Notice of Funding Opportunity for IMLS's Native American Library Services Enhancement Grants Program. The purpose of the program is to assist Native American tribes in improving core library services for their communities. IMLS recognizes that information needs and approaches to

meeting them are evolving at an unprecedented pace in all communities, and to operate within this environment effectively for the benefit of their users, libraries must be able to both strengthen existing services and move quickly to adopt new and emerging technologies.

The goals for this program are to improve digital services to support needs for education, workforce development, economic and business development, health information, critical thinking skills, and digital literacy skills; to improve educational programs related to specific topics and content areas of interest to library patrons and community-based users; and to enhance the preservation and revitalization of Native American cultures and languages.

The 60-day Notice was published in the **Federal Register** on August 22, 2023 (88 FR 57134–57135). The agency received no comments under this Notice.

Agency: Institute of Museum and Library Services.

Title: Native American Library Services Enhancement Grants Program Notice of Funding Opportunity.

OMB Control Number: 3137–0110.

Agency Number: 3137.

Affected Public: Federally Recognized Indian Tribes.

Total Number of Respondents: 40.

Frequency of Response: Once per request.

Average Hours per Response: 35 hours.

Total Burden Hours: 1,400 hours.

Total Annualized Capital/Startup Costs: n/a.

Total Annual Cost Burden: $40,992.

Total Annual Federal Costs: $1,744.

Dated: October 31, 2023.

Suzanne Mbollo,

Grants Management Specialist, Institute of Museum and Library Services.

[FR Doc. 2023–24419 Filed 11–3–23; 8:45 am]

BILLING CODE 7036–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Institute of Museum and Library Services

Submission for OMB Review, Comment Request, Proposed Collection: Native Hawaiian Library Services Grants Notice of Funding Opportunity

AGENCY: Institute of Museum and Library Services, National Foundation on the Arts and the Humanities.

ACTION: Submission for OMB Review, request for comments, collection of information.

SUMMARY: The Institute of Museum and Library Services announces that the following information collection has been submitted to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. This Notice proposes the renewal of the clearance of the Notice of Funding Opportunity for the Native Hawaiian Library Services Grants Program. A copy of the proposed information collection request can be obtained by contacting the individual listed below in the **FOR FURTHER INFORMATION CONTACT** section of this Notice.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section below on or before December 3, 2023.

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 particular information collection request by selecting ''Institute of Museum and Library Services'' under ''Currently Under Review;'' then check ''Only Show ICR for Public Comment'' checkbox. Once you have found this information collection request, select ''Comment,'' and enter or upload your comment and information. Alternatively, please mail your written comments to Office of Information and Regulatory Affairs, Attn.: OMB Desk Officer for Education, Office of Management and Budget, Room 10235, Washington, DC 20503, or call (202) 395–7316.

OMB is particularly interested in comments that help the agency to:

- 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).

FOR FURTHER INFORMATION CONTACT: Jennifer Himmelreich, Senior Program Officer, Office of Library Services, Institute of Museum and Library Services, 955 L'Enfant Plaza North SW, Suite 4000, Washington, DC 20024–2135. Ms. Himmelreich can be reached by telephone at 202–653–4797, or by email at *jhimmelreich@imls.gov.* Persons who are deaf or hard of hearing (TTY users) can contact IMLS at 202–207–7858 via 711 for TTY-Based Telecommunications Relay Service.

SUPPLEMENTARY INFORMATION: The Institute of Museum and Library Services is the primary source of federal support for the nation's libraries and museums. We advance, support, and empower America's museums, libraries, and related organizations through grant-making, research, and policy development. To learn more, visit *www.imls.gov.*

Current Actions: This Notice proposes the clearance of a Notice of Funding Opportunity for IMLS's Native Hawaiian Library Services Grants Program. The purpose of the program is to assist Native Hawaiian libraries in improving core library services for their communities. IMLS recognizes that information needs and approaches to meeting them are evolving at an unprecedented pace in all communities, and to operate within this environment effectively for the benefit of their users, libraries must be able to both strengthen existing services and move quickly to adopt new and emerging technologies.

The 60-day Notice was published in the **Federal Register** on August 22, 2023 (88 FR 57135–57136). The agency received no comments under this Notice.

Agency: Institute of Museum and Library Services.

Title: Native Hawaiian Library Services Grants Program Notice of Funding Opportunity.

OMB Control Number: 3137–0102.

Agency Number: 3137.

Affected Public: Nonprofit organizations that primarily serve and represent Native Hawaiians.

Total Number of Respondents: 8.

Frequency of Response: Once per request.

Average Hours per Response: 35 hours.

Total Burden Hours: 280 hours.
Total Annualized Capital/Startup Costs: n/a.
Total Annual Cost Burden: $8,199.
Total Annual Federal Costs: $348.72.

Dated: October 31, 2023.

Suzanne Mbollo,

Grants Management Specialist, Institute of Museum and Library Services.

[FR Doc. 2023–24420 Filed 11–3–23; 8:45 am]

BILLING CODE 7036–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 70–00143; NRC–2022–0097]

Nuclear Fuel Services, Inc.; U-Metal Project

AGENCY: Nuclear Regulatory Commission.

ACTION: Environmental assessment and finding of no significant impact; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing a finding of no significant impact (FONSI) and accompanying environmental assessment (EA) regarding the NRC's consideration of a license amendment request to amend a Special Nuclear Material (SNM) license, SNM–124, held by Nuclear Fuel Service, Inc. (NFS) at the NFS site located in Erwin, Tennessee. If approved, the amendment would authorize NFS to operate uranium purification and conversion services (U-Metal Project) at the NFS site, pursuant to a contract with the U.S. Department of Energy's National Nuclear Security Administration. Based on the EA, the NRC staff has concluded that there will be no significant impacts to environmental resources from the requested license amendment, and therefore, a FONSI is appropriate.

DATES: The EA and FONSI referenced in this document is available on November 6, 2023.

ADDRESSES: Please refer to Docket ID NRC–2022–0097 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0097. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section of this document.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Ashley Waldron, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–7317, email: *Ashley.Waldron@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is considering issuance of a license amendment request to amend NFS's part 70 of title 10 of the *Code of Federal Regulations* (10 CFR) SNM license, SNM–124. The license amendment would authorize a change to current operations to include a U-Metal Project at NFS's site located in Erwin, Tennessee. As required by 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,'' the NRC prepared an EA. Based on the results of the EA, the NRC has determined not to prepare an environmental impact statement (EIS) for the license amendment request and is issuing a FONSI.

NFS's 10 CFR part 70 license was originally issued by the Atomic Energy Commission to W.R. Grace and Company, Davison Chemical Division, on September 18, 1957. W.R. Grace and Company authorized initial facility operations with enriched uranium. Later, the license was transferred to NFS on December 31, 1963. The license was renewed on the following dates: November 5, 1965; January 27, 1978; March 16, 1979; June 9, 1992; and July 2, 1999. On August 9, 2012, the NRC renewed NFS's license SNM–124 for a period of 25 years, which will allow operations through 2037.

II. Environmental Assessment

Description of the Proposed Action

The proposed action is issuance of a license amendment to NFS's 10 CFR part 70 SNM license, SNM–124, to authorize construction and operation of the U-Metal Project at the NFS facility pursuant to a contract with the U.S. Department of Energy's National Nuclear Security Administration (NNSA).

The proposed action is described in the NFS's application and environmental report dated November 18, 2021, as supplemented by letters dated on March 7, 2022, and January 31, 2023.

Need for the Proposed Action

The proposed action is needed for NFS to maintain the ability to convert oxides to metal, provide a redundancy for the purification of uranium metals, and hedge against the technology risk associated with a new electrorefining facility.

Environmental Impacts of the Proposed Action

The NRC staff considered the potential impacts of the proposed action on land use, historical and cultural resources; visual and scenic resources; meteorology, climatology, and air quality; noise; geologic resource; water resources; ecological resources; socioeconomics; public and occupation health; transportation; environmental justice; and waste management. Given that construction would occur within the industrial facility footprint and within previous disturbed areas, and all other proposed activities would occur in an existing building, the activities associated with the proposed amendment would likely not alter any of the current characteristics of the site. Additionally, the proposed action would not result in significantly increased effluents. The proposed activities would not be expected to add to historical site contamination. Therefore, the proposed action would result in insignificant impacts and would not contribute to potential cumulative impacts when added to the past, present, or reasonably foreseeable future actions on the NFS site. Any future proposal to conduct NRC-regulated activities beyond the scope of the present license amendment would be evaluated, as appropriate, as part of

a separate licensing and environmental review.

Environmental Impacts of the Alternatives to the Proposed Action

As an alternative to the proposed action, the NRC staff considered denial of the proposed action (*i.e.,* the ''no-action'' alternative). Under the no-action alternative, the NRC would not amend the license to authorize construction and operation of new U-Metal Project at the NFS site. The NNSA would not have an option for conversion services to replace the legacy uranium processing equipment temporarily until the new electrorefining technology to purify high-enriched uranium metal is available, nor would NNSA have a redundancy for the purification of uranium metals.

Agencies and Persons Consulted

On March 29, 2023, the NRC staff provided a copy of the draft EA to the State of Tennessee Division of Radiological Health for its review and comment. In its May 4, 2023, email response, the State noted that it has no concerns regarding the environmental impact of the proposed action. The State official concurred with the EA and FONSI.

The NRC completed consultation under section 106 of the National Historic Preservation Act by consulting with the Tennessee State Historic Preservation Office and four Federally recognized Indian Tribes in correspondence dated September 13, 2022. In addition, the NRC staff, consulted with the U.S. Fish and Wildlife Service (FWS) and determined that the proposed action ''may affect, but not likely to adversely affect'' five threatened or endangered species, would have ''no effect'' on one additional species, and would have ''no effect'' on critical habitat. The NRC staff provided its effect determinations to FWS on August 18, 2023, and FWS concurred with those findings on September 28, 2023. Therefore, consultation has been completed under section 7 of the Endangered Species Act.

III. Finding of No Significant Impact

Based on its review of the license amendment request, in accordance with the requirements of 10 CFR part 51, the NRC staff has determined that issuing the requested amendment of SNM–124 to add the U-Metal Project would not significantly affect the quality of human environment. No significant radiological or non-radiological impacts are expected from the proposed action. Therefore, the NRC staff has determined that pursuant to 10 CFR 51.31, ''Determinations based on environmental assessment,'' preparation of an EIS is not required for the proposed action, and pursuant to 10 CFR 51.32, ''Finding of no significant impact,'' a FONSI is appropriate. In accordance with 10 CFR 51.32(a)(4), this FONSI incorporates the EA set forth in this notice by reference.

IV. Availability of Documents

The documents identified in the following table are available to interested persons through ADAMS.

Document description	ADAMS accession No.
Nuclear Fuel Services, License Amendment Application, dated November 18, 2021	ML21327A099.
Nuclear Fuel Services Supplemental Environmental Report, dated November 2021 and revised January 2023.	ML22066B005 and ML23041A236.
Tennessee Department of Environmental Quality email response NRC Request for Review of Draft EA, dated May 4, 2023.	ML23131A361.
Letter to Tennessee State Historic Preservation Office initiating consultation under Section 106 of the National Historic Preservation Act, dated September 13, 2022.	ML22098A154.
NRC letters to Tribal nations initiating consultation under Section 106 of the National Historic Preservation Act, dated September 13, 2022.	ML22256A146 (package).
Fish and Wildlife Service, Information for Planning and Consultation identifying Threatened or Endangered Species, dated June 6, 2023.	ML23202A166.
NRC letter to FWS regarding informal Section 7 consultation, determinations of effect, dated August 18, 2023.	ML23228A158.
Fish and Wildlife Service concurrence on NRC's determinations of effect, dated September 28, 2023	ML23272A109.
Final Environmental Assessment for NFS Proposed U-Metal Project, dated October 26, 2023	ML23299A062.

For the Nuclear Regulatory Commission.

Dated: October 31, 2023.

Michelle S. Rome,

Acting Chief, Environmental Review Materials Branch, Division of Rulemaking, Environmental, and Financial Support, Office of Nuclear Material Safety, and Safeguards.

[FR Doc. 2023–24408 Filed 11–3–23; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2024–29 and CP2024–29]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* November 7, 2023.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the Market Dominant or the Competitive product list, or the modification of an existing product currently appearing on the Market Dominant or the Competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the

Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern Market Dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern Competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2024–29 and CP2024–29; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 12 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 30, 2023; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* November 7, 2023.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2023–24375 Filed 11–3–23; 8:45 am]

BILLING CODE 7710–FW–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

POSTAL REGULATORY COMMISSION

[Docket No. C2023–6; Presiding Officer's Ruling No. 2]

Service Standard Changes

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is providing notice that a hearing and certain procedural events have been scheduled in this proceeding. This notice informs the public of the procedural schedule.

DATES: *Notices of intervention are due:* November 13, 2023; *Prehearing Videoconference:* December 4, 2023, at 1:00 p.m., Eastern Daylight Time, Virtual.

ADDRESSES: Submit notices of intervention electronically via the Commission's Filing Online system at *https://www.prc.gov.* Persons interested in intervening who cannot submit their views electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** David A. Trissell, General Counsel, at 202–789–6820. For additional information, Presiding Officer's Ruling No. 2 can be accessed electronically through the Commission's website at *https://www.prc.gov.*

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

I. Procedural Schedule
II. Additional Case Management Procedures
III. Ruling

I. Procedural Schedule

Intervention. The deadline to file a notice of intervention pursuant to 39 CFR 3010.142 is November 13, 2023.

Discovery. Pursuant to Order No. 6688, the Presiding Officer shall conduct limited discovery for the purpose of determining disputed issues of fact in this case.[1]

At the prehearing videoconference conducted on October 30, 2023, the parties agreed that the discovery process should go forward notwithstanding Complainant's two motions pending before the Commission.[2] After further discussion at the videoconference, Complainant indicated that he would file a notice on the Commission's docket withdrawing his motion for summary judgment without prejudice to refiling once the discovery process has been completed. Should the Commission grant the motion for reconsideration or otherwise expand the scope of the issues, the Presiding Officer will take appropriate action.

The parties may request that the Presiding Officer obtain specific discovery, but may not independently propound discovery on each other.

[1] Order Partially Denying United States Postal Service's Motion to Dismiss and Notice of Limited Formal Proceedings, September 18, 2023, at 8 (Order No. 6688).

[2] *See* Motion to Reconsider Order No. 6688, October 20, 2023; Motion for Oral Argument and Summary Judgment, October 30, 2023.

Order No. 6688 at 8. The parties shall email their initial information requests, encompassing both of the disputed issues of fact, to the Presiding Officer (and cc'ing the other party) no later than Monday, November 6, 2023, at 4:30 p.m.[3] The parties should attach their requests to the email in Microsoft Word format. These proposed information requests need not be filed on the Commission's public docket. Failure to submit an initial information request by the deadline without good cause may result in waiver of the party's right to request discovery in this case.

The Presiding Officer will serve information requests by filing them on the Commission's public docket. Answers to information requests, as well as any objections or claims of privilege, are due by the date and time specified in each information request. Although the Presiding Officer will initially review the proposed information requests and reserves the right to revise or reject any proposed questions on grounds such as relevance, the Presiding Officer's issuance of an information request should not be construed as considering or rejecting any objections or claims of privilege that could conceivably be raised. Procedures for raising good faith objections or claims of privilege, if any, will be set out in the Presiding Officer's information request.

Responses to information requests may be transmitted via email, with the Presiding Officer cc'ed, by the date and time due. Unless otherwise indicated, responses to discovery requests need not be filed on the Commission's public docket.

Further information requests submitted by the parties will be considered by the Presiding Officer only after the parties have submitted their responses to the initial information requests. Pursuant to 39 CFR 3010.170, the Presiding Officer may issue information requests on his own initiative, either independently or along with requests submitted by the parties. The parties are advised, however, that issuance of additional information requests will be considered on a case-by-case basis and is not guaranteed, particularly if the party could have requested the information sought in its initial information request.

Prehearing videoconference. A prehearing videoconference is scheduled to be conducted before the Presiding Officer on December 4, 2023, at 1:00 p.m. Among other things, this videoconference will discuss procedures for the presentation of

[3] All times in this Ruling are Eastern Time.

evidence and legal arguments, the need for any additional information requests, as well as the resolution of any pending discovery-related disputes. Additional prehearing conferences may be scheduled as needed.

Presentation of evidence. The issue of whether the hearing will involve the presentation of oral versus written testimony (including whether it may be appropriate to supplement written testimony with oral testimony for certain witnesses on particular issues in dispute) will be addressed more fully at the December 4, 2023, prehearing videoconference.

Hearing. The date on which the hearing of evidence shall begin will be addressed at the December 4, 2023, prehearing teleconference.

II. Additional Case Management Procedures

Good faith effort to confer. A good faith effort to confer with the opposing party requires at least the placing of one telephone call or the transmittal of one email message to the opposing party or its counsel.

Discovery motions. The parties must make a good faith effort to confer with the opposing party to attempt to resolve any discovery dispute before filing any motions related to discovery. The Presiding Officer will not entertain a motion to compel discovery, motion for sanctions, motion for protective order, or any other discovery motions until this good faith effort has been made. If this good faith effort is unsuccessful, the motion shall (1) state that a good faith effort has been made to resolve the dispute, (2) attach each disputed discovery request, answer, and objection (if applicable), (3) provide available dates and times for a hearing to be conducted by videoconference, and (4) concisely state the relief sought, the basis therefor, and the authority relied upon. Any party opposing the motion shall file a response no later than 7 days after the motion is filed. *See* 39 CFR 3010.160(b). No replies shall be permitted without express authorization of the Presiding Officer. *See* 39 CFR 3010.160(c). Failure to file a timely response may result in the motion being deemed unopposed. The Presiding Officer may decide the dispute based on the motion and any response, set a hearing to be conducted by videoconference, or order further briefing.

Extension of time or continuance. If either party seeks an extension of time or continuance, they must make a good faith effort to confer with the opposing party to determine a proposed mutually agreeable date before filing a motion. The motion must be filed before the specific deadline expires and shall state whether the other party opposes the motion. Extensions of time or continuances will only be granted for good cause shown.

Waiver or modification. If either party seeks to waive or modify the terms of any Presiding Officer's Ruling, the party must make a good faith effort to confer with the opposing party to determine a proposed mutually agreeable resolution before filing a motion. The Presiding Officer may waive or modify the terms of his order for good cause shown.

Oral argument. If either party requests to present oral argument before the Presiding Officer relating to any motion or brief, the party shall include ''ORAL ARGUMENT REQUESTED'' in the caption or title on page 1 of the applicable motion, response, or brief.

III. Ruling

1. The deadline to file a notice of intervention pursuant to 39 CFR 3010.142 is November 13, 2023.

2. A prehearing videoconference will be conducted before the Presiding Officer on December 4, 2023, at 1:00 p.m.

3. The parties and counsel shall follow the procedural schedule and case management procedures established by this Presiding Officer's Ruling.

4. The Secretary shall arrange for publication of the deadline to file a notice of intervention and the date of the prehearing videoconference in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2023–24380 Filed 11–3–23; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Sunshine Act Meetings

TIME AND DATE: Monday, November 13, 2023, at 1:00 p.m.; Tuesday, November 14, 2023, at 12:00 p.m.

PLACE: Washington, DC, at U.S. Postal Service Headquarters, 475 L'Enfant Plaza SW, in the Benjamin Franklin Room.

STATUS: Monday, November 13, 2023, at 1:00 p.m.—Closed. Tuesday, November 14, 2023, at 12:00 p.m.—Open.

MATTERS TO BE CONSIDERED:

Meeting of the Board of Governors

Monday, November 13, 2023, at 1:00 p.m. (Closed)

1. Strategic Issues
2. Financial and Operational Matters
3. Compensation and Personnel Matters
4. Executive Session
5. Administrative Items

Tuesday, November 14, 2023, at 12:00 p.m. (Open)

1. Remarks of the Chairman of the Board of Governors
2. Remarks of the Postmaster General and CEO
3. Approval of the Minutes
4. Committee Reports
5. Financial Matters
   a. FY2023 Annual Financial Report
   b. FY2023 10K and Financial Statements
   c. Annual Report to Congress
   d. FY2024 Integrated Financial Plan and Liquidity Outlook
   e. FY2025 Congressional Reimbursement Request
6. Quarterly Service Performance Report
7. Approval of Tentative Agenda for the February 8, 2024 Meeting
8. Election of the Chairman and Vice Chairman

A public comment period will begin immediately following the adjournment of the open session on November 14, 2023, and shall last no more than 40 minutes. During the public comment period, members of the public present at the meeting may comment on any item or subject listed on the agenda for the open session. Registration of speakers at the public comment period is required. Speakers must register online at *https://www.surveymonkey.com/r/bog-11-14-2023.* No more than 30 minutes of the public comment period shall be allotted to registered speakers present at the meeting, and no more than three minutes shall be allotted to each speaker. The time allotted to each speaker will be determined after registration closes. Registration to speak during the public comment period shall end on November 9 at noon ET. Additionally, a select number of written comments will be read in whole or in part during the public comment period for no more than 10 minutes. Written comments on any item or subject listed on the agenda for the open session may be submitted by United States Mail to the address below or to the email address *bog-inquiries@usps.gov.* If submitted by email, written comments must include a valid email address for the person submitting the comment and the words ''Public Comment Period'' in the subject line. Written comments must be received before November 9 at noon ET. Participation in the public comment period is governed by 39 CFR 232.1(n). The next public comment period is scheduled for November 2024.

CONTACT PERSON FOR MORE INFORMATION: Michael J. Elston, Secretary of the

Board, U.S. Postal Service, 475 L'Enfant Plaza SW, Washington, DC 20260–1000. Telephone: (202) 268–4800.

Michael J. Elston,

Secretary.

[FR Doc. 2023–24527 Filed 11–2–23; 11:15 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2:00 p.m. on Thursday, November 9, 2023.

PLACE: The meeting will be held via remote means and/or at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at *https://www.sec.gov.*

The General Counsel of the Commission, or her designee, has certified that, in her opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

The subject matter of the closed meeting will consist of the following topics:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Resolution of litigation claims; and

Other matters relating to examinations and enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting agenda items that may consist of adjudicatory, examination, litigation, or regulatory matters.

CONTACT PERSON FOR MORE INFORMATION: For further information; please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Authority: 5 U.S.C. 552b.

Dated: November 2, 2023.

J. Lynn Taylor,

Assistant Secretary.

[FR Doc. 2023–24636 Filed 11–2–23; 4:15 pm]

BILLING CODE 8011–01–P

DEPARTMENT OF STATE

[Public Notice: 12253]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: ''Dining with the Sultan: The Fine Art of Feasting'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to agreements with their foreign owners or custodians for temporary display in the exhibition ''Dining with the Sultan: The Fine Art of Feasting'' at the Los Angeles County Museum of Art, Los Angeles, California; the Detroit Institute of Arts, Detroit, Michigan; and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Reed Liriano, Program Coordinator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Nicole L. Elkon,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2023–24411 Filed 11–3–23; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 12254]

Notice of Determinations; Culturally Significant Object Being Imported for Exhibition—Determinations: Exhibition of a ''Volute Krater'' Object

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that a certain object being imported from abroad pursuant to an agreement with its foreign owner or custodian for temporary exhibition or display in the Department of Greek and Roman Art of The Metropolitan Museum of Art, New York, New York, and at possible additional exhibitions or venues yet to be determined, is of cultural significance, and, further, that its temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Reed Liriano, Program Coordinator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Nicole L. Elkon,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2023–24410 Filed 11–3–23; 8:45 am]

BILLING CODE 4710–05–P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 1331]

Snohomish County—Adverse Abandonment—GNP RLY, Inc., in Snohomish County, Wash.

On October 17, 2023, Snohomish County (the County), a noncarrier, filed

an application under 49 U.S.C. 10903 requesting that the Surface Transportation Board (the Board) authorize the third-party, or ''adverse,'' abandonment of an approximately 11.9-mile segment of a freight rail easement owned by GNP RLY, Inc. (GNP), and located between milepost 26.38 and milepost 38.25, in Snohomish County, Wash. (the Line or the Snohomish Segment of the Easement). The Line traverses U.S. Postal Service Zip Codes 98290, 98296, and 98072.

The County explains that in a series of transactions recorded on December 21, 2009, under the Board's line of precedent in *Maine, Department of Transportation—Acquisition & Operation Exemption—Maine Central Railroad,* 8 I.C.C.2d 835 (1991), BNSF Railway Company sold the physical assets of a rail line between milepost 23.8 in Woodinville, Wash., and milepost 38.25 in Snohomish, Wash., to the Port of Seattle (the Port); GNP acquired a permanent freight rail easement for the entirety of that rail line (the Easement); and GNP entered into an operations and maintenance agreement with the Port. The County states that the Easement is subject to a covenant, binding on all successors, requiring the holder of the Easement, upon cessation of rail service, either to seek voluntary abandonment authority and, upon request, to cooperate in railbanking the rail line pursuant to the National Trails System Act (Trails Act), 16 U.S.C. 1247(d), or to cooperate in an adverse abandonment proceeding and, upon request, railbanking of the rail line. According to the County, in 2015, it purchased the physical assets of the Snohomish Segment from the Port, and the City of Woodinville (Woodinville) purchased the physical assets of the segment of the rail line between milepost 23.8 and milepost 26.38 in Woodinville, Wash. (the Woodinville Segment).

The County notes that GNP was authorized to abandon the Woodinville Segment of the Easement in Docket No. AB 1316X, and GNP and Woodinville subsequently entered an interim trail use/railbanking agreement covering that segment. The County explains that it is now seeking adverse abandonment of the Snohomish Segment of the Easement so that segment can also be railbanked, as required by the covenant in the deed from BNSF to the Port creating the Easement and by a settlement agreement the County and GNP entered prior to the County filing its application. The County states that GNP supports and does not oppose the County's adverse abandonment application and agrees to cooperate with the County to pursue interim trail use/railbanking of the Line under the Trails Act.

In a decision served in this proceeding on May 23, 2023, the County was granted exemptions from several statutory provisions as well as waivers of certain Board regulations that the Board concluded were inapplicable and unneeded in connection with the County's anticipated application.

According to the County, the Line may contain federally granted rights of way. The County states that any documentation in its possession will be made available promptly to those requesting it. The County's entire case in chief for adverse abandonment was filed with the application.

The interests of railroad employees will be protected by the conditions set forth in *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979).

Any interested person may file comments concerning the proposed adverse abandonment or protests (including protestant's entire opposition case) by December 1, 2023. Persons who may oppose the proposed adverse abandonment but who do not wish to participate fully in the process by submitting verified statements of witnesses containing detailed evidence should file comments. Persons opposing the proposed adverse abandonment who wish to participate actively and fully in the process should file a protest, observing the filing, service, and content requirements of 49 CFR 1152.25. The County's reply is due by December 18, 2023.

Any request for an interim trail use/railbanking condition under 16 U.S.C. 1247(d) and 49 CFR 1152.29 must be filed by December 1, 2023,[1] and should address whether the issuance of a certificate of interim trail use or abandonment in this case would be consistent with the grant of an adverse abandonment application.

All pleadings, referring to Docket No. AB 1331, should be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on the County's representative, Charles H. Montagne, 426 NW 162nd Street, Seattle, WA 98177. Except as otherwise set forth in 49 CFR part 1152, every document filed with the Board must be served on all parties to this adverse abandonment proceeding 49 CFR 1104.12(a).

A Draft Environmental Assessment (EA) (or environmental impact statement (EIS), if necessary) prepared by the Board's Office of Environmental Analysis (OEA) will be served upon all parties of record and upon any agencies or other persons who commented during its preparation. Any other persons who would like to obtain a copy of the Draft EA (or EIS) may contact OEA by phone at the number listed below. Draft EAs normally will be made available within 33 days of the filing of the application, and the deadline for submission of comments on the Draft EA will generally be within 30 days of its service. The comments received will be addressed in a Final EA (or EIS) and the Board's decision. A Supplemental Final EA (or EIS) may be issued where appropriate.

Persons seeking further information concerning abandonment procedures may contact the Board's Office of Public Assistance, Governmental Affairs, and Compliance at (202) 245–0238 or refer to the full abandonment regulations at 49 CFR part 1152. Questions concerning environmental issues may be directed to OEA at (202) 245–0305. If you require an accommodation under the Americans with Disabilities Act, please call (202) 245–0245.

Board decisions and notices are available at *www.stb.gov*.

Decided: November 1, 2023.

By the Board, Mai T. Dinh, Director, Office of Proceedings.

Tammy Lowery,

Clearance Clerk.

[FR Doc. 2023–24479 Filed 11–3–23; 8:45 am]

BILLING CODE 4915–01–P

[1] Filing fees for interim trail use/railbanking requests can be found at 49 CFR 1002.2(f)(27).

TRADE AND DEVELOPMENT AGENCY

Extension of the Agency's Current Approval for Information Collection

AGENCY: United States Trade and Development Agency.

ACTION: Notice of information collection; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the U.S. Trade and Development Agency's (USTDA's) intention to request an extension for a currently approved information collection for Evaluation of USTDA Performance. USTDA invites the public and other Federal agencies to comment on the proposed extension of USTDA's current approval for information collection. All comments received will

be available for public inspection during regular business hours.

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

ADDRESSES: To access and review all of the documents related to the data collection listed in this notice, please use *http://www.regulations.gov* by searching the agency name. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* or via postal mail, commercial delivery, or hand delivery. All submissions received must include the agency name. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Administrative Officer, U.S. Trade and Development Agency, 1101 Wilson Blvd., Suite 1100, Arlington, VA 22209–3901.

FOR FURTHER INFORMATION CONTACT: Contact Sheneé Turner, Administrative Officer, Attn: PRA, U.S. Trade and Development Agency, 1101 Wilson Blvd., Suite 1100, Arlington, VA 22209–3901; Tel.: (703) 875–4357, Fax: (703) 775–4037; Email: *comments@ustda.gov*.

SUPPLEMENTARY INFORMATION: Comments are invited on: (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) 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 the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Summary Collection Under Review

Type of Request: Extension of a currently approved information collection.

Expiration Date of Previous Approval: 01/31/2024.

Title: Evaluation of USTDA Performance.

Form Number: USTDA 1000E–2014a.

Frequency of Use: Annually for duration of projects.

Type of Respondents: Business or other for profit; not-for-profit institutions; farms; Federal, State, and local government.

Estimated Number of Responses: 1,000 to 1,300 per year.

Estimated Total Annual Burden on Respondents: 334 to 434 hours per year.

Federal Cost: $402,523.

Authority for Information Collection: Government Performance and Results Act of 1993 Public Law 103–62 or GPRA; 107 Stat. 285, the Foreign Aid Transparency and Accountability Act (Pub. L. 114–191) or FATAA, the Information Quality Act (IQA) of 2000 (Pub. L. 106–554), and Foundations for Evidence-Based Policymaking Act of 2018 Public Law 115–435.

Abstract: USTDA will collect information from various stakeholders on USTDA-funded activities regarding development and/or commercial benefits as well as evaluate success regarding GPRA objectives and support evidence-based policymaking.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

Dated: October 31, 2023.

Sheneé Turner,

Administrative Officer.

[FR Doc. 2023–24426 Filed 11–3–23; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2023–2211]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Identification of Foreign-Registered Civil Unmanned Aircraft Operating in the United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The collection involves identifying information regarding foreign-registered civil unmanned aircraft operated in the airspace of the United States. The information to be collected will be used to associate a foreign-registered unmanned aircraft operating in the United States with Remote Identification to the unmanned aircraft operator.

DATES: Written comments should be submitted by January 5, 2024.

ADDRESSES: Please send written comments:

By Electronic Docket: www.regulations.gov (Enter docket number into search field)

By mail: Benjamin Walsh, FAA Flight Standards Service, Emerging Technologies Division, AFS–700, 800 Independence Ave SW, Washington, DC 20591

FOR FURTHER INFORMATION CONTACT: Benjamin Walsh by email at: *ben.walsh@faa.gov;* phone: 202–267–8233

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0782.

Title: Identification of Foreign-Registered Civil Unmanned Aircraft Operating in the United States.

Form Numbers: N/A.

Type of Review: Renewal of an information collection.

Background: The unmanned aircraft remote identification operating requirements in title 14 Code of Federal Regulations, part 89 apply to persons operating foreign civil unmanned aircraft in the United States. The FAA must be able to correlate the remote identification message elements broadcast by foreign civil unmanned aircraft operated in the United States against information that helps FAA and law enforcement identify a person responsible for the operation of the foreign civil unmanned aircraft. Where unmanned aircraft are registered in a foreign jurisdiction, the FAA may not have access to information regarding the unmanned aircraft or its registered owner. Thus, the FAA is allowing a person to operate foreign-registered civil unmanned aircraft with remote identification in the United States only if the person submits a notice of identification to the Administrator in accordance with title 14 Code of Federal Regulations § 89.130. The notice can be submitted online using the notice of identification form in FAA Drone Zone (*https://faadronezone.faa.gov/*). The

notice includes the following information to allow FAA to associate an unmanned aircraft to a responsible person:

(1) An indication whether the person operating the foreign registered civil unmanned aircraft in the United States is an organization or an individual.

(2) The name of the person operating the foreign registered civil unmanned aircraft in the United States, and, if applicable, the person's authorized representative.

(3) The physical address of the person operating the foreign registered civil unmanned aircraft in the United States, and, if applicable, the physical address for the person's authorized representative. If the operator or authorized representative does not receive mail at the physical address, a mailing address must also be provided.

(4) The telephone number(s) where the person operating the foreign registered civil unmanned aircraft in the United States, and, if applicable, the person's authorized representative can be reached while in the United States.

(5) The email address of the person operating the foreign registered civil unmanned aircraft in the United States, and, if applicable, the email address of the person's authorized representative.

(6) An indication whether the unmanned aircraft is a standard remote identification unmanned aircraft or has a remote identification broadcast module.

(7) The unmanned aircraft manufacturer and model name.

(8) The serial number of the unmanned aircraft or remote identification broadcast module.

(8) The country of registration of the unmanned aircraft.

(10) The registration number.

Once a person submits an online notice of identification, the FAA will issue a confirmation of identification. A person operating a foreign-registered unmanned aircraft in the United States must maintain the confirmation of identification at the unmanned aircraft's control station and must produce it when requested by the FAA or a law enforcement officer.

The holder of a confirmation of identification must ensure the information provided under § 89.130(a) remains accurate and is updated prior to operating a foreign registered civil unmanned aircraft with remote identification in the United States. The confirmation of identification expires after one year and can be cancelled or renewed online at FAA Drone Zone.

Respondents: Operators of foreign-registered civil unmanned aircraft with remote identification, as needed (prior to operating in the airspace of the United States) are mandated to report information to this collection. The FAA uses information provided by operators of foreign-registered civil unmanned aircraft operating in the airspace of the United States to identify those aircraft.

Frequency: As needed prior to operation of a foreign-registered civil unmanned aircraft in the United States.

Estimated Average Burden per Response: 6 minutes per response.

Estimated Total Annual Burden: 6 minutes per respondent, 797 hours per year total for all respondents.

Issued in Washington, DC on November 1, 2023.

Joseph Morra,

Manager, Emerging Technologies Division, AFS–700.

[FR Doc. 2023–24427 Filed 11–3–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2023–0002–N–27]

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of information collection; request for comment.

SUMMARY: Under the Paperwork Reduction Act of 1995 (PRA) and its implementing regulations, FRA seeks approval of the Information Collection Request (ICR) summarized below. Before submitting this ICR to the Office of Management and Budget (OMB) for approval, FRA is soliciting public comment on specific aspects of the activities identified in the ICR.

DATES: Interested persons are invited to submit comments on or before January 5, 2024.

ADDRESSES: Written comments and recommendations for the proposed ICR should be submitted on *regulations.gov* to the docket, Docket No. FRA–2023–0002. All comments received will be posted without change to the docket, including any personal information provided. Please refer to the assigned OMB control number (2130–0564) in any correspondence submitted. FRA will summarize comments received in a subsequent 30-day notice and include them in its information collection submission to OMB.

FOR FURTHER INFORMATION CONTACT: Ms. Arlette Mussington, Information Collection Clearance Officer, at email: *arlette.mussington@dot.gov* or telephone: (571) 609–1285 or Ms. Joanne Swafford, Information Collection Clearance Officer, at email: *joanne.swafford@dot.gov* or telephone: (757) 897–9908.

SUPPLEMENTARY INFORMATION: The PRA, 44 U.S.C. 3501–3520, and its implementing regulations, 5 CFR part 1320, require Federal agencies to provide 60-days' notice to the public to allow comment on information collection activities before seeking OMB approval of the activities. *See* 44 U.S.C. 3506, 3507; 5 CFR 1320.8 through 1320.12. Specifically, FRA invites interested parties to comment on the following ICR regarding: (1) whether the information collection activities are necessary for FRA to properly execute its functions, including whether the activities will have practical utility; (2) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (3) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (4) ways for FRA to minimize the burden of information collection activities on the public, including the use of automated collection techniques or other forms of information technology. *See* 44 U.S.C. 3506(c)(2)(A); 5 CFR 1320.8(d)(1).

FRA believes that soliciting public comment may reduce the administrative and paperwork burdens associated with the collection of information that Federal regulations mandate. In summary, comments received will advance three objectives: (1) reduce reporting burdens; (2) organize information collection requirements in a ''user-friendly'' format to improve the use of such information; and (3) accurately assess the resources expended to retrieve and produce information requested. *See* 44 U.S.C. 3501.

The summary below describes the ICR that FRA will submit for OMB clearance as the PRA requires:

Title: Locomotive Crashworthiness.

OMB Control Number: 2130–0564.

Abstract: Under 49 CFR part 229, subpart D, FRA prescribes minimum crashworthiness standards for certain locomotives. These crashworthiness standards are intended to help protect locomotive cab occupants in the event of a train collision or derailment. FRA uses this collection of information to ensure railroads operate locomotives that meet the prescribed minimum performance standards and design load

requirements for newly manufactured and re-manufactured locomotives.

In this 60-day notice, FRA makes adjustments that decrease the previously approved estimated total annual burden hours from 507 hours to 407 hours. These estimate adjustments reflect that FRA anticipates a decrease in the annual petition submissions for approval of substantive and non-substantive changes to locomotive crashworthiness design standards and alternative design standards under the following sections:

- Under § 229.207(c), FRA is decreasing the estimated annual burden hours by 33.50 hours.
- Under § 229.207(d), FRA is decreasing the estimated annual burden hours by 33.50 hours.
- Under § 229.209(b), FRA is decreasing the estimated annual burden hours by 33.50 hours.

Type of Request: Extension without change (with changes in estimates) of a currently approved collection.

Affected Public: Businesses/Public/Interested Parties.

Form(s): N/A.

Respondent Universe: 783 railroads, 4 locomotive manufacturers.

Frequency of Submission: On occasion; one-time.

REPORTING BURDEN

CFR Section	Respondent universe	Total annual responses (A)	Average time per responses (B)	Total annual burden hours (C = A * B)	Total cost equivalent in U.S. dollar (D = C * wage rates) [1]
229.207(b)—Petitions for FRA approval of new locomotive crashworthiness design standards.	783 railroads 4 locomotive manufacturers.	2.00 petitions	50 hours	100.00	$8,593.00
—(c) Petition for FRA approval of substantive changes to FRA-approved locomotive crashworthiness design standard.	783 railroads 4 locomotive manufacturers.	0.33 petition	50 hours	16.50	1,417.85
—(d) Petition for FRA approval of non-substantive changes to existing FRA approved locomotive crashworthiness design standard.	783 railroads 4 locomotive manufacturers.	0.33 petition	50 hours	16.50	1,417.85
229.209(b)—Alternative locomotive crashworthiness designs—Petition for FRA approval.	783 railroads 4 locomotive manufacturers.	0.33 petition	50 hours	16.50	1,417.85
229.211(b)(3)—Processing petitions—Additional information for FRA to appropriately consider the petition.	783 railroads 4 locomotive manufacturers.	1.00 hearing	24 hours	24.00	2,062.32
229.213(a)(3)—Locomotive manufacturing information: retention by railroads.	783 railroads	500 records/stickers/badge plates.	2 minutes	16.67	1,432.45
229.215—(a) Retention and inspection of designs—Retention of records—Original designs.	4 locomotive manufacturers.	24 locomotive records	8 hours	192.00	16,498.56
—(b) Repairs and modifications—Records	783 railroads	6 locomotive crashworthiness modification/repair records.	4 hours	24.00	2,062.32
—(c) Inspection of records	783 railroads	20 records	2 minutes	0.67	57.57
Total [2]	783 railroads	554 responses	N/A	407	34,960

Total Estimated Annual Responses: 554.

Total Estimated Annual Burden: 407 hours.

Total Estimated Annual Burden Hour Dollar Cost Equivalent: $34,960.

FRA informs all interested parties that it may not conduct or sponsor, and a respondent is not required to respond to, a collection of information that does not display a currently valid OMB control number.

[1] The dollar equivalent cost is derived from the 2022 Surface Transportation Board Full Year Wage A&B data series using employee group 200: (Professional & Administrative), hourly wage rate of $49.10. The total burden wage rate (straight time plus 75%) used in the table is $85.93 ($49.10 × 1.75 = $85.93).

[2] Totals may not add up due to rounding.

Authority: 44 U.S.C. 3501–3520.

Christopher S. Van Nostrand,

Acting Deputy Chief Counsel.

[FR Doc. 2023–24450 Filed 11–3–23; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2023–0076]

Pipeline Safety: Information Collection Activities

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, PHMSA invites public comments about PHMSA's intention to request Office of Management and Budget (OMB) approval to renew six information collections that are scheduled to expire in 2024. PHMSA has reviewed each information collection and considers them vital to maintaining pipeline safety. As such, PHMSA will request renewal from OMB, without change, for each information collection.

DATES: Interested persons are invited to submit comments on or before January 5, 2024.

ADDRESSES: Comments may be submitted in the following ways:

E-Gov Website: http://www.regulations.gov. This site allows the public to submit comments on any **Federal Register** notice issued by any agency.

Fax: 1–202–493–2251.

Mail: Docket Management Facility; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590–0001.

Hand Delivery: Room W12–140 on the ground level of DOT, West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9:00 a.m. and 5:00 p.m. ET, Monday through Friday, except Federal holidays.

Instructions: Identify the docket number, PHMSA–2023–0076, at the beginning of your comments. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. You should know that anyone is able to search the electronic form of all comments received into 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.). Therefore, you may want to review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000, (65 FR 19477) or visit *http://www.regulations.gov* before submitting any such comments.

Docket: For access to the docket or to read background documents or comments, go to *http://www.regulations.gov* at any time or to Room W12–140 on the ground level of DOT, West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9:00 a.m. and 5:00 p.m. ET, Monday through Friday, except Federal holidays. If you wish to receive confirmation of receipt of your written comments, please include a self-addressed, stamped postcard with the following statement: ''Comments on: PHMSA–2023–0076.'' The Docket Clerk will date stamp the postcard prior to returning it to you via the U.S. mail. Please note that due to delays in the delivery of U.S. mail to Federal offices in Washington, DC, we recommend that persons consider an alternative method (internet, fax, or professional delivery service) of submitting comments to the docket and ensuring their timely receipt at DOT.

Privacy Act Statement: DOT may solicit comments from the public regarding certain general notices. 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.*

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 notice 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 notice, it is important that you clearly designate the submitted comments as CBI. Pursuant to 49 CFR 190.343, you may ask PHMSA to give confidential treatment to information you give to the Agency by taking the following steps: (1) mark each page of the original document submission containing CBI as ''Confidential''; (2) send PHMSA, along with the original document, a second copy of the original document with the CBI deleted; and (3) explain why the information you are submitting is CBI. Unless you are notified otherwise, PHMSA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this notice. Submissions containing CBI should be sent to Angela Hill, DOT, PHMSA, 1200 New Jersey Avenue SE, PHP–30, Washington, DC 20590–0001. Any commentary PHMSA receives that is not specifically designated as CBI will be placed in the public docket for this matter.

FOR FURTHER INFORMATION CONTACT: Angela Hill by telephone at 202–366–1246 or by email at *Angela.Hill@dot.gov.*

SUPPLEMENTARY INFORMATION: Title 5, Code of Federal Regulations (CFR) section 1320.8(d), requires PHMSA to provide interested members of the public and affected agencies the opportunity to comment on information collection and recordkeeping requests before they are submitted to OMB for approval. This notice identifies six information collection requests that PHMSA will submit to OMB for renewal and requests comment from interested parties. The information collections (including their expiration dates) are as follows: (1) OMB control number 2137–0625, Pipeline Safety: Integrity Management Program for Gas Distribution Pipelines (5/31/2024); (2) OMB control number 2137–0632, Post-Accident Drug Testing for Pipeline Operators (8/31/2024); (3) OMB control number 2137–0048, Recordkeeping Requirements for Liquefied Natural Gas (LNG) Facilities (11/30/2024); (4) OMB control number 2137–0594, Customer-Owned Service Lines (11/30/2024); (5) OMB control number 2137–0618, Periodic Underwater Inspection and Notification of Abandoned Underwater Pipelines (11/30/2024); and (6) OMB control number 2137–0634, Recordkeeping for Underground Natural Gas Storage Facilities (11/30/2024).

The following information is provided for these information collections: (1) Title of the information collection; (2) OMB control number; (3) Current expiration date; (4) Type of request; (5) Abstract of the information collection activity; (6) Description of affected public; (7) Estimate of total annual reporting and recordkeeping burden; and (8) Frequency of collection.

PHMSA will request a three-year term of approval for each of the following information collection activities. PHMSA requests comments on the following information:

1. *Title:* Pipeline Safety: Integrity Management Program for Gas Distribution Pipelines.

OMB Control Number: 2137–0625.

Current Expiration Date: 5/31/2024.

Type of Request: Renewal with no change of a currently approved collection.

Abstract: The Federal Pipeline Safety Regulations require operators of gas distribution pipelines to develop and implement integrity management (IM) programs. The purpose of these programs is to enhance safety by identifying and reducing pipeline integrity risks. PHMSA requires that operators maintain records demonstrating compliance with these requirements for 10 years and that these records must include superseded IM plans.

Affected Public: Operators of gas distribution pipeline systems.

Annual Reporting and Recordkeeping Burden:

Estimated number of responses: 3,882.

Estimated annual burden hours: 723,192.

Frequency of collection: On occasion.

2. *Title:* Post-Accident Drug Testing for Pipeline Operators.

OMB Control Number: 2137–0632.

Current Expiration Date: 8/31/2024.

Type of Request: Renewal with no change of a currently approved information collection.

Abstract: Pursuant to 49 CFR 199.227, operators are required to maintain records of its alcohol misuse prevention program. The post-accident drug testing for pipeline operators information

collection pertains specifically to 49 CFR 199.227(b)(4), that requires operators to maintain records of decisions not to administer post-accident employee alcohol tests for a minimum of three years. Operators must make those records available to PHMSA upon request.

Affected Public: Operators of PHMSA-regulated pipelines.

Annual Reporting and Recordkeeping Burden:

Total Annual Responses: 609.

Total Annual Burden Hours: 1,218.

Frequency of Collection: On occasion.

3. *Title:* Recordkeeping Requirements for Liquefied Natural Gas Facilities.

OMB Control Number: 2137–0048.

Current Expiration Date: 11/30/2024.

Type of Request: Renewal with no change of a currently approved information collection.

Abstract: Pursuant to the Federal Pipeline Safety Regulations, liquefied natural gas facility operators are required to maintain records, make reports, and provide information regarding their liquefied natural gas facilities to PHMSA upon request.

Affected Public: Operators of liquefied natural gas facilities.

Annual Reporting and Recordkeeping Burden:

Estimated number of responses: 40,400.

Estimated annual burden hours: 12,120.

Frequency of Collection: On occasion.

4. *Title:* Customer-Owned Service Lines.

OMB Control Number: 2137–0594.

Current Expiration Date: 11/30/2024.

Type of Request: Renewal with no change of a currently approved information collection.

Abstract: Pursuant to 49 CFR 192.16, operators of gas service lines who do not maintain their customers' buried piping between service lines and building walls or gas utilization equipment are required to send written notices to their customers prescribing the proper maintenance of these gas lines and of the potential hazards of not properly maintaining these gas lines. Operators also must maintain records that include a copy of the notice currently in use and evidence that notices were sent to customers within the previous three years. The purpose of the collection is to provide PHMSA with adequate information about how customer-owned service lines are being maintained to prevent the potential hazards associated with not maintaining the lines. Examples of sufficient notification include a prepared notification with the customer's bill.

Affected Public: State and local governments.

Annual Reporting and Recordkeeping Burden:

Estimated number of responses: 550,000.

Estimated annual burden hours: 9,167.

Frequency of Collection: On occasion.

5. *Title:* Periodic Underwater Inspection and Notification of Abandoned Underwater Pipelines.

OMB Control Number: 2137–0618.

Current Expiration Date: 11/30/2024.

Type of Request: Renewal with no change of a currently approved information collection.

Abstract: The Federal Pipeline Safety Regulations at 49 CFR 192.612 and 49 CFR 195.413 require operators of pipelines in the Gulf of Mexico and its inlets in waters less than 15 feet (4.6 meters) deep to conduct periodic underwater inspections to determine whether the pipelines are exposed underwater pipelines or pose a hazard to navigation. If an operator discovers that its underwater pipeline is exposed or poses a hazard to navigation, among other remedial actions, the operator must contact the National Response Center by telephone within 24 hours of discovery and report the location of the exposed pipeline or hazardous pipeline.

PHMSA's regulations for reporting the abandonment of underwater pipelines can be found at 49 CFR 192.727 and 49 CFR 195.59. These provisions contain certain requirements for disconnecting and purging abandoned pipelines and require operators to notify PHMSA of each abandoned offshore pipeline facility and each abandoned onshore pipeline facility that crosses over, under, or through a commercially navigable waterway.

Affected Public: Operators of pipeline facilities.

Annual Reporting and Recordkeeping Burden:

Estimated number of responses: 92.

Estimated annual burden hours: 1,372.

Frequency of collection: On occasion

6. *Title:* Recordkeeping for Underground Natural Gas Storage Facilities.

OMB Control Number: 2137–0634.

Current Expiration Date: 11/30/2024.

Type of Request: Renewal with no change of a currently approved information collection.

Abstract: The Federal Pipeline Safety Regulations at 49 CFR 192.12 require operators of underground natural gas storage facilities to maintain documentation and provide information to PHMSA upon request. Examples of the required records include operations and maintenance procedures, results of required tests, records of inspections and repairs, and notifications to the public.

Affected Public: Operators of underground natural gas storage facilities.

Annual Reporting and Recordkeeping Burden:

Estimated number of responses: 136.

Estimated annual burden hours: 220.

Frequency of Collection: On occasion.

Comments are invited on:

(a) The need for the renewal and revision of these collections of information for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(b) The accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(d) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; and 49 CFR 1.48.

Issued in Washington, DC, under authority delegated in 49 CFR 1.97.

John A. Gale,

Director, Standards and Rulemaking Division.

[FR Doc. 2023–24445 Filed 11–3–23; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

[Docket No. DOT–OST–2023–0166]

Transportation Services for Individuals With Disabilities: ADA Standards for Transportation Facilities

AGENCY: Department of Transportation (DOT).

ACTION: Request for information on accessibility improvements for transportation facilities.

SUMMARY: The U.S. Department of Transportation (DOT, or Department) is considering whether to amend the accessibility requirements for transportation facilities under the Americans with Disabilities Act of 1990 (ADA) currently contained in Appendix A to DOT's regulations governing transportation services for individuals with disabilities. The Department may consider whether to improve access beyond the minimum standards established by the U.S. Access Board

and Appendix A. The Department seeks suggestions from all transportation stakeholders—including transportation agencies, transportation riders (particularly those with disabilities), community members, advocacy groups, planning officials, States, cities, researchers and technology companies, and the private sector—on enhancements that the Department could consider with regard to the ADA standards for transportation buildings and facilities. The Department specifically seeks feedback on areas including, but not limited to vertical access, communications, and wayfinding. The Department also invites comment on any other aspects of the current accessibility requirements for transportation facilities under the ADA contained in DOT's regulations governing transportation services for individuals with disabilities.

DATES: Comments should be submitted on or before January 5, 2024. DOT will consider comments filed after this date to the extent practicable.

ADDRESSES: You may file comments identified by docket number DOT–OST–2023–0166 by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov* and follow the online instructions for submitting comments.
- *Mail:* Docket Operations, 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 9:00 a.m. and 5:00 p.m. ET, Monday through Friday, except Federal holidays.
- *Fax:* (202) 493–2251.

All submissions received must include the agency name and docket number DOT–OST–2023–0166. All comments received will be posted without change to *www.regulations.gov,* including any personal information provided. For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

For access to the docket to read background documents or comments received, go to *www.regulations.gov* at any time and search for docket number DOT–OST–2023–0166.

FOR FURTHER INFORMATION CONTACT: For general questions, Holly Ceasar-Fox, DOT Office of General Counsel, (202) 366–7420 or *holly.ceasarfox@dot.gov.* For program questions related to transit, John Day, FTA Office of Civil Rights, (202) 366–1671 or *john.day@dot.gov.* For legal questions related to transit, Bonnie Graves, FTA Office of Chief Counsel, (202) 366–0944 or *bonnie.graves@dot.gov.* For questions related to intercity or high-speed rail, Alana Kuhn, FRA Office of Chief Counsel, (202) 493–0842 or *alana.kuhn@dot.gov.*

SUPPLEMENTARY INFORMATION:

Background

42 U.S.C. 12204 requires the Architectural and Transportation Barriers Compliance Board (Access Board) to issue minimum guidelines for accessibility under Titles II & III of the ADA. The ADA statute at 42 U.S.C. 12149 requires the Secretary of Transportation to develop and implement regulations for certain public transportation facilities, vehicles, and services consistent with the Access Board's guidelines. The Secretary may issue regulations that result in greater accessibility than the minimum guidelines established by the Access Board.

The current guidelines were developed nearly a quarter century ago and adopted as regulatory standards by the Department in 2006.[1] The Department's experience administering these minimum standards for the past two decades suggests that they have resulted in greater accessibility than the standards [2] that preceded them, but in many cases extra efforts may still be required on the part of people with disabilities to enter and use a facility. For example, accessible entrances may be located in isolated locations away from entrances used by members of the general public who do not require an accessible entrance, and persons with sensory disabilities may need to rely on information on a message board at station entrances while other members of the general public are informed via public address systems. In other cases, persons unable to navigate staircases may be faced with lengthy ramps to cross from one rail platform to another. Such continuing barriers may mean that many wheelchair users and persons with sensory, cognitive, or processing disabilities remain dependent on paratransit or private transportation rather than being able to use integrated fixed route service.

There have also been many developments such as advances in technology since the standards were last updated, and the Department is considering both physical access to and usability of facilities by persons with sensory, cognitive, and other disabilities. The Department strives to provide for equitable access to persons with disabilities similar to that available to people without disabilities, including the usability of the facility, so that persons with disabilities are able to access and navigate public transit with the same ease, reliability, and independence as any other user.

Complaints filed by the public, feedback from the disability community, observations of and information gathered by Departmental employees (with and without disabilities), media articles, and the results of the Department's oversight activities have led the Department to solicit feedback on the current standards. For some disabilities, such as those affecting hearing, vision, or cognitive function, the Department is aware of technological advancements (for example, induction loops and mobile device applications), that would help persons with those disabilities navigate the transportation system with ease and independence. The Department is interested in learning more about these technologies. For other disabilities, such as those affecting mobility, the Department seeks feedback regarding, for example, minimum standards that rely on a single point of access that creates a situation where a single point of failure renders an entire facility inaccessible and unusable by persons with disabilities, while access to nondisabled persons is unaffected. The Department is interested in learning how transportation facilities can be designed and constructed such that accessibility features are resilient and always available. The Department also seeks input to assist it in understanding the magnitude of potential access issues that may exist in transportation facilities and therefore requests any available information and comments stakeholders may have on the number of all end-users, not limited to users with disabilities, who would benefit from specific standards in 49 CFR part 37 that may be improved or implemented.

In addition to learning about specific standards in 49 CFR part 37 that may be improved or implemented, the Department is interested in the end-user experience generally. These include experiences in transportation facilities related to vertical access, communication, wayfinding, or any other aspects of transportation facilities that represent barriers for people with disabilities. The Department will consider the extent to which the

[1] The Access Board published a Notice of Proposed Rulemaking in the **Federal Register** on November 16, 1999, and issued the Final Rule on July 23, 2004. The Department of Justice adopted the standards on September 15, 2010.

[2] The standards adopted by the Department on September 6, 1991, were in effect until 2006.

Department has authority under the ADA to remove such barriers.

Through this request for information (RFI), the Department seeks input as it considers whether to revise the existing DOT ADA requirements for transportation buildings and facilities including public transportation and intercity rail transportation (including Amtrak). The Department poses seven questions below and looks forward to feedback from all interested parties.

Vertical Access

1. It has become increasingly apparent that elevator maintenance and reliability are a critical component of ensuring the accessibility of a multi-level transportation facility such as subway and rail stations. While the existing DOT ADA regulations require accessibility features to be maintained in working order, repairs can be complex and many entities do not have employees with the skillset necessary to repair an elevator or the necessary components readily available, which can add a level of difficulty to the repair process.[3] Thus, unreliable elevators create operational and administrative burdens for entities covered by DOT's ADA regulations and can render transportation facilities inaccessible for users for extended durations. The Department is interested in learning about standards that would ensure elevator reliability in transportation facilities.

2. Elevators that are frequently out of service significantly impact the ability of persons who cannot negotiate stairs to use such transportation services. As a result, the Department understands that many agencies involved in the construction or alteration of stations initially plan for two or more elevators per bank instead of just one, so that the station is not rendered inaccessible when one elevator requires maintenance or repair. Despite planners' intentions, budgetary considerations often result in the minimum legally required (not just for accessibility), which means only a single elevator is provided. The Department seeks public input on the impacts of the installation, for future construction and alterations, of at least two elevators in transportation facilities, or a combination of ramps and elevators, where currently one elevator is required.

3. Many commuter and intercity rail stations rely on long switch-back ramps to provide an accessible route between platforms on either side of the tracks, or to multiple platforms within a station. These ramps, which can be hundreds of feet long, often present a barrier to persons who cannot negotiate steps, but also cannot travel the distances required to traverse the ramp. However, the simplicity of a non-mechanical ramp means that maintenance costs are relatively low and repairs are few and far between, unlike more complex elevators. The Department is seeking comment on the use of elevators in lieu of ramps in transportation facilities, or a single elevator in addition to the ramp, if the vertical distance or ramp length exceeds a certain threshold, including information on an appropriate threshold.

Communications

4. The Department of Justice's current ADA standards for buildings and facilities contain provisions requiring assistive listening systems in assembly areas. *See* 28 CFR 35.151(c)(3); 36 CFR pt. 1191, app. B at 344. The Department seeks comment on the feasibility of extending such requirements to transportation facilities such as rail stations to enable real-time announcements for persons who are deaf or hard of hearing or because of their disability rely on text-based communications to access information. Current requirements for transportation facilities stipulate only that the same information provided audibly must be provided visually. This often takes the form of messages written on a dry-erase board in the station entrance by personnel or information relayed directly to the passenger by personnel, which prevents the transmission of real-time announcements that often relate to service changes or safety/security matters, forces passengers who are deaf or hard of hearing to identify themselves, is not reliable at larger stations with multiple entrances, and is not possible at unstaffed stations. The Department is aware that induction loop technology is in use in some stations, enabling those with a T-coil in their hearing aids to receive messages directly, but seeks comment on how widespread this technology is used among deaf and hard of hearing persons. The Department also seeks comment on other technologies that may provide the same benefit to the same or a larger audience at transportation facilities, such as real-time text-messaging.

5. The Department also seeks comment on other means by which the content of audible announcements of the type typically relayed by public address systems at transportation facilities can be provided in real-time in a visual format, such as changeable electronic message boards, as well as information pertaining to the number and placement of necessary displays throughout a station environment, including spacing, scale, and frequency.

6. In addition, the Department seeks comment on technologies that can provide an audible component to information currently displayed in visual format at transportation facilities. For example, many transit systems and intercity stations use changeable electronic message displays to communicate information about the next train scheduled to arrive at a station, such as the line, number of cars, and estimated time of arrival. Most such systems lack an audible component to make this information accessible to individuals who are blind or have low vision. What commercially available technologies might be appropriate for deployment in a transit, Amtrak, or commuter rail station environment to convey information provided visually in an audible format? How should such information be broadcast? Would an interface with a smart device be appropriate or sufficient, or should an audible component be provided directly on the station's display device?

Wayfinding

7. The Department seeks comment on technologies to enable effective wayfinding within the transit station, intercity and commuter rail station environments for persons who are blind or have low vision, and to accommodate neurodiversity (*e.g.,* autism, intellectual disability, etc.). The Department is aware of technologies capable of real-time transcription of speech and those involving the use of Bluetooth beacons that interface with smart devices and seeks comment on the usability of such systems from the end-user perspective. The Department is also interested in alternative technologies that may be available, potentially without the use of handheld devices, and the acceptance of technologies that do rely on such devices within the general community of persons who are blind, have low-vision, and/or are neurodiverse.

General

In addition, the Department invites comment on all other areas of the current DOT ADA standards, found in Appendix A to 49 CFR part 37, which govern rail stations and stops of all types, bus stops and transfer stations, landside facilities, office buildings housing transit agency personnel,

[3] The Department recognizes that many elevator manufacturers require that only their employees work on the elevator, and that there are examples of arrangements where the third-party repair person is available 7 days a week, 24 hours per day, but the Department is also aware of arrangements where same-day, after hours, weekend, or holiday service is not guaranteed (or is charged at a premium).

conference facilities of the type often employed for board meetings and public hearings, businesses housed in transit facilities, and individual elements such as track crossings, ramps, parking lots and structures, fare vending machines and collection equipment, and accessible paths of travel. If the public has information on how these standards do or do not currently support equitable access, please submit comments to the docket for this rulemaking activity.

All interested parties are encouraged to respond to this RFI. Submissions are strictly voluntary. Individuals or entities responding to this RFI should state their role as well as knowledge of and experience with the ADA in a transportation environment. DOT may request additional clarifying information from any or all respondents. If a respondent does not wish to be contacted by DOT for additional information, a statement to that effect should be included in the response. All information submitted should be unclassified and should not contain proprietary information, as it will be posted to *www.regulations.gov* without changes.

DOT is not obligated to officially respond to the information received, but the responses will assist DOT in its consideration of whether to revise the ADA standards for transportation buildings and facilities.

Comments may be submitted and viewed at Docket No. DOT–OST–2023–0166 at *https://www.regulations.gov.*

Signed pursuant to authority delegated at 49 CFR 1.27(a) on October 31, 2023.

Subash S. Iyer,

Acting General Counsel, Department of Transportation.

[FR Doc. 2023–24422 Filed 11–3–23; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. DOT–OST–2023–0161]

Notice of Rights and Protections Available Under the Federal Antidiscrimination and Whistleblower Protection Laws

AGENCY: Department of Transportation—Office of the Secretary.

ACTION: No FEAR Act notice.

SUMMARY: This Notice implements Title II of the Notification and Federal Employee Antidiscrimination and Retaliation Act of 2002 (No FEAR Act of 2002). In doing so, the Department of Transportation notifies all employees, former employees, and applicants for Federal employment of the rights and protections available to them under the Federal Anti-discrimination and Whistleblower Protection Laws.

FOR FURTHER INFORMATION CONTACT: Yvette Rivera, Associate Director, Equity and Access Division (S–32), Departmental Office of Civil Rights, Office of the Secretary, Department of Transportation, 1200 New Jersey Avenue SE, Room W78–306, Washington, DC 20590, 202–366–5131 or by email at *Yvette.Rivera@dot.gov.*

SUPPLEMENTARY INFORMATION:

Electronic Access

You may retrieve this document online through the Federal Document Management System at *http://www.regulations.gov.* Electronic retrieval instructions are available under the help section of the website.

No FEAR Act Notice

On May 15, 2002, Congress enacted the ''Notification and Federal Employee Antidiscrimination and Retaliation Act of 2002,'' now recognized as the No FEAR Act (Pub. L. 107–174). The No FEAR Act was amended on January 1, 2021, by the ''Elijah E. Cummings Federal Employee Antidiscrimination Act of 2020,'' now recognized as the Cummings Act. One purpose of the No FEAR Act, which was strengthened by the Cummings Act, is to ''require that Federal agencies be accountable for violations of antidiscrimination and whistleblower protection laws.'' (Pub. L. 107–174, Summary). In support of this purpose, Congress found that ''agencies cannot be run effectively if those agencies practice or tolerate discrimination.'' (Pub. L. 107–174, Title I, General Provisions, section 101(1)). The No FEAR Act also requires the Department of Transportation (DOT) to issue this Notice to all DOT employees, former DOT employees, and applicants for DOT employment. This Notice informs such individuals of the rights and protections available under Federal antidiscrimination and whistleblower protection laws.

Antidiscrimination Laws

A Federal agency cannot discriminate against an employee or applicant with respect to the terms, conditions, or privileges of employment because of race, color, religion, sex, gender identity, sexual orientation, pregnancy, national origin, age, disability, marital status, genetic information, political affiliation, or in retaliation for a protected activity. One or more of the following statutes prohibit discrimination on these bases: 5 U.S.C. 2302(b)(1), 29 U.S.C. 631, 29 U.S.C. 633a, 29 U.S.C. 206(d), 29 U.S.C. 791, 42 U.S.C. 2000e–16, 2000ff, 2000gg.

If you believe you have experienced unlawful discrimination on the bases of race, color, religion, sex, gender identity, sexual orientation, pregnancy, national origin, age, retaliation, genetic information, and/or disability and wish to pursue a legal remedy, you must contact a DOT Equal Employment Opportunity (EEO) counselor within 45 calendar days of the alleged discriminatory action, or in the case of a personnel action, within 45 calendar days of the effective date of the action. A directory of DOT EEO counselors is available on the DOT Departmental Office of Civil Rights website at *http://www.transportation.gov/civil-rights;* you can also contact the Departmental Office of Civil Rights by phone at 202–366–4648 for more information. Once you contact the EEO counselor, you will be offered the opportunity to resolve the matter through the informal complaint process; if you are unable to resolve the matter through the informal complaint process, you can file a formal complaint of discrimination with DOT (see, *e.g.,* 29 CFR part 1614). Parties who complete the informal complaint process are provided with an electronic Individual Complaint of Employment Discrimination Form. The form can be submitted electronically at *https://secure.dot.gov/form/eeoc* or by email at *Patricia.Fields@dot.gov.* You may also contact the EEO Complaints and Investigations Division, Departmental Office of Civil Rights by phone at 202–366–9370 or by email at *DOCR_CMB@dot.gov* if you need additional assistance.

If you believe you experienced unlawful discrimination based on age, you must either contact an EEO counselor as noted above or file a civil action in a United States District Court under the Age Discrimination in Employment Act against the head of the alleged discriminating agency. If you choose to file a civil action, you must give notice of intent to sue to the Equal Employment Opportunity Commission (EEOC) within 180 days of the alleged discriminatory action, and not less than 30 days before filing a civil action. You may file such notice in writing with the EEOC via mail at P.O. Box 77960, Washington, DC 20013, the EEOC Public Portal at *https://www.eeoc.gov/employees/charge.cfm,* hand delivery at 131 M St. NE, Washington, DC 20507, or Fax at 202–663–7022.

If you are alleging unlawful discrimination based on marital status or political affiliation, you may file a written discrimination complaint with the U.S. Office of Special Counsel (OSC)

using Form OSC–14. Form OSC–14 can be submitted electronically at the OSC website *http://www.osc.gov,* under the tab ''File a Complaint.'' You also have the option to call the Case Review Division at 1–800–872–9855 for additional assistance. In the alternative (or in some cases, in addition), you may pursue a discrimination complaint by filing a grievance through the DOT administrative or negotiated grievance procedures, if such procedures apply and are available.

If you are alleging unlawful compensation discrimination pursuant to the Equal Pay Act and wish to pursue your allegations through the administrative process, you must contact an EEO counselor within 45 calendar days of the alleged discriminatory action, as such complaints are processed under EEOC's regulations at 29 CFR part 1614. Alternatively, you can file a civil action in a court of competent jurisdiction within two years, or if the violation is willful, three years of the date of the alleged violation, regardless of whether you pursued any administrative complaint processing. The filing of a complaint or appeal pursuant to 29 CFR part 1614 shall not toll the time for filing a civil action.

Whistleblower Protection Laws

A DOT employee with authority to take, direct others to take, recommend, or approve any personnel action must not use that authority to take, or fail to take, or threaten to take a personnel action against an employee or applicant because of a disclosure of information by that individual that is reasonably believed to evidence violations of law, rule, or regulation; gross mismanagement; gross waste of funds; an abuse of authority; or a substantial and specific danger to public health or safety, unless the disclosure of such information is specifically prohibited by law and such information is specifically required by Executive Order to be kept secret in the interest of national defense or the conduct of foreign affairs.

Retaliation against a DOT employee or applicant for making a protected disclosure is prohibited (5 U.S.C. 2302(b)(8)). If you believe you are a victim of whistleblower retaliation, you may file a written complaint with the U.S. Office of Special Counsel using Form OSC–14. Form OSC–14 can be filed electronically at *http://www.osc.gov.* You may also contact the DOT Office of Inspector General Hotline by phone at 1–800–424–9071, by fax at 202–366–7749, by email at *hotline@oig.dot.gov,* online at *https://www.oig.dot.gov/hotline,* or by mail at 1200 New Jersey Avenue SE, West Bldg 7th Floor, Washington, DC 20590.

Retaliation for Engaging in Protected Activity

A Federal agency cannot retaliate against an employee or applicant because that individual exercises their rights under any of the Federal antidiscrimination or whistleblower protection laws listed above. If you believe that you are the victim of retaliation for engaging in protected activity, you must follow, as appropriate, the procedures described in the Antidiscrimination Laws and Whistleblower Protection Laws sections or, if applicable, the administrative or negotiated grievance procedures in order to pursue any legal remedy.

Disciplinary Actions

Under existing laws, DOT retains the right, where appropriate, to discipline a DOT employee who engages in conduct that is inconsistent with Federal Antidiscrimination and Whistleblower Protection laws up to and including removal from Federal service. If DOT takes an adverse action under 5 U.S.C. 7512 against an employee for a discriminatory act, it must include a notation of the adverse action and the reason for the action in the employee's personnel record. If OSC initiates an investigation under 5 U.S.C. 1214, DOT must seek approval from the Special Counsel to discipline employees for, among other activities, engaging in prohibited retaliation (5 U.S.C. 1214). Nothing in the No FEAR Act alters existing laws or permits an agency to take unfounded disciplinary action against a DOT employee, or to violate the procedural rights of a DOT employee accused of discrimination.

Additional Information

For more information regarding the No FEAR Act regulations, refer to 5 CFR part 724, as well as the appropriate office(s) within your agency (*e.g.,* EEO/civil rights offices, human resources offices, or legal offices). You can find additional information regarding Federal antidiscrimination, whistleblower protection, and retaliation laws at the EEOC website at *http://www.eeoc.gov* and the OSC website at *http://www.osc.gov.*

Existing Rights Unchanged

Pursuant to section 205 of the No FEAR Act, neither the No FEAR Act nor this notice creates, expands, or reduces any rights otherwise available to any employee, former employee, or applicant under the laws of the United States, including the provisions of law specified in 5 U.S.C. 2302(d).

Issued in Washington, DC, on October 26, 2023.

Irene Marion,

Director, Departmental Office of Civil Rights, U.S. Department of Transportation.

[FR Doc. 2023–24446 Filed 11–3–23; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Bureau of Transportation Statistics

Agency Information Collection: Activity Under OMB Review; Electric Vehicle Inventory and Use Survey (eVIUS)

AGENCY: Bureau of Transportation Statistics (BTS), Office of the Assistant Secretary for Research and Technology (OST–R), DOT.

ACTION: Notice and Request for Comments.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act of 1995, this notice announces the intention of the Bureau of Transportation Statistics (BTS) to request the Office of Management and Budget's (OMB) approval of a new information collection related to the nation's battery electric vehicles (BEVs) and plug-in hybrid electric vehicles (PHEVs)—collectively referred to electric vehicles (EVs). The information collected will be used to produce national statistics on the characteristics and uses of EVs as well as the charging patterns and preferences related to EVs. A summary report of survey findings will also be published by BTS on the BTS web page: *www.bts.gov.*

DATES: Send comments on or before December 6, 2023.

FOR FURTHER INFORMATION CONTACT: Jina Mahmoudi, VIUS/eVIUS Program Manager, (800) 853–1351, *eVIUS@dot.gov,* BTS, OST–R, Department of Transportation, 1200 New Jersey Ave. SE, Room E34–471, Washington, DC 20590. Office hours are from 8 a.m. to 5:30 p.m., E.T., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: Electric Vehicle Inventory and Use Survey (eVIUS).

Type of Request: Approval for a new information collection.

Affected Public: Registered owners of battery electric vehicles (BEVs) and plug-in hybrid electric vehicles (PHEVs).

Background: As the pace of electric vehicles' adoption and use increases on the nation's roadways, the U.S.

Department of Transportation (U.S. DOT)'s Bureau of Transportation Statistics (BTS) is planning to conduct the first national-level Electric Vehicle Inventory and Use Survey (eVIUS). The eVIUS will be conducted to gain an in-depth understanding of the characteristics, usage, and charging patterns of electric vehicles (EVs) as well as the demographics and charging preferences of EV owners. The data collected through eVIUS will inform policy and planning decisions on future transportation systems and infrastructure investments.

The survey will be administered to owners of a nationally representative sample of battery electric vehicles (BEVs) and plug-in hybrid electric vehicles (PHEVs). The survey scope will be inclusive of passenger cars and light-duty vehicles (up to 10,000 pounds).

As there is no existing national-level data source for EV use and charging patterns, the eVIUS will provide valuable data and information that can assist transportation professionals and other stakeholders at the federal, state, and local levels to decipher the characteristics and usage of the EVs being driven on US roadways, as well as the charging preferences and needs of EV owners. The national-level data will inform policy and planning decisions related to EV charging infrastructure in the US, thereby leading to increased mobility, safety, air quality, and equity on the nation's roadways.

Data Confidentiality Provisions: This will be a voluntary data collection. A summary report of aggregate findings will be published on the BTS web page at *www.bts.gov,* and no individual and company's information or names will be included in the published reports. The Bureau of Transportation Statistics, its employees and agents, will use the information provided by respondents for statistical purposes only and will hold individuals' information in confidence to the full extent permitted by law. In accordance with the Confidential Information Protection and Statistical Efficiency Act of 2002 (Title 5 of Pub. L. 107–347) and the Foundations for Evidence-Based Policymaking Act of 2018 (Title 3 of Pub. L. 115–435) along with other applicable Federal laws, no responses will not be disclosed in an identifiable form without the respondent's informed consent. Per the Federal Cybersecurity Enhancement Act of 2016, Federal information systems are protected from malicious activities through cybersecurity screening of transmitted data.

Frequency: One time.

Estimated Average Burden per Response: The burden per respondent is estimated to be an average of 16 minutes (0.27 hours). This estimation is based on pre-test surveys conducted (with an average respondent burden of 15 minutes) plus an additional minute to account for log in time.

Estimated Total Annual Burden: Based on an estimated average burden of 0.27 hours per respondent and a 30% response rate, the total annual burden is estimated to be in the range of 4,050 hours (for a minimum number of 50,000 respondents) and 12,150 hours (for a maximum number of 150,000 respondents).

Response to Comments: A 60-day notice requesting public comment was issued in the **Federal Register** on March 9, 2023 (88 FR 14667, page 14667–14668, published 03/09/2023). Three comments were received by BTS in response to the 60-day public notice. The BTS' responses to those comments are provided below:

BTS' Response to Comment 1 (from The Association for the Work Truck Industry (NTEA):

For this initial round of eVIUS, BTS would like to focus on light-duty electric vehicles (EVs). The reasons for this decision are:

- According to the International Energy Agency, the light-duty EV is becoming a fast-growing mode of transportation as EV sales are increasing substantially, and the electric vehicle (BEVs and PHEVs) sales in the United States increased 55% in 2022 reaching a sales share of 8%. Since the light-duty EVs (*e.g.,* passenger cars) comprise the majority of EV population, to aid determination of charging infrastructure gaps and inform policy decisions, it is essential to collect timely data on use and charging patterns of EVs as currently there is no existing source of such data and national statistics;
- Vehicles using the other suggested alternative fuels (*i.e.,* hydrogen fuel cell, propane, natural gas and other possible future methods of propulsion) are operated differently from EVs. Consequently, expansion of the scope of the eVIUS to include these vehicles would require adding many questions to the survey questionnaire to measure the characteristics and use of such vehicles. This will greatly increase the complexity and length of the survey questionnaire and add to the respondent burden;
- Further, adding other alternatively fueled vehicles in the eVIUS survey would require inclusion of an adequate number of such vehicles in the sample frame, which will increase the sample size and potentially reduce the overall survey estimation precision, and add to the time and budget required for data collection. As alternatively fueled vehicles comprise a small proportion of the entire vehicle population in the U.S., producing robust statistics will be a challenge due to a small population size, which leads to an inadequate sample size.

The eVIUS sample frame is the states' vehicle registration data; therefore, any EVs registered in the states have a chance to be sampled and included in the sample frame—*i.e.,* government-owned fleets (federal, state, local) will not be actively excluded. The eVIUS survey questionnaire includes multiple-choice questions that ask respondents about the ownership type and usage purpose of the vehicle—allowing them to select options that indicate if the vehicle is a government-owned vehicle (state or local) and if the vehicle is used for a government business purpose.

Since increasing the eVIUS scope to include alternatively fueled vehicles would result in the data collection operation schedule and the respondent burden considerations becoming less flexible, it is not a feasible option for this first round of eVIUS as BTS intends to produce timely data (within one year). BTS is considering a future data collection specific to the other alternatively fueled vehicles, depending on availability of funds.

BTS' Response to Comment 2 (from Alliance for Automotive Innovation):

A multiple-choice format has been used for the eVIUS as suggested.

The survey includes questions related to vehicle background and type of use, home base, miles traveled, long-distance travel, general charging behavior and needs, as well as demographics—capturing information for most of the proposed targeted questions.

BTS' Response to Comment 3 (from The National Automobile Dealers Association (NADA)):

The eVIUS sample frame has been expanded to include owners of plug-in hybrid electric vehicles (PHEVs) as suggested. For this initial round of eVIUS, BTS will focus on light-duty EVs due to reasons previously outlined (please see ''BTS' Response to Comment 1'' above). BTS is considering future data collections focusing on vehicles above 10,000 pounds, depending on availability of funds.

A multiple-choice format has been used for the eVIUS as suggested.

A draft survey was not provided in the sixty-day notice (88 FR 14667). The survey questionnaire was developed and finalized in collaboration with subject matter experts and stakeholders. In addition, subject matter experts from

various agencies/organizations, including academia, have provided BTS with suggestions for survey questions. These suggestions were carefully considered, and where appropriate, incorporated into the survey questionnaire.

To test question understanding and clarity of instructions, a pre-test of the draft survey was also conducted with participation of five EV owners. Following completion of the survey, one hour long cognitive interviews were conducted with each of the pre-testers to collect information on their survey experience and other feedback for improving the survey. Overall, the pre-testers reported that the survey was clear, and they did not have any major issues with understanding the survey questions/instructions.

Public Comments Invited: Interested parties are invited to send comments regarding any aspect of this information collection, including, but not limited to: (1) the necessity and utility of the information collection for the proper performance of the functions of the DOT; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, clarity and content of the collected information; and (4) ways to minimize the collection burden without reducing the quality of the collected information.

Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725–17th Street NW, Washington, DC 20503, Attention: BTS Desk Officer.

Issued in Washington, DC, on 3rd of October, 2023.

Cha-Chi Fan,

Director, Office of Data Development and Standards, Bureau of Transportation Statistics, Office of the Assistant Secretary for Research and Technology.

[FR Doc. 2023–24397 Filed 11–3–23; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Bureau of Transportation Statistics

[Docket Number OST–2023–0115]

Agency Information Collection Activity; Notice of Request for Approval To Collect New Information: Safe Maritime Transportation System (SafeMTS)—Voluntary Near-Miss Incident Reporting and Analysis System

AGENCY: Bureau of Transportation Statistics (BTS), Office of the Assistant Secretary for Research and Technology (OST–R), U.S. Department of Transportation.

ACTION: 30-Day notice of new information collection and request for comments.

SUMMARY: On August 8, 2023, the Bureau of Transportation Statistics (BTS) announced its intention in a **Federal Register** Notice to request that the Office of Management and Budget (OMB) approve the following information collection: SafeMTS—Voluntary Near-Miss Reporting and Analysis System, a voluntary program for confidential reporting of 'near-misses' occurring on vessels within the Maritime Transportation System (MTS). BTS encouraged interested parties to submit comments to docket number 2023–0115 during the 60-day comment period. One comment was received, from the National Transportation Safety Board (NTSB) expressing the agency's support for such a program.

DATES: Written comments should be submitted within 30 days of publication of this notice.

ADDRESSES: BTS seeks public comments on its proposed information collection. Comments should address whether the information will have practical utility; the accuracy of the estimated burden hours of the proposed information collection, ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology. Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725–17th Street NW, Washington, DC 20503, Attention: BTS Desk Officer.

FOR FURTHER INFORMATION CONTACT: Allison Fischman, Bureau of Transportation Statistics, Office of the Assistant Secretary for Research and Technology, USDOT, Office of Safety Data and Analysis, RTS–34 E36–303, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, Phone No. (202) 748–0546; email: *allison.fischman@dot.gov.*

Data Confidentiality Provisions: The confidentiality of the Safe Maritime Transportation System (SafeMTS) data is protected under the Confidential Information Protection and Statistical Efficiency Act (CIPSEA) of 2018 (Pub. L.: 115–435 Foundations for Evidence-Based Policymaking Act of 2018, Title III of the Foundations for Evidence-Based Policymaking Act of 2018). In accordance with CIPSEA, only aggregated and non-identifying data will be made publicly available by BTS through its reports for statistical purposes only. BTS will not release information that might reveal the identity of individuals or organizations mentioned in event notices or reports without explicit consent of the respondent and any other affected entities.

SUPPLEMENTARY INFORMATION: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on August 8, 2023 at 88 FR 53594.

Title: Near-Miss Reporting and Analysis Program for the Maritime Transportation System.

OMB Control Number: Not yet known.

Type of Review: New collection.

Respondents: Businesses in the maritime industry that involve ownership or operation of vessels.

Estimated Number of Respondents: 100, submitted on a quarterly basis.

Estimated Time per Response: 1 hour.

Total Annual Burden: 400 hours.

Allison Fischman,

Acting Director, Office of Safety Data and Analysis.

[FR Doc. 2023–24467 Filed 11–3–23; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0342]

Agency Information Collection Activity: Application and Training Agreement for Apprenticeship and On-the-Job Training Programs

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before January 5, 2024.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System

(FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0342'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20420, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0342'' in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA'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 respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: 10 U.S.C. 16131(d), 16136, and section 510 of chapter 31, 38 U.S.C. 3034(a)(1), 3241(a)(1), 3323(a), 3534(a), 3671, 3672, 3687(a), 38 CFR 21.4150(c), 21.4261(b) and (c), 21.5250(a), 21.7220(a), 21.7720, and Section 903 of Public Law 96–342.

Title: Application and Training Agreement for Apprenticeship and On-the-Job Training Programs, VA Forms 22–8864 and 22–8865.

OMB Control Number: 2900–0342.

Type of Review: Revision of a currently approved collection.

Abstract: The Training Agreement, VA Form 22–8864 is no longer being submitted to VA, therefore it no longer needs an OMB approval. VA mostly requires employers with OJT or Apprenticeship programs approved for VA benefits to provide a training agreement to prospective Veterans using VA benefits while training with their company. The 22–8864 has always been an option for these employers to use if they didn't have their own training agreement or use one from their state department of labor. Employers used to submit a copy of the VA Form 22–8864 or their own as a condition of the Veteran receiving VA benefits. The employer is still required to provide a training agreement to their trainees, but VA no longer collects it as a condition of paying EDU benefits.

The Employer's Application to Provide Job Training, VA Form 22–8865 (or the equivalent tool provided by the SAAs) is used to ensure that training programs meet the statutory and regulatory requirements for approval.

Affected Public: Individuals and Households.

Estimated Annual Burden: 1,710 hours.

Estimated Average Burden Time per Respondent: 90 minutes.

Frequency of Response: Once.

Estimated Number of Respondents: 1,140.

By direction of the Secretary:

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2023–24443 Filed 11–3–23; 8:45 am]

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FEDERAL REGISTER

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Part II

Securities and Exchange Commission

17 CFR Parts 232 and 240
Volume-Based Exchange Transaction Pricing for NMS Stocks; Proposed Rule

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 232 and 240

[Release No. 34–98766; File No. S7–18–23]

RIN 3235–AN29

Volume-Based Exchange Transaction Pricing for NMS Stocks

AGENCY: Securities and Exchange Commission.

ACTION: Proposed rule.

SUMMARY: The Securities and Exchange Commission (''Commission'') is proposing a new rule under the Securities Exchange Act of 1934 (''Exchange Act'') to prohibit national securities exchanges from offering volume-based transaction pricing in connection with the execution of agency-related orders in certain stocks. If exchanges offer such pricing for their members' proprietary orders, the proposal would require the exchanges to adopt rules and written policies and procedures related to compliance with the prohibition, as well as disclose, on a monthly basis, certain information including the total number of members that qualified for each volume tier during the month.

DATES: Comments should be received on or before January 5, 2024.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/2023/10/feetiers*); or
- Send an email to *rule-comments@sec.gov.* Please include file number S7–18–23 on the subject line.

Paper Comments

- Send paper comments to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number S7–18–23. 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 of submission. The Commission will post all comments on the Commission's website (*https://www.sec.gov/rules/proposed.shtml*). Comments are also available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Operating conditions may limit access to the Commission's Public Reference Room. Do not include personal information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright.

Studies, memoranda, or other substantive items may be added by the Commission or staff to the comment file during this rulemaking. A notification of the inclusion in the comment file of any materials will be made available on the Commission's website. To ensure direct electronic receipt of such notifications, sign up through the ''Stay Connected'' option at *www.sec.gov* to receive notifications by email.

A summary of the proposal of not more than 100 words is posted on the Commission's website (*https://www.sec.gov/rules/2023/10/feetiers*).

FOR FURTHER INFORMATION CONTACT: Richard Holley III, Assistant Director, Yvonne Fraticelli, Special Counsel, Terri Evans, Special Counsel, or Julia Zhang, Special Counsel, at (202) 551–5500, Office of Market Supervision, Division of Trading and Markets, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

SUPPLEMENTARY INFORMATION: The Commission is proposing to add new 17 CFR 240.6b–1 (Rule 6b–1 under the Exchange Act) and amend 17 CFR 232.101 (Rule 101 of Regulation S–T) and 17 CFR 232.405 (Rule 405 of Regulation S–T).

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I. Introduction

A. Background

National securities exchanges (''exchanges'') that trade NMS stocks [1] maintain pricing schedules that set forth the transaction pricing they apply to their broker-dealer members [2] that execute orders on their trading platforms.[3] As self-regulatory organizations under the Exchange Act, exchanges are subject to unique principles and processes that do not apply to other businesses.[4] For example, all proposed rules of an exchange,[5] including exchange transaction pricing proposals, must be filed with the Commission.[6] In addition, pricing schedules must be publicly posted on the exchange's website.[7]

The Exchange Act further requires that exchange pricing proposals, among other things, provide for the ''equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities'' [8] that ''are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers'' [9] and ''do not impose any burden on competition not necessary or appropriate in furtherance of the purposes of'' the Exchange Act.[10] With respect to the requirement that the rules of an exchange not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act, the Senate Banking, Housing and Urban Affairs Committee report that accompanied the 1975 amendments to the Exchange Act stated that ''this paragraph is designed to make clear that a balance must be struck between regulatory objectives and competition, and that unless an interference with competition is justified in terms of the achievement of a statutory objective, it cannot stand.'' [11]

Section 11A of the Exchange Act [12] directs the Commission to facilitate the establishment of a national market system in accordance with specified Congressional findings. Among the Congressional findings are assuring (i) fair competition among brokers and dealers and among exchange markets, and (ii) the practicability of brokers executing investors' orders in the best market.[13] Rather than setting forth minimum components of the national market system, the Exchange Act grants the Commission broad authority to oversee the implementation, operation, and regulation of the national market system consistent with Congressionally determined goals and objectives.[14]

B. Volume-Based Exchange Transaction Pricing

As part of its ongoing efforts to assess whether aspects of the national market system continue to meet the statutory goals and objectives as markets and market participants evolve, the Commission is considering the impact of volume-based exchange transaction pricing in NMS stocks. Many exchanges use increasingly complex transaction pricing schedules that feature differentiated incentives (*e.g.,* lower fees or higher rebates) that depend on member volume.[15] These exchanges

[1] *See* 17 CFR 242.600(b)(55) (defining ''NMS stock'').

[2] Exchange rules limit their membership to registered brokers or dealers. *See, e.g.,* Cboe BZX Exchange, Inc. (''Cboe BZX'') Rule 2.3.

[3] This release uses the term ''price'' or ''pricing'' to refer to the fees (charges incurred for an execution), rebates (refundable credits in connection with an execution), and other incentives (*e.g.,* discounts or caps that are not refundable credits but are credited to the member's billing account) that exchanges assess to their members for transactions on the exchange. Rebates are refundable because they can exceed the fees (transaction fees and other fees) that members incur. *See, e.g.,* Remarks of Chris Concannon, Cboe Global Markets, before the SEC Roundtable on Market Data Products, Market Access Services, and Their Associated Fees, Oct. 25, 2018, Transcript at 74–75, available at *https://www.sec.gov/spotlight/equity-market-structure-roundtables/roundtable-market-data-market-access-102518-transcript.pdf* (''Five out of the top 10 get a check from us after the costs of their connectivity and market data. So we are cutting them a check monthly after their costs.'') (''Remarks of Chris Concannon'').

[4] *See, e.g.,* 15 U.S.C. 78f and 78s.

[5] *See* 15 U.S.C. 78c(a)(27) (defining ''rules'') and 17 CFR 240.19b–4(c) (providing further information on the phrase ''stated policies, practices, and interpretations'').

[6] *See* 15 U.S.C. 78s(b). Exchange pricing proposals are effective immediately upon filing with the Commission because the Exchange Act does not require advance notice or Commission approval before an exchange may implement a pricing change. 15 U.S.C. 78s(b)(3)(A)(ii). Within 60 days after the date of filing of an immediately effective proposal, the Commission may summarily temporarily suspend the proposal if it appears to the Commission that a suspension is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Exchange Act. *See* 15 U.S.C. 78s(b)(3)(C). If the Commission suspends the proposal, the Commission will institute proceedings under section 19(b)(2)(B) (15 U.S.C. 78s(b)(2)(B)) of the Exchange Act to determine whether the proposal should be approved or disapproved. *See* 15 U.S.C. 78s(b)(3)(C). At the conclusion of the proceedings, the Commission shall approve a proposal if it finds that it is consistent with the requirements of the Exchange Act, or it shall disapprove the proposal if it does not make such a finding. *See* 15 U.S.C. 78s(b)(2)(C). If the Commission does not suspend an immediately effective filing on or before the sixtieth day after the filing date, the Exchange Act does not deem the proposal to have been approved by the Commission. *See* 15 U.S.C. 78s(b)(2)(D) (providing when a proposed rule change shall be deemed to have been approved by the Commission).

[7] *See* 17 CFR 240.19b–4(m).

[8] 15 U.S.C. 78f(b)(4).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78f(b)(8).

[11] Securities Acts Amendments of 1975, Report of the Senate Comm. on Banking, Housing and Urban Affairs to Accompany S.249, S. Rep. No. 94–75, 94th Cong., 1st Sess. 11 (1975), at 96 (''Senate Report'').

[12] 15 U.S.C. 78k–1.

[13] 15 U.S.C. 78k–1(a)(1)(C)(ii) and (iv).

[14] *See* Senate Report, *supra* note 11, at 8–9.

[15] Exchange transaction pricing for NMS stocks is characterized by three different pricing models: (1) maker-taker (where the liquidity providing ''maker'' receives a rebate from the exchange and the ''taker'' that executes against that resting order pays a fee to the exchange); (2) taker-maker or inverted (where liquidity takers are offered a rebate and liquidity providers are assessed a fee); and (3) flat (where an exchange does not offer rebates and instead charges a fee to neither side of a trade, one side of a trade, or both sides of a trade). In rebate pricing models, the exchange's transaction revenue (''net capture'') is the difference between the fee it collects on one side of the trade and the rebate it pays out on the other side of the trade. As of Mar. 2023, nine exchanges had a maker-taker pricing model. *See* Cboe BZX pricing schedule, available at *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/;* Cboe EDGX Exchange, Inc. (''Cboe EDGX'') pricing schedule, available at *https://www.cboe.com/us/equities/membership/fee_schedule/edgx/;* Nasdaq PHLX, LLC (''Phlx (PSX)'') pricing schedule, available at *https://listingcenter.nasdaq.com/rulebook/phlx/rules/phlx-equity-7;* The Nasdaq Stock Market LLC (''Nasdaq'') pricing schedule, available at *http://nasdaqtrader.com/Trader.aspx?id=PriceListTrading2#rebates;* NYSE Arca, Inc. (''NYSE Arca'') pricing schedule, available at *https://www.nyse.com/publicdocs/nyse/markets/nyse-arca/NYSE_Arca_Marketplace_Fees.pdf;* NYSE American LLC (''NYSE American'') pricing schedule, available at *https://www.nyse.com/publicdocs/nyse/markets/nyse-american/NYSE_America_Equities_Price_List.pdf;* New York Stock Exchange, LLC (''NYSE'') pricing schedule, available at *https://www.nyse.com/publicdocs/nyse/markets/nyse/NYSE_Price_List.pdf;* MEMX, LLC pricing schedule, available at *https://info.memxtrading.com/fee-schedule/;* and MIAX PEARL, LLC (''MIAX Pearl'') equities pricing schedule, available at *https://www.miaxoptions.com/sites/default/files/fee_schedule-files/MIAX_Pearl_Equities_Fee_Schedule_01012023_1.pdf.* As of Mar. 2023, four exchanges had a taker-maker pricing model. *See* Cboe BYX Exchange, Inc. (''Cboe BYX'') pricing schedule, available at *https://www.cboe.com/us/equities/membership/fee_schedule/byx/;* Cboe EDGA Exchange, Inc. (''Cboe EDGA'') pricing schedule, available at *https://www.cboe.com/us/equities/membership/fee_schedule/edga/;* and NYSE National, Inc. (''NYSE National'') pricing schedule, available at *https://www.nyse.com/publicdocs/nyse/regulation/nyse/NYSE_National_Schedule_of_Fees.pdf.* Nasdaq BX, Inc. (''BX'') also uses the taker-maker pricing model but charges a $0.0007 fee if a member fails to reach any liquidity removing rebate tier. *See* BX pricing schedule, available at *http://www.nasdaqtrader.com/trader.aspx?id=bx_pricing.* As of Mar. 2023, Investors Exchange LLC (''IEX'') and NYSE Chicago, Inc. (''NYSE Chicago'') offer a flat pricing model. *See* IEX pricing schedule, available at *https://www.iexexchange.io/resources/trading/fee-schedule#transaction-fees* and NYSE Chicago pricing schedule, available at *https://www.nyse.com/publicdocs/nyse/NYSE_Chicago_Fee_Schedule.pdf.* As of Sept. 1, 2023, IEX began offering a rebate of $0.0004 per share on displayed orders that add liquidity for executions at or above $1. Another exchange, Long-Term Stock Exchange,

Continued

offer members lower fees or higher rebates as the number of shares the member executes on the exchange reaches successively higher predefined volume-based levels (''tiers''). The transaction volume that qualifies a member for a better fee or rebate tier typically is measured as a fraction of total consolidated market volume, rather than a fixed value. Such tiers are commonly based on a member achieving a designated average daily volume on the exchange that equals or exceeds a certain percentage of *total* market volume in a given month (*e.g.,* an average daily volume on the exchange that equals or exceeds 0.10% of the total consolidated market volume).[16] Each member's tier is calculated by the exchange as of the end of a month and reset thereafter on a monthly basis.[17] The large number of available tiers, and possible combinations of some tiers,[18] greatly complicate exchange pricing schedules and that complexity can make it more difficult for the public to understand and meaningfully comment on exchange pricing proposals.[19]

Volume-based exchange transaction pricing raises competitive concerns among exchange members as well as among exchanges. With respect to members competing for customers,[20] members with lower exchange volume do not qualify for the more favorable volume-based exchange transaction pricing tiers available to high-volume members. Accordingly, lower-volume members may find it difficult to compete for customer order flow because they are unable to pass through to customers the favorable exchange transaction pricing or lower commissions that are available to higher-volume members.[21] Similar competitive concerns also may be present for members as a result of volume-based exchange transaction pricing when they trade proprietarily using principal orders where no customers are involved.

As a result of volume-based exchange transaction pricing, lower-volume members may seek to route some or all of their orders through high-volume members to qualify for better exchange pricing.[22] As that happens, the lower-volume members that are otherwise competing with the high-volume members become customers of their high-volume competitors. This dynamic can lead to order flow becoming increasingly concentrated among a small number of high-volume members, who then qualify for even higher tiers (*i.e.,* tiers that feature lower fees or higher rebates) as a result of that flow, which further impacts the ability of lower-volume members to compete with them in a self-reinforcing cycle.[23] This concentration impacts customers by reducing the number of exchange members capable of offering them competitive exchange transaction pricing. Further, lower-volume exchange members provide a subsidy for the high-volume members when exchanges use the higher fees and lower rebates of the lower-volume members to fund the lower fees and higher rebates the exchange offers to high-volume members.[24] Accordingly, the Commission is concerned that volume-based exchange transaction pricing may have the effect of ensuring that high-volume members retain a persistent competitive advantage over lower-volume exchange members.[25]

In addition, volume-based transaction pricing tiers may provide incentives to members of more than one exchange to route orders to one particular exchange in order to qualify for that exchange's tiers and achieve lower fees and higher

Inc., (''LTSE'') does not charge fees to transact. *See https://ltse.com/trading/market-overview.*

[16] Tier criteria typically reference a member's average total daily traded share volume on the exchange during the month as a percentage of the average *total* daily market volume in stocks reported by one or more of the consolidated tapes (''Tapes'') during the month pursuant to effective national market system plans that govern the collection, consolidation, processing, and dissemination of certain national market system information. *See, e.g.,* Nasdaq pricing schedule, *supra* note 15. There currently are three such effective national market system plans. They are: (1) the Consolidated Tape Association Plan (''CTA Plan''); (2) the Consolidated Quotation Plan (''CQ Plan''); and (3) the Joint Self-Regulatory Organization Plan Governing the Collection, Consolidation, and Dissemination of Quotation and Transaction Information for Nasdaq-Listed Securities Traded on Exchanges on an Unlisted Trading Privileges Basis (''UTP Plan'') (together, the ''Equities Data Plans''). The Equities Data Plans disseminate SIP data over three separate networks: (1) Tape A for securities listed on NYSE; (2) Tape B for securities listed on exchanges other than NYSE and Nasdaq; and (3) Tape C for securities listed on Nasdaq. The CTA Plan governs the collection, consolidation, processing, and dissemination of last sale information for Tape A and Tape B securities. The CQ Plan governs the collection, consolidation, processing, and dissemination of quotation information for Tape A and Tape B securities. Finally, the UTP Plan governs the collection, consolidation, processing, and dissemination of last sale and quotation information for Tape C securities. *See also* Securities Exchange Act Release No. 98271 (Sept. 1, 2023), 88 FR 61630 (Sept. 7, 2023) (File No. 4–757) (Order directing the exchanges and the Financial Industry Regulatory Authority (''FINRA'') to file a national market system plan regarding consolidated equity market data).

[17] Currently, as exchanges assess transaction pricing to their members on a monthly basis in arrears, exchanges apply the highest tier a member achieves during a month to all of the member's executions during that month (*e.g.,* if a member qualifies for Tier 2 in June (out of 4 tiers), all of its June volume will be assessed at the Tier 2 rate, including volume transacted at the lower Tiers 4 and 3 earlier in the month). Separately, the Commission has proposed to require exchanges to make the amounts of all fees and rebates determinable at the time of execution, which would require volume-based exchange transaction pricing to be applied prospectively rather than retroactively to the start of a month. *See* Securities Exchange Act Release No. 96494 (Dec. 14, 2022), 87 FR 80266, 80270 (Dec. 29, 2022) (File No. S7–30–22) (''Access Fee Proposal''). The Commission encourages commenters to review the Access Fee Proposal to determine whether it might affect their comments on this release. As exchanges compete to attract liquidity, frequent pricing changes (typically effective and/or operative on the first business day of a month) are common. *See, e.g., id.* at 87 FR at 80311 (stating that between Jan. 2018 and June 2022, market participants interacting with all exchanges had to adjust to an average of 155 fee changes per year across all exchanges).

[18] *See infra* Table 2 (showing the number of available tiers at each exchange in March 2023, ranging from 0 to 93). Some exchanges offer additive incentives, including ''step-up'' rebates, that can be earned in addition to a standard tiered incentive. *See, e.g.,* Cboe BZX Fee Schedule's Step-Up Tiers, available at *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/. See also infra* Tables 1 and 2.

[19] *See* Letter to Brent Fields, Secretary, Commission, from Rich Steiner, RBC Capital Markets (Oct. 16, 2018) (''RBC Letter'') at 8 (comment letter on File No. S7–05–18) (''Our analysis identifies at least 1,023 pricing paths across the exchanges. Over one-third, or 381, of these paths consist of rebates. These 1,023 pricing paths are themselves determined by at least 3,762 pricing variables.'').

[20] A ''customer'' of a member is anyone using the services of the member to access the exchange, including another exchange member, a non-member broker-dealer, an institution, or any other person.

[21] *See* Letter from Tyler Gellasch, President and CEO, Healthy Markets Association, to Gary Gensler, Chair, Commission, dated Nov. 16, 2022 at 4 (''Healthy Markets Letter''), available at *https://healthymarkets.org/wp-content/uploads/2022/12/HMA-Ltr-re-Volume-Based-Pricing-11-16-22-1.pdf* (stating that to ''the extent that different competitors fall into different pricing tiers, it will directly impact the competitive balance between those firms''). The letter also includes suggestions for potential reforms to exchange routing incentives and transaction pricing fees. *See id.* at 4.

[22] *See, e.g.,* Securities Exchange Act Release No. 63241 (Nov. 3, 2010), 75 FR 69792 at 69793 (Nov. 15, 2010) (''Rule 15c3–5 Adopting Release'') (discussing that certain market participants may find the wide range of access arrangements, including sponsored and/or direct market access, beneficial and that such arrangements may ''reduce trading costs by lowering operational costs, commissions, and exchange fees'').

[23] *See infra* section IV.B.4 (The Market to Provide Exchange Access).

[24] *See id.*

[25] See 15 U.S.C. 78f(b)(4) (requiring that the rules of an exchange provide for the equitable allocation of reasonable dues, fees, and other charges among its members); (b)(5) (requiring that the rules of an exchange, among other things, not be designed to permit unfair discrimination); (b)(8) (requiring that the rules of an exchange not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act); and 15 U.S.C. 78k–1(a)(1)(C) (finding it in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure fair competition among brokers and dealers, and among exchange markets).

rebates as a result.[26] With respect to customer orders, an economic incentive to route customer orders to a particular exchange to achieve volume tiers on that specific exchange can present a conflict of interest between members and customers when members do not fully pass-through exchange transaction fees and rebates to their customers and instead retain for themselves the benefits of tiered exchange transaction pricing.[27]

Volume-based exchange transaction pricing also can impact competition among exchanges. For example, when a primary listing exchange bases pricing in its closing auction on the volume that a member executes on the exchange during regular trading hours, members that prefer (or whose customers prefer) the primary listing exchange's closing auction are incentivized to route orders to the exchange during the regular hours trading session in order to obtain more favorable pricing in the closing auction, which could negatively affect the ability of other exchanges to compete for that volume during regular trading hours.[28]

As discussed below, the proposed rule would prohibit exchanges from offering volume-based transaction fees, rebates, or other incentives in connection with the execution of agency or riskless principal orders in NMS stocks.[29] This prohibition is designed to remove a competitive impediment between higher-volume and lower-volume members when they compete for customer business, and also to mitigate the conflict of interest between members and customers presented by volume-based exchange transaction pricing tiers when members are routing customer orders to an exchange for execution. Because the prohibition in proposed Rule 6b–1 would be limited to agency and riskless principal orders, exchanges would continue to have the ability to provide tiered transaction pricing for member proprietary volume, and therefore this proposed prohibition does not seek to address any potential concerns associated with the routing of proprietary orders.

With respect to proprietary volume, the proposed rule would enhance transparency of tiered exchange transaction pricing for such volume by requiring exchanges to disclose the number of members that qualify for each of their pricing tiers. This information is intended to facilitate the Commission's review of proposed pricing changes and provide the public with additional relevant information for assessing and providing informed comment on exchange pricing proposals, including assessing exchange statements about the number of members that may qualify for a proposed tier, assessing the actual effect of a pricing change, and assessing whether a tier meets the applicable statutory standards.[30]

C. Commission Concerns

As introduced above and further discussed below, the Commission has several concerns about volume-based exchange transaction pricing. First, the Commission is concerned about the impact of volume-based exchange transaction pricing, as tiered pricing has expanded and evolved, on competition among exchange members, such as when broker-dealers are competing for customers. Second, the Commission is concerned that the desire to qualify for volume-based transaction pricing tiers exacerbates a conflict of interest between members and their customers when members route customers' orders for execution because the member can economically benefit from its routing decision. Specifically, tiered transaction pricing exacerbates that conflict because the benefit to the member increases as the number of orders it executes on the exchange increases, and for the highest tier it meets during a month, the member receives that higher rebate or lower fee on all of its orders that it executed on that exchange during the month. Finally, the Commission is concerned that tiered pricing may impose a burden on exchange competition, especially when exchanges base pricing for an auction, trading session, or special program on volume submitted during regular trading hours outside that auction, trading session, or program.

As discussed above, the Commission is able to summarily temporarily suspend individual exchange proposed rule changes related to transaction pricing shortly after they are filed.[31] This post hoc filing-by-filing approach, however, does not address similar pricing across other exchanges. The Commission is proposing this rule as a cross-exchange approach intended to facilitate investor protection and the public interest while enhancing competition among members and among exchanges.

1. Competition Among Members

Some exchange pricing schedules have evolved to the point of offering exceptionally specific pricing tiers, where some observers have questioned whether certain tiers may be available to only a limited number of members.[32] The Commission is concerned that exchanges' tiered transaction pricing may confer an inappropriate benefit on a small group of members to the detriment of other members by offering the best prices (*i.e.,* the lowest fees and highest rebates) only to the exchange's highest volume members.[33] In turn, this advantage may significantly limit the ability of lower-volume members to compete with higher-volume members for the order flow volume necessary to reach higher tiers.

By design, volume-based exchange transaction pricing involves an exchange assessing different fees and offering different rebates and other incentives to different members for executions of orders with identical terms (symbol, price, size, side, order type, etc.). The range in fees and rebates can vary considerably, as shown below in Table 1. While the transaction price for each execution is small in absolute dollar terms, the percentage difference between what different members are

[26] Membership can overlap across the exchanges. For example, as of Feb. 21, 2023, MIAX Pearl Equities Exchange had 49 members and NYSE had 143 members. *See https://www.miaxoptions.com/exchange-members/pearl-equities* and *https://www.nyse.com/markets/nyse/membership.* Forty-two of those MIAX Pearl Equities Exchange's members were also members of NYSE.

[27] The Commission understands that full pass-through of exchange transaction pricing by members to their customers is less common.

[28] *See, e.g.,* NYSE pricing schedule, *supra* note 15 (offering incremental per share discounts on market-at-the-close orders depending on a member's average daily trading volume that added liquidity to NYSE during the billing month as a percentage of CADV). According to NYSE, the proposed discounts were designed ''to align incentives among both trading on the close and intraday trading on the Exchange.'' *See* Securities Exchange Act Release No. 94543 (Mar. 19, 2022), 87 FR 19544 at 19543 (Apr. 4, 2022). The NYSE further stated ''that other marketplaces provide discounts based on intraday adding volume, and that aligning incentives for lower pricing at the close with additional intraday volume is thus neither novel nor an unreasonable stance in a competitive marketplace.'' *Id.* at 19546.

[29] While the proposed rule addresses only NMS stocks, the Commission is requesting comment below on whether the proposal should be applied to options.

[30] *See supra* notes 8–10 and accompanying text (discussing the Exchange Act principles applicable to exchange pricing proposals).

[31] *See supra* note 6. *See also* 15 U.S.C. 78s(b)(3)(C).

[32] *See* John Ramsay, Chief Market Policy Officer, IEX, *Why Exchange Rebate Tiers are Anti-Competitive* (June 5, 2023), available at *https://www.iex.io/article/why-exchange-rebate-tiers-are-anti-competitive* (''Ramsay Article'') (stating that some ''exchanges offer specialized 'bespoke' volume tiers with formulas that are so specific, they can appear to be specifically designed to benefit one or a few firms, and it is widely assumed that some are'' (citation omitted) and that ''tailored-tier rates seems to have the effect, if not the purpose, of allowing the highest-volume firms that already have a competitive edge to keep it''). *See id. See also infra* Table 2.

[33] *See supra* note 26 and accompanying text. *See also infra* section IV.B.1.b, Volume-Based Pricing Tiers.

assessed can be large, and the cumulative effect may quickly add up across the billions of shares executed each trading day. To show the range of individual tiered transaction fees that apply to different members engaged in the same activity, Table 1 shows the primary pricing model for each equities exchange and presents a general summary of the number and dollar range of each exchange's basic volume-based transaction tiers applicable during regular trading hours.[34]

TABLE 1—SUMMARY OF TRANSACTION-BASED PRICING SCHEDULES FOR DISPLAYED/REGULAR ORDERS ON EQUITIES EXCHANGES DURING REGULAR TRADING HOURS AS OF MAR. 2023

Fees and rebates for transactions at or above $1.00 on Tapes A, B & C *			
Exchange	Pricing model	Fees (# of categories)	Rebates (# of categories)
Cboe BZX	Maker-Taker	$0.0030 (Tapes A, B & C—1 each)	($0.0016)–($0.0031) (Tapes A, B & C—7 each).
Cboe BYX	Taker-Maker	$0.0012–$0.0020 (Tapes A, B & C—6 each)	($0.0002)–($0.0015) (Tapes A, B & C—2 each).
Cboe EDGA	Taker-Maker	$0.0015–$0.0030 (Tapes A, B & C—4 each)	($0.0016)–($0.0022) (Tapes A, B & C—3 each).
Cboe EDGX	Maker-Taker	$0.00275–$0.0030 (Tapes A, B & C—2 each)	($0.0016)–($0.0029) (Tapes A, B & C—4 each).
BX	Taker-Maker/Flat	$0.0012–$0.0030 (Tapes A, B & C—5 each)	($0.0004)–($0.0018) ** (Tapes A, B & C—5 each).
Phlx (PSX)	Maker-Taker	$0.0030 (Tapes A, B & C—1 each)	($0.0020)–($0.0032) (Tapes A, B & C—2 each).
Nasdaq	Maker-Taker	$0.0030 (Tapes A, B & C—1 each)	($0.0013)–($0.00305) (Tapes A, B & C—11 each).
NYSE Arca	Maker-Taker	$0.0029–$0.0030 (Tape A—1, Tapes B & C—2 each).	($0.0016)–($0.0034) (Tape A—7, Tapes B & C—10 each).
NYSE American	Maker-Taker	$0.0026–$0.0030 (Tapes A, B & C—3 each)	($0.0020)–($0.0026) (Tapes A, B & C—3 each).
NYSE	Maker-Taker	$0.0026–$0.0030 (Tapes A & B—1 each, Tape C—3).	($0.0012)–($0.0031) (Tape A—2, Tape B—4 & Tape C—5).
NYSE National	Taker-Maker	$0.0020–$0.0029 (Tapes A, B & C—5 each)	$0.000–($0.0030) (Tapes A, B & C—5 each).
NYSE Chicago	Flat	$0.0010 (Tapes A, B & C—1 each)	$0.00 (0).
IEX	Flat	$0.0009 (Tapes A, B & C—1 each)	$0.000 (0).
MEMX	Maker-Taker	$0.0029–$0.0030 (Tapes A, B & C—3 each)	($0.0018)—($0.00335) (Tapes A, B & C—5 each).
MIAX Pearl	Maker-Taker	$0.00275–$0.00295 (Tapes A, B & C—3 each).	($0.0029)–($0.0036) (Tapes A, B & C—4 each).
LTSE	Free	$0.0000 (0)	$0.0000 (0).

* Table 1 reflects that, as of Mar. 2023, some exchanges apply fees and rebates according to the market data Tape on which a security is disseminated, which is based on the security's primary listing exchange. Tape A is for securities listed on NYSE, Tape B is for securities listed on exchanges other than NYSE and Nasdaq, and Tape C is for securities listed on Nasdaq.

** BX charges a $0.0007 fee for Tapes A, B and C if a member fails to reach any liquidity removing rebate tier.

Volume-based exchange transaction pricing is more complicated and varied than what is presented in Table 1. For example, many exchanges also offer additional step-up tiers that increase the amount of rebates offered, as well as specific tiering programs for registered market-maker activity, selected order types that an exchange seeks to incentivize, or special programs like retail liquidity programs. Fees also may vary depending on whether an order is displayable or non-displayed or is executed in the opening or closing auction. To show the complexity of volume-based exchange transaction pricing, Table 2 identifies the number of volume-based pricing levels each exchange offers.[35]

TABLE 2—COUNT OF TRANSACTION PRICING LEVELS THAT ARE BASED ON VOLUME FOR EXECUTIONS AT OR ABOVE $1 AS OF MAR. 2023

Exchange	Volume-based pricing levels
NYSE	93
Nasdaq	74
NYSE Arca	72
Cboe BZX	26

[34] The fees and rebates shown in Table 1 are derived from the exchanges' Mar. 2023 pricing schedules. *See supra* note 15. Table 1 shows only the generally available core pricing tiers, meaning it excludes fees and rebates applicable to special activities that may not apply to every member: orders not executed on the exchange (*i.e.,* routed to an away exchange); executions resulting from an auction or specific order types (*e.g.,* closing auctions or retail liquidity program order types or non-displayed order types); incentives for specific purposes (*e.g.,* setting the best bid or offer price); registered market-maker incentives; non-rebate incentives; and cross-asset tiers (options versus equities). Table 1 also excludes fees and rebates tied to increased volume compared to a specific date because those additive rebates are not generally available pricing tiers. Moreover, the dollar ranges in Table 1 do not net together additive fees or rebates and count them as a separate tier (*e.g.,* where a base rebate could be combined with a step-up additive rebate) because those are in addition to other tiers and the exchanges do not identify them as separate named tiers. Further, the number of categories is a count of those separately listed fees or rebates used in determining the range of an exchange's basic fees or rebates for purposes of Table 1.

[35] Table 2 counts separately listed fee or rebate levels that are based on the achievement of a specified volume level and assessed on a per share basis. Additive rebates or other incentives were only counted once and not added together and counted separately with each applicable base price. Different Tapes with differing fees or rebates were counted separately, but Tapes with the same fee or rebate were not counted separately. Different fees for separate order types that reference the same volume level were counted separately. Base fees and rebates that are not based on volume were not counted.

TABLE 2—COUNT OF TRANSACTION PRICING LEVELS THAT ARE BASED ON VOLUME FOR EXECUTIONS AT OR ABOVE $1 AS OF MAR. 2023—Continued

Exchange	Volume-based pricing levels
BX	20
Cboe EDGX	19
MEMX	13
Cboe BYX	11
NYSE National	11
NYSE American	10
Cboe EDGA	8
MIAX Pearl	8
Phlx (PSX)	4
IEX	0
LTSE	0
NYSE Chicago	0

Unless the terms of the pricing tier provide otherwise, a member's customer volume and its proprietary orders typically are combined for purposes of determining whether the member qualifies for a volume tier. Once a member attains a volume tier, the pricing advantage it receives from reaching that volume tier may turn into a competitive advantage in two ways.[36] First, the member can use the advantaged pricing it receives to benefit its proprietary trading business (*i.e.,* it may pay lower fees or receive higher rebates on that business compared to other members that do not qualify for the favorable pricing tier). Second, the member may be able to attract additional order flow from customers because it can offer customers the same lower fees and higher rebates either directly through pass-through exchange transaction pricing or indirectly through lower commissions. This would allow the member to further increase and consolidate customer order flow, which in turn would help the member reach and maintain higher tiers. The gap in transaction pricing between base fees and rebates and top-tier fees and rebates can make it more difficult for new and lower-volume members to compete, putting both their proprietary and customer business at a competitive disadvantage.

Members at the best exchange pricing tiers can further widen the competitive gap by using their tiered pricing advantage to sell sponsored access[37] and direct market access[38] services to customers (including other member and non-member broker-dealers with whom they compete as well as any other customer that wants direct access to an exchange), through which the customer (including other broker-dealers) uses the sponsoring member's systems and connectivity to access an exchange. The sponsoring member benefits by being able to count the volume from its sponsored customers toward its own volume tiers, which can benefit the sponsored customers if they receive better pass-through pricing or lower commissions as a result, as well as the sponsoring member's proprietary trading business that also receives that better transaction pricing.[39] In turn, if the sponsored customer receives pass-through pricing from the sponsoring member, the sponsored customer may be able to share in part of the sponsoring member's advantaged pricing (subject to the fees or mark-up it pays to the sponsoring member for the services), which can result in the sponsored customer paying lower exchange fees or earning higher exchange rebates than if it executed transactions on the exchange directly.[40] These private arrangements between a sponsoring member and its sponsored customer, however, work to further entrench the competitive advantage that exchange pricing tiers provide to high-volume members because, as the Commission understands, sponsoring members typically do not pass along the entirety of their transaction pricing advantage to their sponsored broker-dealer customers (thereby maintaining the sponsoring members' exchange transaction pricing advantage). As a result, the sponsoring members' broker-dealer customers depend on using the services of their competitors—the sponsoring members—to access any advantaged exchange transaction pricing their competitors are able to obtain through these access arrangements, which the sponsored broker-dealer customers could not obtain on their own. The extent to which any such pass-through transaction pricing is provided to sponsored customers is uncertain because these arrangements are not disclosed.[41]

2. Conflicts of Interest

With respect to agency brokerage activity, where the member transacts on an exchange for purposes of filling an order for another person, the Commission is concerned that volume-based exchange transaction pricing exacerbates a conflict of interest between the member and its customer.[42] Specifically, when the member executes an agency order, it faces an economic incentive to route the order to one particular exchange over others to achieve volume tier requirements on that exchange that could result in reduced fees or increased rebates (and, in both cases, the member would retain some or all of the benefit for itself if it does not pass through that better exchange transaction pricing to its customer).[43]

While exchange fees and rebates in general may contribute to a conflict of interest between a member and its customer when routing orders, volume-based fees and rebates can exacerbate that conflict because they present an additional economic incentive to

[36] *See* Healthy Markets Letter, *supra* note 21, at 5–6 (stating that pricing tiers ''offer cheaper trading for larger firms with greater order volumes [which] puts smaller firms at a competitive disadvantage on order and execution prices'' and further stating that as a consequence, ''several larger trading firms will then use their lower rates to attract greater order flow—consolidating order flow at the largest trading firms'' and as ''order flow has aggregated to the largest firms, this has increased their ability to garner for themselves even better rates; further expanding the gap between themselves and smaller firms'').

[37] Sponsored access generally refers to an arrangement whereby a member permits a customer to route orders directly to an exchange using technology supplied by the customer that bypasses the member's trading system but not its market access checks. *See* Rule 15c3–5 Adopting Release, *supra* note 22, at 69793 (describing sponsored access as ''referring to an arrangement whereby a broker-dealer permits customers to enter orders into a trading center that bypass the broker-dealer's trading system and are routed directly to a trading center . . .'').

[38] Generally, direct market access refers to an arrangement whereby a member permits a customer to use its trading systems to send orders directly to a trading center. *See id.* at 69793 (describing direct market access as an ''arrangement whereby a broker-dealer permits customers to enter orders into a trading center but such orders flow through the broker-dealer's trading systems prior to reaching the trading center'').

[39] *See, e.g., id.* at 69793 n. 11 (stating that ''[e]xchange members may use access arrangements as a means to aggregate order flow from multiple market participants under one MPID to achieve higher transaction volume and thereby qualify for more favorable pricing tiers'').

[40] *See id.* at 69793 (discussing, in part, how direct market access or sponsored access arrangements may help to reduce certain costs such as exchange fees). *See also infra* section IV.B.4.

[41] *See infra* section IV.B.4.b.

[42] While some rules may seek to address conflicts of interest in the context of agency brokerage activity, this proposal seeks to mitigate the conflict specific to volume-based exchange transaction pricing at its source through the proposed prohibition. *See, e.g.,* Securities Exchange Act Release No. 96496 (Dec. 14, 2022), 88 FR 5440 (Jan. 27, 2023) (''Regulation Best Execution Proposing Release''). The Commission encourages commenters to review the Regulation Best Execution Proposing Release to determine whether it might affect their comments on this release.

[43] Customers could benefit from exchange tiered pricing if members pass some or all of the savings through to the customers either directly or in the form of lower commissions or other subsidies. *See also* Access Fee Proposal, *supra* note 17 (proposing, among other things, revisions to the access fee cap in 17 CFR 242.610 (Rule 610 of Regulation NMS)). The Commission encourages commenters to review the Access Fee Proposal to determine whether it might affect their comments on this release.

members when selecting an exchange for routing: the member's desire to reach volume tiers on an exchange to achieve preferential pricing. Specifically, volume-based pricing may incentivize members to route customer order flow to certain exchanges for the purpose of meeting tier qualification, which has the potential to be costly to customers if it comes at the expense of execution quality. Moreover, this incentive may be particularly enticing for members because customer volume can accrue towards the member's total volume level, giving it the ability to achieve more favorable tiered pricing for all of its order flow, including proprietary orders that the member sends to the exchange for its own account. The fact that volume-based exchange transaction pricing applies to both agency-related and proprietary order flow even further exacerbates the conflict of interest between a member and its customer because the routing decisions a member makes with respect to its agency-related order flow can also benefit its unrelated proprietary business. Finally, it may be challenging for customers to understand and assess the impact that tiered exchange pricing may have on broker-dealer routing decisions due to the complexity of the exchanges' tiered pricing schedules, which makes it difficult for customers to provide a check against any conflicts of interest.[44] Accordingly, the economic incentive presented by tiered exchange transaction pricing may affect members' order routing decisions, exacerbating a conflict of interest that can potentially harm investors with inferior executions when members route customer orders to exchanges.[45]

3. Exchange Competition

An exchange's volume-based transaction pricing schedule is designed to entice members to route orders to that exchange over other exchanges by lowering fees or increasing rebates as volume-based transaction tiers are met. Pricing tiers that are based on total consolidated volume may create additional incentives for members to route to certain exchanges, particularly towards the end of each month as members seek to achieve tier targets to qualify for a better pricing tier on that exchange. This dynamic may harm the ability of other exchanges to compete for order flow during that time.

Further, certain forms of exchange transaction pricing tiers can raise unique issues and concerns. For example, if a primary listing exchange for a stock were to base its closing auction pricing on the volume a member executes during regular trading hours outside of the auction, members that send customer orders in that stock to the primary listing exchange's closing auction may be incentivized to also route to the exchange during regular hours to qualify for tiered pricing in the closing auction.[46] In this scenario, the exchange is leveraging its role as the primary listing exchange for a stock, in addition to the closing auction it provides for that stock, to use members' desire to achieve tiered pricing in the closing auction as an incentive for those members to also route to the exchange during the regular trading session.

Accordingly, the Commission is concerned about the potential for exchanges to use some forms of volume-based exchange transaction pricing to insulate certain portions of member volume from competition while at the same time over-emphasizing competition based on fee tiering, which can constrain innovation among exchanges in other areas and impose a burden on competition among exchanges that may be inconsistent with the goals of a national market system.

II. Description of Proposed Rule

A. Overview of Proposed Rule

The Commission is proposing a rule designed to address its specific concerns with volume-based exchange transaction pricing schedules.[47] Proposed Rule 6b–1 has three components. First, the proposed rule would prohibit equities exchanges from offering volume-based exchange transaction pricing in connection with the execution of agency or riskless principal orders in NMS stocks (''agency-related volume'').[48] The proposed rule would not prohibit exchanges from offering volume-based exchange transaction pricing for member proprietary volume where the member is trading solely for its own account and not in connection with filling an order for a customer.[49]

Second, the proposed rule contains an anti-evasion clause that would require equities exchanges that have volume-based transaction pricing for member proprietary volume to adopt rules to require members to engage in practices that facilitate the exchange's ability to comply with the prohibition on volume-based exchange transaction pricing in connection with the execution of agency-related volume.[50] The proposed rule also would require exchanges to establish, maintain, and enforce written policies and procedures that are reasonably designed to detect and deter members from receiving volume-based exchange transaction pricing in connection with the execution of agency or riskless principal orders in NMS stocks.[51] This requirement would help to promote an exchange's compliance with the proposed rule by ensuring that an exchange develops mechanisms that would prevent its members from inappropriately receiving volume-based

[44] *See* Healthy Markets Letter, *supra* note 21, at 4 (''The inherent conflict of interest created by different pricing tiers may also impact how brokers treat their own customers in a way that isn't quite as transparent as simply chasing the higher rebate or lower fee venue. For example, a broker with a less-sophisticated customer may send orders to a venue so that the firm would reach a certain tier threshold, despite the broker's awareness that executions on that venue may result in inferior execution outcomes to investors. However, the same broker, if faced with the same order from a more-sophisticated customer, may not.''). *See also* Recommendation of the SEC Investor Advisory Committee Regarding Exchange Rebate Tier Disclosure (Jan. 24, 2020), available at *https://www.sec.gov/spotlight/investor-advisory-committee-2012/exchange-rebate-tier-disclosure.pdf*. In the recommendation, the Investor Advisory Committee stated that ''[t]he lack of public disclosure concerning the structure of rebates for executing brokers'' exacerbates ''a principle-agency conflict in the receipt of rebates for orders executed on behalf of clients but not shared with clients.''

[45] *See infra* section IV.B.3.

[46] *See also infra* section IV.B.1.c.

[47] The proposed rule would provide a consistent approach to these issues, which the Commission could not achieve through piecemeal suspensions of individual exchange pricing filings.

[48] *See* proposed Rule 6b–1(a).

[49] *See infra* section IV.E.1 and 2 (proposing alternatives that would prohibit exchanges from offering volume-based exchange transaction pricing for member proprietary volume).

[50] *See* proposed Rule 6b–1(b)(1). Exchanges would have flexibility under the proposed rule as to what rules to adopt. For example, an exchange may allow members to designate that certain of their ports or sessions handle exclusively agency-related orders or exclusively proprietary orders as a means to facilitate the exchange's ability to comply with the prohibition. If the member does not use separate ports in that manner, the exchange could require members to indicate for billing purposes which orders are agency-related and ineligible for tiered pricing if the exchange does not already have a mechanism to distinguish those orders. Or, if a member does not conduct an agency business and only trades proprietarily or does not trade proprietarily and only trades on an agency basis, an exchange may not need to require anything additional from that member for purposes of this proposed rule.

[51] *See* proposed Rule 6b–1(b)(2). For example, if an exchange allows members to designate that certain of their ports or sessions handle exclusively agency-related orders or exclusively proprietary orders as a means to facilitate the exchange's ability to comply with the prohibition, an exchange might adopt a policy and procedure to review the ports and sessions designated by members to make sure that members are not, for example, submitting agency-related orders though a port or session the member has designated as solely for proprietary orders.

exchange transaction pricing for agency-related orders.[52]

Third, the proposed rule would require equities exchanges that have volume-based transaction pricing for member proprietary volume to submit electronically to the Commission disclosures of the number of members that qualify for their volume-based transaction pricing.[53] Specifically, such exchanges would be required to submit electronic, machine-readable structured data tables of their volume-based transaction pricing tiers and the number of members that qualify for each tier in an Interactive Data File in accordance with 17 CFR 232.405 (Rule 405 of Regulation S–T),[54] and the public would be able to access those disclosures through the Commission's EDGAR system.[55] Additional public transparency regarding the number of members that qualify for each pricing tier for their proprietary volume would help the Commission, members, and the public understand how the benefits of volume-based pricing are distributed and the potential impact on members, which should facilitate and inform members', the public's, and other exchanges' efforts to submit comment letters on volume-based exchange transaction pricing proposals to further inform the Commission as it considers those proposals. For example, information on the number of members that have qualified for a newly adopted pricing tier would allow the Commission and interested parties to assess exchange statements regarding the number of members that the exchange estimated should qualify for a proposed new tier or amended tier. In addition, such information would provide a data point for the Commission to consider in determining whether a proposed tier meets the applicable statutory standards and whether the Commission should temporarily suspend the newly adopted pricing tier.

B. Prohibition on Volume-Based Exchange Transaction Pricing for Agency-Related Volume

The Commission is concerned about the impact of exchange tiered transaction pricing on competition among an exchange's members. As discussed above, volume-based exchange transaction pricing can frustrate and impede the ability of new and lower-volume members to compete with high-volume members, including for customer order flow, which can reduce the number of members that are able to offer customers the highest-tiers of exchange transaction pricing.[56] For example, if a member that qualifies for the best pricing tier can offer a customer pass-through of its $0.0015 take fee for executing on Exchange A, but a member that does not qualify for a tier can only offer a customer pass-through of its $0.0030 take fee on that same exchange for execution of the same customer order, the lower-volume member faces a distinct and measurable disadvantage even though both are members of Exchange A. The Commission also is concerned that volume-based exchange transaction pricing that applies to agency-related volume exacerbates a conflict of interest between members and their customers when members face an economic incentive to earn increasingly lower fees or higher rebates or other incentives from an exchange in connection with the execution of more customer orders on that exchange.[57]

Accordingly, to address the Commission's concerns with member competition, as well as the conflict of interest between members and their customers, the prohibition on volume-based exchange transaction pricing in proposed Rule 6b–1(a) would apply to agency-related volume. Specifically, the proposed rule would prohibit exchanges from offering volume-based transaction fees, rebates, or other incentives in connection with the execution of agency or riskless principal orders in NMS stocks.[58]

The proposed prohibition would apply broadly to all executions where a member is executing an agency or riskless principal order in an NMS stock for the purpose of filling a customer order and is not trading for its own account. For purposes of the proposed rule, customers could include, for example, other members, non-member broker-dealers, institutions, an affiliate of the member, natural persons, or any person that uses the member to access an exchange, including through direct market access or sponsored access services.

The proposed rule would define riskless principal to mean ''a transaction in which, after having received an order to buy from a customer, the broker or dealer purchased the security from another person to offset a contemporaneous sale to such customer or, after having received an order to sell from a customer, the broker or dealer sold the security to another person to offset a contemporaneous purchase from such customer.'' That definition is consistent with other Commission definitions of the term.[59]

[52] *See, e.g.,* section 6(b)(1) of the Exchange Act, 15 U.S.C. 78f(b)(1) (requiring an exchange to be so organized and have the capacity ''to be able to carry out the purposes of [the Exchange Act] and to comply, and . . . to enforce compliance by its members and persons associated with its members with the provisions of [the Exchange Act], the rules and regulations thereunder, and the rules of the exchange'').

[53] *See* proposed Rule 6b–1(c). Consistent with the proposed disclosure requirement, the Commission also is proposing to amend 17 CFR 232.101 (Rule 101 of Regulation S–T) to add the disclosure required under proposed Rule 6b–1(c) as a filing that must be submitted electronically.

[54] *See* proposed 17 CFR 232.405(b)(6). Rule 405 of Regulation S–T applies to the submission of Interactive Data Files. The Commission is proposing conforming changes in Rule 405 of Regulation S–T to reflect the inclusion of proposed Rule 6b–1(c). Such files must be submitted using Inline XBRL. *See* proposed 17 CFR 232.405(a)(3). The Commission also is proposing conforming changes to Rule 101 of Regulation S–T to reflect the inclusion of proposed Rule 6b–1. *See* proposed 17 CFR 232.101.

[55] As discussed below in section II.D, Request for Comments, the Commission is soliciting comment on other potential metrics for the disclosures, including the volume of shares at each tier and the dollar amount of fees, rebates, or other incentives at each tier.

[56] *See supra* sections I.B (Volume-Based Exchange Transaction Pricing), and I.C.1 (Competition Among Members).

[57] *See supra* section I.C.2 (Conflicts of Interest).

[58] To comply with the prohibition, an exchange that offers volume-based transaction fees, rebates, or other incentives in connection with the execution of agency or riskless principal orders in NMS stocks would need to file a proposed rule change on Form 19b–4 to remove any such pricing from its pricing schedule.

[59] *See, e.g.,* 17 CFR 240.3a5–1(b) (exempting banks from the definition of ''dealer'' under the Exchange Act when acting in a riskless principal capacity when certain conditions are met, which states that ''[f]or purposes of this section, the term riskless principal transaction means a transaction in which, after having received an order to buy from a customer, the bank purchased the security from another person to offset a contemporaneous sale to such customer or, after having received an order to sell from a customer, the bank sold the security to another person to offset a contemporaneous purchase from such customer.''); 17 CFR 240.3a5–2 (exemption from the definition of ''dealer'' for banks effecting transactions in securities issued pursuant to Regulation S); 17 CFR 255.6(c)(2) (other permitted proprietary trading activities); 17 CFR 240.31(a)(14) (Section 31 transaction fees); 17 CFR 230.144A(a)(5) (private resales of securities to institutions); and 17 CFR 230.144 (persons deemed not to be engaged in a distribution and therefore not underwriters) (defining the term ''riskless principal transaction'' generally without reference to price, but further providing in 17 CFR 230.144(f)(1)(iii) the possible manners of sale, one of which is a riskless principal transaction where the offsetting trades are executed at the same price). Generally, the exchanges use the terms ''agency'' and ''riskless principal'' in their rules without defining them because the terms are widely and commonly understood. For example, Cboe BZX refers to the terms ''agency'' and ''riskless principal'' 12 times each in its rulebook (covering equities and options rules), but does not separately define either term, except with respect to retail orders under its Retail Order Attribution Program. *See* Cboe BZX Rule 11.25(a)(2) (retail order attribution program, referring to a ''riskless principal order that meets the criteria of FINRA Rule 5320.03''). Moreover, each of the exchange rules that implement the Consolidated Audit Trail, which requires the capture of the capacity of the member executing the order, whether principal, agency, or riskless principal, uses those terms in an identical manner

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Like agency orders, riskless principal orders are one way for a member to fill a customer's order. Riskless principal orders involve contemporaneous buys and sells that are ''riskless'' to the member, in that the member does not take on the market risk of price moves in the stock because it buys or sells to promptly transfer the position to a customer rather than retain the position for any significant length of time in its own account.

Some rules, in contexts other than exchange transaction pricing, include definitions of the term ''riskless principal'' that require the price of both legs of the riskless principal trade be at the same price.[60] In addition, FINRA has a definition of riskless principal that specifies that the member's principal trade and the customer fill occur at the ''same price.'' [61]

The definition of riskless principal in proposed Rule 6b–1 does not require the principal leg and customer leg to occur at the same price. Proposed Rule 6b–1 uses a broader definition of riskless principal to achieve the purposes of the proposed rule and to limit the ability of members to easily circumvent the proposed rule's prohibition by an economically insignificant amount. For example, if the proposed rule contained a ''same price'' requirement in the definition of riskless principal, a member might attempt to circumvent the prohibition by providing an economically insignificant different price on the customer leg—one that varied by the smallest fraction of a penny possible—to avoid classifying the transaction as ''riskless principal.'' If proposed Rule 6b–1 excluded such a transaction from its definition of riskless principal, the member would qualify for volume-based exchange transaction pricing on the principal leg of the transaction even though the transaction had the defining characteristics of a riskless principal trade because the member did not take on the market risk of price moves in the stock and promptly transferred the position to the customer. A definition that includes the concept of ''same price'' therefore would not achieve the Commission's goals of prohibiting volume-based exchange transaction pricing for agency-related volume.

Because orders executed in the capacity of agent and riskless principal both are done to fill a customer order, the conflict of interest exacerbated by exchange tiered transaction pricing is equally present for both: the member faces conflicting economic incentives when choosing the exchange execution venue, and the customer bears any costs associated with an execution that results from that decision. The Commission therefore proposes to treat riskless principal orders the same as agency orders for purposes of proposed Rule 6b–1(a).

Finally, because proposed Rule 6b–1(a) would prohibit exchanges from offering volume-based transaction pricing in connection with the execution of agency or riskless principal orders in NMS stocks, which represent a member's agency-related volume, it would prohibit exchanges from counting that agency-related volume towards any volume-based transaction tiers applicable to the member's proprietary volume. For example, if a member is engaged in proprietary trading (*e.g.,* as a registered market maker on the exchange) and also has a separate division or affiliate that is engaged in a customer brokerage business (*e.g.,* as an executing broker for non-member brokers), an exchange could not count the member's agency-related volume towards any volume-based transaction tiers the member qualifies for on its proprietary volume. Similarly, because the proposal would prohibit volume-based exchange transaction pricing in connection with the execution of agency or riskless principal orders in NMS stocks, it would prohibit exchanges from basing transaction pricing in an auction on agency-related volume executed within or outside the auction. In either case, an exchange could count only the member's proprietary volume to determine the pricing tier for the member's proprietary trades.

Prohibiting volume-based exchange transaction pricing for agency-related orders is intended to promote competition among members for customer business. It also is intended to mitigate the conflict of interest between members and customers that is exacerbated by exchange tiered pricing where the member economically benefits from its choice of exchange execution venue for customer orders. The proposed rule would eliminate one incentive—reaching a volume tier—for a member to route a customer order to a particular exchange when doing so might not be in the customer's interest.

Request for Comments

The Commission generally requests comment from the public on all aspects of proposed Rule 6b–1(a), including its objectives and its terms to achieve those objectives. More specific requests for comment are set forth below. As much as possible, commenters are requested to provide empirical data in support of any arguments or analyses and to offer explanations for their views.

1. Do commenters believe that volume-based exchange transaction pricing impacts competition among members when competing for customers on an agency basis? Do sponsored access and direct market access arrangements contribute to these competitive effects when exchange members compete for customers? Why or why not? Does volume-based exchange transaction pricing impact competition among members when trading proprietarily? If there is an impact, is the impact greater for members when they are competing for customers or when they are trading proprietarily, or is the impact equivalent?

2. Do commenters believe that volume-based exchange transaction pricing exacerbates the conflict of interest between members and customers when members are routing customer orders, because of the member's desire to qualify for volume-based transaction tiers? Would complete pass through of exchange pricing to the member's customer eliminate that conflict? Why or why not? To what extent do members completely or partially pass through all exchange pricing to their customer? Do customers prefer pass through exchange transaction pricing or broker commissions, and for what reasons? Is the Commission's understanding correct that full and partial pass-through of exchange transaction pricing by members to their customers is less common? For sponsored access and direct market access arrangements, how common is pass-through of exchange transaction fees? What types of pass-through arrangements are most common and how much does the sponsoring member typically retain as compensation?

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without defining them. *See, e.g.,* Nasdaq General 7, Section 3(a)(1)(E)(iv); BZX Rule 4.7(a)(1)(E)(iv). *See also* Limited Liability Company Agreement of Consolidated Audit Trail, LLC, Article VI, Section 6.3(d)(v)(D). Those terms also are not defined within the CAT NMS Plan.

[60] *See, e.g.,* 17 CFR 242.201(a)(8) (concerning ''short exempt'' order marking for certain riskless principal orders) and 17 CFR 240.10b–18 (purchases of certain equity securities by the issuer and others).

[61] *See, e.g.,* FINRA Rule 5320.03 (excluding riskless principal transactions from FINRA's Prohibition Against Trading Ahead of Customer Orders) and FINRA Rule 6380B(d)(3)(B) (concerning reporting to the FINRA/NYSE Trade Reporting Facility). The FINRA rule prohibiting trading ahead of customer orders generally prohibits members from trading for their own account at a price that would satisfy the customer order, subject to an exception for riskless principal orders. Exchanges have incorporated FINRA's rule by reference or have adopted similar rules. *See, e.g.,* FINRA Rule 5320.03 and BZX Rule 12.6.03.

3. To what extent does volume-based exchange transaction pricing impact competition among exchanges, and/or between exchanges and off-exchange venues, such as alternative trading systems (''ATSs'') and wholesaler broker-dealers?

4. To what extent is volume-based exchange transaction pricing used by exchanges to attract specific types of members or customers of members, such as proprietary traders, registered market makers, or agency customers? Among agency customers, are any particular types of customers particularly attracted by volume-based exchange transaction pricing, such as long-term investors, short-term traders, investment advisers, and institutional investors?

5. To what extent is the ability of an exchange to attract order flow from specific types of members or customers through volume-based exchange transaction pricing or other forms of targeted pricing necessary to support competition between exchanges and off-exchange venues? For example, if exchanges lack the ability to offer such pricing on agency-related order flow, could that potentially make off-exchange venues relatively more attractive as a destination for that flow? If so, should the Commission address such a competitive disparity? For example, should the Commission expand the scope of the prohibition on volume-based transaction pricing for agency-related volume in certain stocks to off-exchange venues such as ATSs?

6. How consistently do individual exchange members hit specific tiers over time? How do members respond to volume-based exchange transaction pricing changes and how do those member responses differ across different exchanges?

7. How does using volume-based exchange transaction pricing as a means of compensating liquidity providers compare to other fee and non-fee methods of attracting those liquidity providers? Do exchange-registered market makers react differently from other members that provide liquidity to exchange transaction pricing? Does volume-based exchange transaction pricing affect liquidity taking orders differently from liquidity providing orders?

8. Would the proposed prohibition on volume-based exchange transaction pricing in connection with the execution of agency or riskless principal orders in NMS stocks address the concerns the Commission identified about member competition and conflicts of interests between members and customers? Why or why not?

9. Is the proposed definition of riskless principal in proposed Rule 6b–1(a) appropriate? Why or why not? If the definition included a ''same price'' requirement, do commenters agree that the Commission would not be able to achieve its objectives for the proposed rule? Why or why not?

10. Do exchanges have rules and policies and procedures in place that require members to mark their orders for transaction billing purposes in a manner that would readily allow exchanges to comply with the proposed prohibition, or would those rules and policies and procedures need to be revised to accommodate the proposed prohibition?

11. Should the Commission also prohibit volume-based exchange transaction pricing for member proprietary volume (*i.e.,* should the Commission prohibit exchanges from offering volume-based transaction pricing for all volume in NMS stocks)? [62] Why or why not? Would doing so obviate the need for the anti-evasion provisions in proposed Rule 6b–1(b) and the proposed disclosures in proposed Rule 6b–1(c) since tiered pricing would no longer be permitted? Would a broader prohibition that includes both agency-related and proprietary orders address the Commission's concerns, discussed above in section I.C, about competition among members and competition among exchanges, as well as the conflict of interest between members and customers with respect to agency-related order flow? How would a broader prohibition affect exchange fees and rebates compared to what they offer today? Would exchanges be able to extend their best fee and rebate pricing to all members? Why or why not? If not, and if the purpose of tiered transaction pricing is to attract more order flow from members, why would exchanges not be able to offer the best pricing to all members to attract the greatest possible volume?

12. If the Commission extends the prohibition on volume-based exchange transaction pricing to member proprietary volume, should displayed liquidity-adding orders from an exchange's registered market makers in their registered or appointed symbols not be subject to the prohibition in order to provide exchanges with a means to incentivize displayed quotes from their registered market makers? In other words, should the Commission prohibit exchanges from offering volume-based transaction pricing for all volume in NMS stocks, but subject to a carve-out only for displayed liquidity providing orders from exchange registered market makers in their registered or appointed symbols? [63] Should such an exception be limited to registered exchange market makers that are subject to minimum quantitative and qualitative quotation requirements that meet or exceed the highest such standards in place among national securities exchanges to avoid conferring a benefit without meaningful corresponding obligations that protect investors? Would continuing to allow volume-based exchange transaction pricing for displayed liquidity-adding orders from such exchange registered market-makers in their registered or appointed symbols be an appropriate benefit to encourage members to become and remain registered market makers and to provide publicly displayed quotes, consistent with their quoting obligations? Would tiered pricing encourage greater quoted depth or narrower quoted spreads, or both, for displayed quotes? If the Commission adopted a broader prohibition on volume-based transaction pricing with a carve-out for registered market makers, would the anti-evasion provisions in proposed Rule 6b–1(b) and the transparency disclosures in proposed Rule 6b–1(c) be less relevant in circumstances where the only reportable activity would be the activity of registered market makers who are subject to exchange market making rules?

13. Instead of prohibiting volume-based exchange transaction pricing, should the Commission instead allow exchanges to offer volume-based pricing to attract order flow, but require the volume tiers to be based on total aggregate volume submitted to the exchange, with the associated tiered pricing applied to all members uniformly? For example, an exchange could establish a volume-based pricing tier that considers cumulative exchange-level liquidity-adding activity, where all liquidity-adding volume executions from all members is combined to count towards the tier, and, after a tier threshold is reached, the enhanced rebate would be available to all members equally. Would this alternative address the Commission's concerns regarding competition among members? Would it impose a burden on competition among exchanges and a conflict of interest between members and customers when routing customer orders because of the incentives to reach tiers? Would that burden and conflict be greater than, or less than, under the current tiering structure? Would this alternative obviate the need for the anti-

[62] *See infra* section IV.E.1.

[63] *See infra* section IV.E.2.

evasion provisions in proposed Rule 6b–1(b) and the transparency disclosures in proposed Rule 6b–1(c)?

14. If exchanges continue to offer volume-based transaction pricing for member proprietary orders, should the Commission prohibit an exchange from basing tiers on total consolidated volume (''TCV''), or another metric that is based on volume transacted on other exchanges and off-exchange, and instead limit volume-based transaction tiers to volume that occurs solely on the exchange as a means of promoting competition among exchanges? Do tiers based on TCV constrain competition among exchanges by seeking primarily to preserve relative exchange market share? Why or why not? Even if tiers were not permitted to be based on TCV, could exchanges effectively circumvent such a prohibition by replicating a similar approach using absolute numbers and updating them on a monthly basis based on future estimates of total consolidated market volume? Why or why not?

15. If exchanges continue to offer volume-based transaction pricing for member proprietary orders, should the Commission prohibit exchanges from basing tiers in an auction, trading session, or special program or order types (*e.g.,* retail liquidity program) on volume done outside that auction, trading session, or program or order type? For example, should the Commission prohibit exchanges from basing tiers in the closing auction on volume transacted during regular trading hours in order to prevent an exchange from leveraging its closing auction in a manner that harms the ability of other exchanges to compete with it in the regular hours trading session? Do these types of arrangements impact competition among exchanges and among members? Why or why not?

16. Should the Commission prohibit volume-based exchange transaction pricing for agency-related orders also for listed options? Why or why not? Would extending the prohibition to listed options implicate the same costs and benefits that would apply to a prohibition on volume-based exchange transaction pricing for NMS stocks, or are there unique aspects of the listed options markets that would apply different costs or result in different benefits? What would those differences be?

17. If the Commission also prohibits volume-based exchange transaction pricing for member proprietary volume in NMS stocks, should listed options also be included within the broader prohibition? If the Commission were to adopt a broader prohibition on all volume-based exchange transaction pricing and apply it to all NMS securities (including NMS stocks and listed options), should it carve-out displayed liquidity-adding orders from an exchange's registered market makers in their assigned options classes and series from such a prohibition? Should there be any particular minimum quantitative and qualitative quoting requirements to qualify for the carve-out? Would such a carve-out for listed options be an appropriate benefit to encourage members to become and remain registered market makers and undertake registered market making obligations in the same way that it would for NMS stocks? Does tiered pricing encourage greater quoted depth or narrower quoted spreads, or both, for listed options in a similar manner to NMS stocks? If the Commission were to allow exchanges to offer volume-based transaction pricing but require that tiers be aggregated across all members and the associated pricing be applicable to all members uniformly, should that condition apply to listed options as well as NMS stocks?

18. Instead of prohibiting volume-based exchange transaction pricing for agency and riskless principal orders, should the Commission instead prohibit exchanges from offering tiers that are reasonably achievable by only one or a few members based on those members' order flow? Why or why not? If such a prohibition were adopted, would it be appropriate, for example, to prohibit tiers for which fewer than 50% of an exchange's members could have met the tier criteria during the prior month? Would assuring that exchanges set tier criteria at levels for which at least 50% of the exchange's members are capable of meeting based on order flow they route help assure that such tiered pricing meets the applicable statutory standards because at least a majority of members would be eligible to receive it? Would such a prohibition increase competition among members for customers while providing exchanges with the ability to offer tiered pricing at levels that incentivize members to contribute additional liquidity to the exchange? Alternatively, would it be appropriate, for example, to prohibit tiers for which only one, two, three, or four members are capable of qualifying to prevent tiers that are only achievable by only a few members and help assure that tiers meet the applicable statutory standards? Should any of the above prohibitions also be applied to proprietary orders for the account of a member? Why or why not? Should such a prohibition also apply to listed options? Why or why not?

C. Anti-Evasion

The prohibition in proposed Rule 6b–1(a) is intended in part to address the conflict of interest between members and customers that is exacerbated by volume-based exchange transaction pricing schedules when members route customer orders to an exchange, as well as address burdens on competition that volume-based exchange transaction pricing can impose on members competing for customer business. In light of the combination of these conflicts and potential competitive advantages, the Commission is concerned that members may have a financial incentive to mischaracterize their agency-related orders to continue to qualify for volume-based pricing.

To mitigate this incentive to mischaracterize order capacities, proposed Rule 6b–1(b)(1) would require an equities exchange that offers volume-based transaction pricing for member proprietary orders to have a rule to require its members to engage in practices that facilitate the exchange's ability to comply with the prohibition on volume-based exchange transaction pricing in connection with the execution of agency-related volume.[64] The proposed rule would provide exchanges with flexibility to adopt a rule that is tailored to its needs, systems, and members. For example, an exchange rule could require members to identify, for transaction pricing and billing purposes, their proprietary orders for their own account and submit or mark them in a distinct manner from all other orders. Similarly, an exchange could adopt or enhance any existing rule that requires members to properly label orders or identify which types of orders are submitted through specific ports or sessions to ensure the accuracy of order marking and ensure that members do not mislabel or misdirect orders specifically for transaction billing purposes.[65] Proposed Rule 6b–1(b)(1) would support proposed Rule 6b–1(a)'s prohibition on volume-based transaction fees, rebates, or other incentives in connection with the execution of agency or riskless principal orders in NMS stocks.

Second, proposed Rule 6b–1(b)(2) would require the exchange to establish,

[64] If an exchange does not offer volume-based transaction pricing, then it would not be required to adopt such a rule.

[65] Many exchanges already have rules requiring members to accurately mark their orders. *See, e.g.,* Nasdaq General 3, Rule 1032(a)(6) (requiring members to ''input [ ] accurate information into the System. . . .'').

maintain, and enforce written policies and procedures reasonably designed to detect and deter members from receiving volume-based pricing in connection with the execution of agency-related volume. While exchanges generally already establish, maintain, and enforce written policies to detect and deter non-compliance with their rules and the Federal securities laws and rules to ensure compliance with their obligations under the Exchange Act,[66] the Commission is adding a specific and complementary requirement in proposed Rule 6b–1 to help ensure exchange compliance with the proposed rule. Proposed Rule 6b–1(a) would apply specifically to exchange pricing schedules and how exchanges assess and collect fees and offer rebates and other incentives to members. For example, exchanges could develop written policies and procedures to audit member activity to ensure the proper marking of orders and review trading records to ensure that the exchange is not unintentionally offering tiered transaction pricing on agency-related volume. Proposed Rule 6b–1(b)(2) would complement existing exchange rules requiring the accurate marking of orders and thereby facilitate the ability of exchanges to comply with proposed Rule 6b–1(a).

Request for Comments

The Commission generally requests comment from the public on all aspects of proposed Rule 6b–1(b), including its objectives and its terms to achieve those objectives. More specific requests for comment are set forth below. As much as possible, commenters are requested to provide empirical data in support of any arguments or analyses and to offer explanations for their views.

19. Is the anti-evasion clause in proposed Rule 6b–1(b) appropriately designed to ensure exchange compliance with the proposed prohibition on volume-based exchange transaction pricing in connection with the execution of agency or riskless principal orders? Why or why not? To what extent are practices or systems already in place that could facilitate members accurately marking orders so that exchanges can distinguish proprietary and agency orders for transaction billing purposes?

D. Transparency for Volume-Based Pricing on Member Proprietary Orders

Proposed Rule 6b–1(c) would add a new public disclosure requirement for exchanges that offer volume-based transaction pricing in connection with the execution of proprietary orders in NMS stocks for the account of a member.[67] For purposes of proposed Rule 6b–1(c), proprietary orders are those where the member is trading solely for its own account and not in connection with filling an order for a customer. Proprietary orders are principal capacity orders and are not agency or riskless principal capacity orders.

Disclosing information about the manner in which an exchange's tiered transaction pricing applies across its membership would enhance public transparency regarding the application of an exchange's tiered pricing structure for member proprietary volume. In turn, the increased transparency would enhance the ability of members, other exchanges, and the public in considering and commenting on whether proposed volume-based pricing changes applicable to member proprietary volume provide for the ''equitable allocation of reasonable dues, fees, and other charges'' [68] that are ''not designed to permit unfair discrimination'' between broker-dealers [69] and that do not ''impose any burden on competition not necessary or appropriate in furtherance of the purposes'' [70] of the Exchange Act. For example, monthly disclosures would provide timely information during the 60 day suspension period of an exchange's proposed pricing change that would allow the public to see the impact of a new or revised pricing tier during the first month it was in effect. The Commission and the public could use that information to assess exchange statements about the number of members that the exchange expected to qualify for a proposed tier, and commenters could use that information to provide comment as to whether a tier change meets the applicable statutory standards.

The Commission also believes that the public disclosure of such information would be consistent with section 11A of the Exchange Act in that it could assist in assuring ''fair competition among brokers and dealers, [and] among exchange markets'' and ''the practicability of brokers executing investors' orders in the best market.'' [71] For example, the proposed disclosures would allow interested parties to see how many members have qualified for an exchange's pricing tiers, and how members have responded to tiered pricing changes (*e.g.,* by looking at month-to-month disclosures to see how many members moved up to a new or revised tier to qualify for a more generous pricing incentive). That information could be useful in helping the Commission and public commenters assess whether pricing tier changes are reasonable, equitably allocated, not unfairly discriminatory, and do not impose a burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act.[72]

Specifically, proposed Rule 6b–1(c) would require equities exchanges to submit electronically to the Commission, within five calendar days after the end of each calendar month, the information described below. Given that exchanges assess transaction prices to their members on a monthly basis according to their respective pricing tiers, the Commission believes that such information should be readily available to exchanges, since they are already familiar with the pricing tier for which each member qualifies. Further, submitting the disclosures within five calendar days after the end of each calendar month would help ensure that the information is available in a timely manner for the Commission and the public's consideration after an exchange implements a new pricing change to show the impact of the pricing change during the first month that it was billed to members. This timing would allow time for the Commission and the public to review this data before the expiration of the period within which the Commission is able to summarily temporarily suspend a proposed rule change.[73]

The content of the disclosures is intended to show a high-level and anonymized summary of the volume-based transaction tiers applicable to the execution of proprietary orders in NMS stocks for the account of a member and how many members qualify for each tier. Monthly tables would show, for example, the potential impact of any recent tiered transaction pricing change for member proprietary orders during the month that it was first in effect following the exchange's proposed rule change as well as how members qualify over time for pricing tiers that do not change. While the Commission reviews each proposed rule change, the actual

[66] *See, e.g.,* 15 U.S.C. 78s(g)(1).

[67] Exchanges that do not offer any volume-based transaction pricing would not be required to submit the disclosures required under proposed Rule 6b–1(c).

[68] 15 U.S.C. 78f(b)(4).

[69] 15 U.S.C. 78f(b)(5).

[70] 15 U.S.C. 78f(b)(8).

[71] 15 U.S.C. 78k–1(a)(1)(C)(ii) and (iv).

[72] Under the proposed rule, an exchange would not have to identify its members by name in the proposed transparency disclosures.

[73] *See supra* note 6 and accompanying text (discussing suspensions).

effect of a pricing change cannot be known in advance or guaranteed. The information in the proposed disclosures is intended to provide the Commission and the public with insight into the application of an exchange's volume-based transaction pricing schedule, which would allow interested persons to better assess an exchange's volume tiers, particularly where the highest rebate or lowest tiers on an exchange are occupied by only one or a few members. Therefore, having more timely and readily available information with respect to the actual effect of an exchange transaction pricing change would be useful to the Commission in determining whether to summarily temporarily suspend a proposed rule change before the deadline to summarily temporarily suspend expires. Further, the Commission also believes such information would be useful to the public in assessing the impact of the proposed rule change and further informing their comments on a proposed pricing change.

First, proposed Rule 6b–1(c)(1) would require every exchange that offers volume-based transaction fees, rebates, or other incentives in connection with the execution of proprietary orders in NMS stocks to submit electronically to the Commission each calendar month, within five calendar days after the end of the month, the number of members that executed proprietary orders in NMS stocks on the exchange for the member's account. The proposed rule would require monthly submissions because exchange fees are typically effective at the beginning of a calendar month and revised as frequently as monthly.[74] The Commission believes that this information could be used to better understand the impact of an exchange's volume-based transaction pricing structure across its members. Specifically, this number would provide the baseline denominator against which one could calculate percentages of members that met a specific tier.[75] Seeing the total number of members with proprietary orders during a month would thus provide the baseline against which the number of members qualifying for any one tier in that month could be understood.

Second, proposed Rule 6b–1(c)(2) would require every exchange that offers volume-based transaction fees, rebates, or other incentives in connection with the execution of proprietary orders in NMS stocks to disclose a structured data table for each volume-based transaction fee, rebate, and other incentive that includes information to promote transparency regarding how that tier applies among the exchange's membership. Exchanges would be required to submit electronically to the Commission each calendar month, within five calendar days after the end of the month, the following information for each month:

1. *A label to identify the* ''*base*'' *fee and rebate.* Showing the base fee or rebate allows the reader of the table to compare and evaluate each tiered pricing level against what the exchange otherwise would assess to its members in the absence of volume-based pricing.[76] The inclusion of the base fee and rebate information in structured data format also would allow data analysis and computations to be performed, which would facilitate comparisons over time and across exchanges.

2. *A label to identify each pricing tier.* For example, ''Liquidity Providing Rebate Tier 1,'' ''Step-up Rebate Tier 1,'' or ''Removing Tier 2.'' The label used in the disclosure would be required to correspond to the label the exchange uses in its pricing schedule so that the public can easily locate the tier on the exchange's pricing schedule. Providing a label in structured data format also would allow for data analysis using those labels to identify each pricing tier. Results from such analysis would then be easily referenced against the exchange's pricing schedule.

3. *The amount of the fee, rebate, or other incentive.* This information would allow the reader of the table to understand what pricing applies to each pricing tier without having to consult the exchange's pricing schedule. In addition, the inclusion of the pricing amount in a structured data format would allow data analysis and computations to be performed, which would facilitate comparisons over time and across exchanges.

4. *An explanation of the tier requirements.* Including this explanation would allow the reader of the table to understand the requirements for achieving each tier without having to consult the exchange's pricing schedule. In addition, having this information in structured data format would allow data analysis and computations to be performed, which would facilitate comparisons over time and across exchanges.

5. *The total number of members that qualified for the base fee, base rebate, or each tier during the month.* This disclosure would provide important transparency into the application of volume-based exchange transaction pricing and how the prices apply among an exchange's membership. Among other things, it could provide members with insight as to the tiers that other members with whom they compete qualify, which could be useful in considering whether an exchange's pricing is imposing a burden on the member's ability to compete with those other members. It also may provide insight into how an exchange's fees and rebates are distributed among members and whether those fees that fund the rebates the exchange offers, as well as fund part of the exchange's operations, constitute an equitable allocation among members. It also would provide data against which exchange representations made as part of or in connection with proposed pricing changes could be verified.

Proposed Rule 6b–1(c) would require that the information be provided in an easily understandable table format, using structured data specified by the Commission.[77] Exchanges would be required to retain those records and information pursuant to 17 CFR 240.17a–1 (Rule 17a–1).[78]

Request for Comments

The Commission generally requests comment from the public on all aspects of proposed Rule 6b–(c), including its objectives and its terms to achieve those objectives. More specific requests for comment are set forth below. As much as possible, commenters are requested to provide empirical data in support of any arguments or analyses and to offer explanations for their views.

20. Is the definition of proprietary order described in section II.D. appropriate? If the definition described in section II.D. is not appropriate, what definition should the Commission use for purposes of Rule 6b–1? Should the Commission include the definition

[74] *See supra* note 17 and accompanying text. Further, as discussed above, monthly disclosure would also provide the Commission with timely information to consider whether to temporarily suspend a proposed rule change within the statutory deadline of 60 days beginning on the date of filing of such proposed rule change. *See* 15 U.S.C. 78s(b)(3)(C).

[75] *See infra* section II.D., Request for Comments (requesting comment on other benchmarks).

[76] The base fee would be the highest fee that the exchange assesses to members by default if no incentives apply. Similarly, the base rebate would be the lowest rebate that the exchange provides to members if no incentives apply.

[77] *See* proposed Rule 6b–1(c)(3). Under proposed Rule 6b–1(c)(3), exchanges would be required to provide information using Interactive Data File in accordance with Rule 405 of Regulation S–T.

[78] 17 CFR 240.17a–1. Generally, Rule 17a–1(b) requires national securities exchanges to retain specified documents for a period of not less than five years, the first two years in an easily accessible place.

described in section II.D (or another definition) in Rule 6b–1, or is the term commonly understood without needing to be defined in the rule?

21. Does the proposed 5 calendar day deadline for exchanges to submit the transparency disclosures after the end of each calendar month under proposed Rule 6b–1(c) provide exchanges with sufficient time to prepare and submit the disclosures? If an exchange files a proposed rule change related to transaction pricing that becomes effective on the first day of a month, does the proposed 5 calendar day deadline after the end of that month provide sufficient time for the Commission and commenters to consider the disclosures before the expiration of the 60-day statutory deadline to summarily temporarily suspend the proposed rule change at issue? If 5 calendar days is not sufficient for exchanges to submit the transparency disclosures, would a 7 or 10 calendar day deadline provide sufficient time? If an exchange files a proposed rule change related to transaction pricing that becomes effective on the first day of a month, would a 7 or 10 calendar day deadline after the end of that month provide sufficient time for the Commission and commenters to consider the disclosures before the expiration of the 60-day statutory deadline to summarily temporarily suspend the proposed rule change at issue?

22. Should the transparency disclosures under proposed Rule 6b–1(c) also require exchanges to report the number of their registered market makers on the exchange during a month if an exchange offers volume-based transaction pricing tiers solely applicable to its market makers, in order to allow the public to see how many registered market makers qualify for exchange tiered pricing that is applicable only to such members? Would that information be useful to calculate percentages for the volume-based transaction tiers that apply specifically to market makers (*e.g.,* to be able to calculate that 10% of registered market makers qualified for the market-maker liquidity providing rebate Tier 2)? Would that information be helpful to better understand the impact of exchange tiered transaction pricing on competition between registered market maker members and members that trade proprietarily but not as registered market makers?

23. Should the transparency disclosure under proposed Rule 6b–1(c) also require exchanges to separately report the number of members that participated during the month in any program that has its own volume-based transaction pricing in order to be able to compute percentages specific to the program? For example, tiers specific to Tape A, B, and C, to stocks under $1, to a retail liquidity program, or to the closing auction. Would that more granular level of information be useful to commenters in commenting on specific individual pricing proposals that affect such programs? For example, if an exchange has tiers for Tape B and reports only ten members that qualified for them in a month, would it be useful to know that only 12 out of forty members transacted in Tape B stocks on the exchange that month so that percentages can be calculated out of eligible entities rather than all members? Why or why not?

24. Should the transparency disclosure under proposed Rule 6b–1(c) also require exchanges to report the following:

a. the applicable trading session (*e.g.,* pre-market, opening auction, regular hours, closing auction, post-market) to allow readers of the tables to more quickly identify with certainty which tiers apply to which trading session and allow researchers to be able to use electronic means to parse that data;

b. the applicable securities (*e.g.,* Tape A, B, or C; sub-$1, exchange traded funds, etc.) to allow readers of the tables to more quickly identify with certainty which tiers apply to which securities and allow researchers to be able to use electronic means to parse that data;

c. whether the fee, rebate, or other incentive is applicable to adding or removing liquidity to allow readers of the tables to more quickly identify with certainty which tiers apply to which types of activity and allow researchers to be able to use electronic means to parse that data;

d. the number of MPIDs qualifying for the price level during the month to provide a different metric to assess how many members qualify for each pricing tier;

e. the cumulative volume of shares qualifying for the tier during the month to provide more context to understand the amount of volume that qualifies at each pricing tier, which the number of members alone would not capture, and to allow comparison with the exchange's overall volume;

f. the cumulative dollar amount of fees, rebates, or other incentives (as applicable) at the tier during the month to better understand the financial impact of each pricing tier, both on members and on the exchange, and allow comparison of that impact between tiers; and

g. the average transaction fee paid and rebate received by members during the month.

25. Would additional columns allow easier sorting and analysis of the tables by machine or otherwise? If so, please explain.

26. Should the transparency disclosures under proposed Rule 6b–1(c) require exchanges to report every net price combination for any volume-based fee, rebate, or other incentive, including all additive or creditable pricing (*e.g.,* a liquidity providing rebate of $0.0028 plus a step-up tier of $0.0003 would be reported as its own pricing tier of $0.0031)? Would doing so be helpful to show whether volume-based transaction tiers are customized to a specific member?

27. Should the transparency disclosures under proposed Rule 6b–1(c) be posted on an exchange's website in addition to, or instead of, being submitted electronically to the Commission? Why or why not?

28. Are there uses beyond those identified in this release for the transparency disclosures? For example, would having volume-based exchange transaction fees in a structured data format help members as well as other market participants and academics parse the pricing schedules across exchanges and track changes over time? Would the transparency disclosures affect routing preferences among members trading proprietarily? Would members use the disclosures to comment on exchange proposed rule change filings or advocate for exchanges to change their transaction pricing if they have more transparency of the tiers for which their competitors qualify? Would that transparency provide a useful datapoint to assess whether volume-based exchange transaction pricing proposals meet the applicable statutory standards? Why or why not?

29. Would the proposed disclosure provision raise any issues related to disclosures of proprietary trading information or other confidentiality concerns, especially if the disclosures were read in conjunction with broker-dealer Rule 605/606 reports?

30. Do exchanges enter into arrangements with members about transaction pricing for proprietary and/or agency-related orders that result in or are connected to an exchange proposal to adopt or amend a specific volume-based transaction pricing tier? If so, what types of terms and conditions might such an arrangement include? To what extent are these arrangements memorialized in writing? How many such arrangements, if any, do exchanges enter into each year? If such

arrangements exist but are not commonly memorialized in writing, should the Commission add a provision to proposed Rule 6b–1 to require exchanges to ''document any arrangement, whether written or oral, concerning volume-based transaction pricing, including the parties to the arrangement, all qualitative and quantitative terms concerning the arrangement, and the date and terms of any changes to the arrangement''?

III. Paperwork Reduction Act

Certain provisions of proposed Rule 6b–1 contain ''collection of information requirements'' within the meaning of the Paperwork Reduction Act of 1995 (''PRA'').[79] The Commission is submitting these collections of information to the Office of Management and Budget (''OMB'') for review in accordance with 44 U.S.C. 3507(d) and 5 CFR 1320.11.[80] An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the agency displays a currently valid control number.[81] The title of the new collection of information is ''Volume-Based Exchange Transaction Pricing for NMS Stocks.''

A. Summary of Collections of Information

The proposed rule includes collection of information requirements within the meaning of the PRA.

1. Rule 6b–1(a)—Prohibition on Volume-Based Pricing for Agency-Related Volume

As discussed above, proposed Rule 6b–1(a) provides that equities exchanges shall not offer volume-based transaction fees, rebates, or other incentives in connection with the execution of agency or riskless principal orders in NMS stocks. This prohibition would require equities exchanges that currently offer volume-based transaction pricing for agency-related orders to file a proposed rule change with the Commission to update their price lists.

2. Rule 6b–1(b)(1)—Rules To Prevent Evasion

Proposed Rule 6b–1(b)(1) would require an equities exchange that offers volume-based transaction pricing in connection with the execution of proprietary orders in NMS stocks for the account of a member to adopt a rule to require its members to engage in practices that facilitate the exchange's ability to comply with the prohibition in proposed Rule 6b–1(a).

3. Rule 6b–1(b)(2)—Policies and Procedures To Prevent Evasion

Proposed Rule 6b–1(b)(2) would require an equities exchange that offers volume-based transaction pricing in connection with the execution of proprietary orders in NMS stocks for the account of a member to establish, maintain, and enforce written policies and procedures reasonably designed to detect and deter members from receiving volume-based pricing in connection with the execution of agency or riskless principal orders in NMS stocks.

4. Rule 6b–1(c)—Transparency for Volume-Based Pricing on Member Proprietary Orders

Proposed Rule 6b–1(c) would require an equities exchange that offers volume-based transaction fees, rebates, or other incentives in connection with the execution of proprietary orders in NMS stocks for the account of a member to submit electronically to the Commission information regarding those fees, rebates, or other incentives, including how many members qualify for such fees, rebates, or other incentives on a monthly basis.

B. Proposed Use of Information

1. Rule 6b–1(a)—Prohibition on Volume-Based Pricing for Agency-Related Volume

The collection of information associated with Rule 6b–1(a) would be exchange rule filings with the Commission to eliminate volume-based pricing for agency-related orders from their pricing schedules. The collection of information would bring the exchanges into compliance with Rule 6b–1(a), which would foster competition among broker-dealers and mitigate conflicts of interest for agency-related volume.

2. Rule 6b–1(b)(1)—Rules To Prevent Evasion

Proposed Rule 6b–1(b)(1) would assist exchanges in complying with proposed Rule 6b–1(a) by requiring exchanges to impose rules that require members to engage in practices, such as accurate order marking, to better enable the exchange to assess its pricing in compliance with the proposed rule.

3. Rule 6b–1(b)(2)—Policies and Procedures To Prevent Evasion

Proposed Rule 6b–1(b)(2) would assist national securities exchanges in complying with proposed Rule 6b–1(a) by requiring them to adopt policies and procedures reasonably designed to detect and deter members from receiving volume-based exchange transaction pricing in connection with the execution of agency or riskless principal orders in NMS stocks.

4. Rule 6b–1(c)—Transparency for Volume-Based Pricing on Member Proprietary Orders

The disclosure of information about how an exchange's volume-based transaction pricing for member proprietary orders applies across its membership would enhance the transparency of an exchange's tiered pricing structure. In turn, the increased transparency would enhance the ability of members, other exchanges, and the public in considering and commenting on proposed volume-based pricing changes applicable to member proprietary volume.

C. Respondents

The respondents to these collections of information would be national securities exchanges that offer volume-based transaction fees, rebates, or other incentives in connection with the execution of orders in NMS stocks. Currently, while there are 16 national securities exchanges that trade NMS stocks, only 13 offer volume-based transaction pricing. Therefore, there are 13 estimated respondents.

D. Total Initial and Annual Reporting and Recordkeeping Burdens

1. Rule 6b–1(a)—Prohibition on Volume-Based Pricing for Agency-Related Volume

As discussed above, proposed Rule 6b–1(a) would require equities exchanges that currently offer volume-based transaction pricing to file a rule change with the Commission to update their price list, if necessary, to eliminate any existing volume-based pricing that would not comply with the proposed rule. This would be a one-time initial burden, and exchanges should not incur an ongoing burden once they have updated their rules. However, the PRA burden associated with the collection of information resulting from exchange rule filings that would be required pursuant to proposed Rule 6b–1(a) would be covered by the existing PRA burden estimates for Rule 19b–4 because those changes would be filed on Form 19b–4.[82]

[79] 44 U.S.C. 3501 *et seq.*

[80] 44 U.S.C. 3507; 5 CFR 1320.11.

[81] 5 CFR 1320.11(l).

[82] *See* SEC File No. 270–38, OMB Control No. 3235–0045 (June 21, 2023), available at *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202304-3235-017*.

2. Rule 6b–1(b)(1)—Rules To Prevent Evasion

Proposed Rule 6b–1(b)(1) would require an equities exchange that offers volume-based transaction pricing to have rules to require its members to engage in practices that facilitate the exchange's ability to comply with the prohibition in proposed Rule 6b–1(a). Similar to the burden for Rule 6b–1(a), this would be a one-time initial burden, although an exchange may decide to amend the rule it adopts pursuant to proposed Rule 6b–1(b)(1) from time to time. However, the PRA burden associated with the collection of information resulting from exchange rule filings that would be required pursuant to proposed Rule 6b–1(b)(1) would also be covered by the existing PRA burden estimates for Rule 19b–4 because those changes would be filed on Form 19b–4.[83] The Commission encourages comments on this point.

3. Rule 6b–1(b)(2)—Policies and Procedures To Prevent Evasion

Proposed Rule 6b–1(b)(2) would require exchanges to establish, maintain, and enforce written policies and procedures to detect and deter members from receiving volume-based exchange transaction pricing in connection with the execution of agency or riskless principal orders in NMS stocks. Exchanges would incur an initial burden and an annual ongoing burden associated with proposed Rule 6b–1(b)(2). The Commission believes that many exchanges generally already have rules and policies and procedures in place to ensure that members are correctly marking their orders, though those policies and procedures may need to be updated to ensure compliance with the proposed rule in the context of exchange transaction pricing.

Exchanges, at a minimum, would be required to review their existing policies and procedures. Certain exchanges may need to supplement or revise their policies and procedures to ensure that they are reasonably designed to deter and detect members from receiving tiered pricing on orders for which tiered pricing is prohibited. Although the exact nature and extent of compliance with proposed Rule 6b–1(b)(2) would likely differ based on the existing policies and procedures of each respondent, the Commission estimates that the one-time, initial burden to update or adopt any additional written policies and procedures required under proposed Rule 6b–1(b)(2) would be approximately 50 hours per exchange or 650 burden hours across 13 exchanges that have volume-based transaction pricing.[84]

The 13 equities exchanges that have volume-based transaction pricing would incur annual ongoing burden hours to maintain and review their policies and procedures adopted under proposed Rule 6b–1(b)(2) to ensure their effectiveness. Those exchanges also would need to review for compliance pursuant to their policies and procedures. The Commission estimates that each exchange would likely spend an average of 25 hours per year on an ongoing basis, for a total of 325 hours across all 13 exchanges.[85]

4. Rule 6b–1(c)—Transparency for Volume-Based Pricing on Member Proprietary Orders

Proposed Rule 6b–1(c) would require exchanges that offer volume-based transaction pricing for the execution of proprietary orders in NMS stocks for the account of a member to submit electronically to the Commission aggregated information regarding how many members qualify for those pricing tiers. These submissions would be accessible to the public via the EDGAR system and would reflect each exchange's particular pricing structure. The exchanges would likely incur an initial burden and an annual ongoing burden associated with Rule 6b–1(c). Exchanges have ready access to all of the underlying information and data necessary to comply with proposed Rule 6b–1(c) because the disclosures are summaries of the pricing schedules that exchanges maintain and the exchanges know the number of members that qualify for a particular pricing tier because they calculate the fees, rebates, and other incentives applicable to their members on a monthly basis. Consequently, the proposed rule would not require exchanges to acquire or record an entirely new and unfamiliar set of information. The exchanges, however, would be required to present the required information and data in a new structured data format and submit such information electronically to the Commission on a monthly basis.

Exchange pricing schedules are publicly available and identify all of the exchange's volume-based transaction fees, rebates, and other incentives. To comply with proposed Rule 6b–1(c)(2), the exchange would have to identify each volume-based transaction fee, rebate, and other incentive, and: (i) use a label to identify the base fee or rebate, (ii) use a label to identify each pricing tier that corresponds to the label used in the exchange's pricing schedule, (iii) identify the amount of the fee, rebate, or other incentive, (iv) provide an explanation of the tier requirement, and (v) provide the total number of members that qualified for the base fee, base rebate, or each tier during the month. Parts (i) through (iv) would require the exchange to take information from its publicly accessible pricing schedule and put it into the required structured data format. The information required for part (v) would be readily available to the exchange since it assesses transaction prices to its members on a monthly basis in accordance with its pricing schedule and thus knows which members qualify for which tiers though exchanges currently are not required to publicly disclose a tally of that information by tier.

Furthermore, proposed Rule 6b–1(c)(1) requires the exchange to identify the number of members that executed proprietary orders in NMS stocks for the member's account on the exchange during the month. Exchanges do not currently publicly disclose a tally of this information. However, exchanges generally have ready access to trading information of their members that would reveal this information and exchanges generally know which of their members are engaged in an agency business, which are engaged in proprietary trading, and which are engaged in both because exchanges broadly know about what lines of business their members are engaged in as part of their membership registration. Accordingly, the burden on exchanges to calculate the number of members engaged in proprietary trading would be low.

The Commission estimates that each exchange would incur 58 initial burden

[83] *See id.*

[84] The Commission derived the total estimated burdens from the following estimates: (Attorney at 30 hours) + (Compliance Counsel at 10 hours) + (Chief Compliance Officer at 5 hours) + (General Counsel at 5 hours) = 50 burden hours. 50 burden hours per exchange × 13 respondents = 650 total burden hours. The Commission's estimate is informed by the estimated filing burden for Form 19b–4 (34 hours). *See* Supporting Statement for the Paperwork Reduction Act Information Collection Submission for Form 19b–4 (Apr. 18, 2023), available at *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202304-3235-017.* The Commission believes that the policies and procedures required under proposed Rule 6b–1(b)(2) may require more effort to prepare than the proposed rule change required under proposed Rule 6b–1(b)(1).

[85] The Commission derived the total estimated burdens from the following estimates: (Compliance Attorney at 12 hours) + (Compliance Manager at 8 hours) + (Business analyst at 5 hours) = 25 burden hours. 25 burden hours per exchange × 13 respondents = 325 total burden hours. The ongoing burden hours associated with proposed Rule 6b–1(b)(2) is estimated to be lower than the initial burdens because the Commission expects it to be less burdensome to maintain and review existing policies and procedures than to establish new ones.

hours for the creation of new tables to ensure that data responsive to the proposed disclosure requirements is correctly collected and formatted, and to set up automated programs where appropriate, or 754 total initial burden hours across 13 exchanges.[86] The Commission does not believe the information required to be aggregated and included in disclosures made pursuant to proposed Rule 6b–1(c) would require respondents to acquire new hardware or systems to process the information required in the reports. Rather, the exchanges' initial burden would consist of creating and formatting a table that would be responsive to the requirements of proposed Rule 6b–1(c). As described above, this would require the exchanges to convert a portion of the information available on their publicly accessible pricing schedules into a structured data format. Once created, these tables should not change unless the exchanges create new pricing tiers or change the requirements or dollar amounts of existing tiers. The Commission solicits comment on the accuracy of these estimates.

Furthermore, because exchanges are not currently subject to EDGAR filing requirements, equities exchanges would incur a one-time compliance burden of submitting Form ID in order to be able to submit the disclosures electronically to the Commission through EDGAR. Respondents would apply for access to EDGAR using Form ID and receive access codes to submit documents through the EDGAR system. The Commission estimates that each filer that currently does not have access to EDGAR would incur an initial, one-time burden of 0.30 hours to complete and submit a Form ID.[87] However, the PRA burden associated with completing and submitting a Form ID would be covered by the existing PRA burden estimates for Form ID.[88]

The 13 equities exchanges that have volume-based transaction pricing also would incur annual ongoing burden hours to aggregate and disseminate the information required under proposed Rule 6b–1(c). Proposed Rule 6b–1(c) would require exchanges to submit electronically updated information each month. An exchange generally would not need to update the disclosure information required under proposed Rule 6b–1(c)(2)(i)–(iv) unless the exchange amends its pricing schedule, in which case the exchange would need to make targeted changes to these disclosures in accordance with the changes it makes to its pricing schedule. The Commission expects that the disclosures required by proposed Rule 6b–1(c)(1) and Rule 6b–1(c)(2)(v) would possibly change and could need to be updated as frequently as each month. The Commission believes the exchanges would use automated programs to meet the ongoing monthly reporting obligation under proposed Rule 6b–1(c) but each report may require staff to verify the accuracy of the information. The Commission estimates that each exchange would incur 8 burden hours per monthly report for a total of 96 ongoing burden hours on an annual basis.[89] Therefore, the Commission estimates 1,248 total ongoing annual burden hours across 13 exchanges.[90]

TABLE 3—PRA SUMMARY TABLE

Rule	Number of respondents	Initial burden hours per respondent	Total initial burden hours	Ongoing burden hours per respondent on annual basis	Total ongoing burden hours on annual basis
Rule 6b–1(b)(2)	13	50	650	25	325
Rule 6b–1(c)	13	58	754	96	1,248
Total		108	1,404	121	1,573

E. Collection of Information Is Mandatory

The collection of information discussed above would be a mandatory collection of information.

F. Confidentiality of Responses to Collection of Information

The collection of information under proposed Rule 6b–1(a) and 6b–1(b)(1) would not be confidential because exchange proposed rule changes filed with the Commission are public information. Similarly, the collection of information under proposed Rule 6b–1(c) also would not be confidential. Rather, each exchange would be required to submit electronically to the Commission the information required under proposed Rule 6b–1(c) and this information would be made publicly available. The collection of information under proposed Rule 6b–1(b)(2) concerning the written policies and procedures would contain information about an exchange's regulatory program because those materials would provide details on how the exchange enforces compliance with its rules, specifically how the exchange detects and deters members from receiving volume-based transaction pricing in connection with the execution of agency and riskless principal orders in NMS stocks. Accordingly, where the Commission requests that an exchange produce those documents, an exchange can request confidential treatment of the information. If such confidential treatment request is made, the Commission anticipates that it will keep the information confidential subject to applicable law.

[86] The Commission derived the total estimated burdens from the following estimates: (Sr. Programmer at 25 hours) + (Sr. Systems Analyst at 10 hours) + (Compliance Manager at 10 hours) + (Compliance Attorney at 8 hours) + (Director of Compliance at 5 hour) = 58 burden hours. 58 burden hours per exchange × 13 respondents = 754 total burden hours.

[87] Form ID (OMB control number 3235–0328) must be completed and filed with the Commission by all individuals, companies, and other organizations who seek access to file electronically on EDGAR. Accordingly, a filer that does not already have access to EDGAR must submit a Form ID, along with the notarized signature of an authorized individual, to obtain an EDGAR identification number and access codes to file on EDGAR. *See* Supporting Statement for the Paperwork Reduction Act Information Collection Submission for Form ID (Dec. 20, 2021), available at *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202112-3235-003* (stating that it takes 0.3 hours to prepare Form ID).

[88] *See id.*

[89] The Commission derived the total estimated burdens from the following estimates: (Compliance Attorney at 6 hours) + (Compliance Manager at 2 hours) = 8 burden hours per monthly filing. 8 burden hours × 12 months = 96 annual burden hours per respondent.

[90] 96 annual burden hours per exchange × 13 respondents = 1,248 total burden hours per year.

G. Retention Period for Recordkeeping Requirements

National securities exchanges would be required to retain records and information pursuant to Rule 17a–1 under the Exchange Act [91] for a period of five years.

H. Request for Comments

The Commission requests comment on whether the estimates for burden hours and costs are reasonable. Pursuant to 44 U.S.C. 3506(c)(2)(B), the Commission solicits comments to: (1) evaluate whether the proposed collections of information are necessary for the proper performance of the functions of the Commission, including whether the information would have practical utility; (2) evaluate the accuracy of the Commission's estimate of the burden of the proposed collections of information; (3) determine whether there are ways to enhance the quality, utility, and clarity of the information to be collected; and (4) determine whether there are ways to minimize the burden of the collections of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

Persons submitting comments on the collection of information requirements should direct them to the Office of Management and Budget, Attention: Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Washington, DC 20503, and should also send a copy of their comments to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090, with reference to File Number S7–18–23. Requests for materials submitted to OMB by the Commission with regard to this collection of information should be in writing, with reference to File Number S7–18–23 and be submitted to the Securities and Exchange Commission, Office of FOIA/PA Services, 100 F Street NE, Washington, DC 20549–2736. As OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication.

IV. Economic Analysis

A. Introduction

The Commission is mindful of the economic effects, including the benefits and costs, of the proposed rule. Section 3(f) of the Exchange Act provides that when engaging in rulemaking that requires the Commission to consider or determine whether an action is necessary or appropriate in the public interest, to also consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation.[92] Section 23(a)(2) of the Exchange Act also requires the Commission to consider the effect that the proposed rule would have on competition, and it prohibits the Commission from adopting any rule that would impose a burden on competition not necessary or appropriate in furtherance of the Exchange Act.[93] The analysis below addresses the likely economic effects of the proposed rule, including the anticipated benefits and costs of the amendments and their likely effects on efficiency, competition, and capital formation. The Commission also discusses the potential economic effects of certain alternatives to the approaches taken in this proposal.

The Commission is proposing to prohibit volume-based transaction fees, rebates, or other incentives in connection with the execution of agency or riskless principal orders in NMS stocks, as well as the disclosure of, among other things, the number of exchange members that qualify for different transaction pricing tiers.

The proliferation of tiered transaction pricing schedules across many exchanges has resulted in a complex system of transaction-based fees, which, along with a lack of transparency regarding how many members qualify for the various pricing tiers, makes it difficult for market participants to assess the tiered transaction pricing schedules' impact on the fees and rebates ultimately realized across exchange members. Further, it may be the case that some tiers only have a single market participant that ultimately qualifies for that tier in a given month. This lack of transparency presents a challenge to other exchange members, exchanges, and interested parties to assess for themselves whether an exchange's proposed transaction price schedule meets the applicable statutory standards, so that they can comment on such a proposed fee rule. It is also possible that the general complexity of the tiers inhibits the ability of all market participants to understand the price of exchange services and understand the impact of the particular price schedules implemented. By prohibiting the application of volume-based pricing for agency-related orders the proposed rule would help simplify pricing for agency-related order flow whilst the proposed disclosure provisions will help promote transparency for principal order flow, for which volume-based transaction pricing will continue to be permitted.

While exchanges compete, in part, on the basis of their price schedules, volume-based transaction pricing may reduce competition among executing brokers, which could increase costs for investors. With volume-based transaction pricing, rebates go up and fees go down as a broker-dealer's volume increases, meaning that such pricing gives higher-volume broker-dealers lower trading costs. As a result, smaller firms, such as new entrants, face higher trading costs relative to high-volume incumbent broker-dealers, potentially reducing competition and raising costs for investors.

The implementation of volume-based transaction fee and rebate pricing introduce additional incentives to concentrate order flow on a given exchange. Volume-based tiers may encourage the concentration of a member's order flow on the exchange by offering more favorable pricing to a member who executes greater trading volume on their platform. Not only does volume-based transaction price tiering incentivize the concentration of order flow, it also indirectly increases the opportunity cost of routing orders to a competing venue, because by doing so the exchange member lowers the likelihood that it will qualify for a better pricing tier. This concentration also directly reduces the ability of an exchange not offering rebates to compete with those that do. Rebates themselves are a less transparent means of incentivizing liquidity as compared with bid-ask spreads. Thus, the proliferation of volume-based tiers may reduce efficiency by making a non-rebate-focused model difficult to sustain.

The application of volume-based pricing to non-principal order flow adds to the conflict of interest between a broker and its customer as broker-dealers may be incentivized to execute customer orders in a manner that would not be consistent with the broker-dealer's duty of best execution (to execute customer trades at the most favorable terms reasonably available under the circumstances).[94] Tier qualification is based on the exchange member's total monthly trading volume

[91] 17 CFR 240.17a–1.

[92] *See* 15 U.S.C. 78c(f).

[93] *See* 15 U.S.C. 78w(a)(2).

[94] The Commission has previously described a non-exhaustive list of factors that may be relevant to a broker-dealers' best execution analysis. *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 at 37538 (June 29, 2005).

and upon qualification the pricing of that tier applies to the entirety of the member's trading volume on the exchange. Diverting order flow to other trading venues may risk the member losing out on higher rebates or lower fees for a whole swath of their order flow. Volume-based pricing tiers thereby generate the potential for exchange members to concentrate customer order flow onto particular exchanges in order to increase the likelihood of tier qualification possibly contrary to the interests of individual customers.

Exchanges, particularly those with the largest market share, are unlikely to unilaterally reduce the use of transaction pricing tiers or address the advantages that the application of these pricing tiers to agency-related volume creates for high-volume broker-dealers.[95] An exchange may perceive that unilaterally excluding agency trading volume from volume-based transaction pricing tiers would reduce one incentive for members to concentrate agency orders on their exchange, risking that their members instead direct that order flow to competing exchanges with volume-based pricing tiers. Because of this incentive to concentrate order flow, an exchange that unilaterally eliminated volume-based transaction pricing tiers for agency-related order flow could experience a loss of trading volume, especially if competing venues continue to reward agency-related order flow concentration. If all existing exchanges moved to exclude agency-related volume from volume-based transaction pricing tiers, the potential gains from a single exchange (or new entrant) deviating and charging volume-based prices could be very high, reducing the likelihood that such an effort would be successful without the aid of a regulatory prohibition. In this case the exchanges, particularly those with members with high-volume agency order flow, may also lose activity as the reduced incentive to concentrate order flow may result in broker-dealers routing order-flow to other venues.

Exchanges are required to file changes to their price schedules with the Commission and publish their pricing schedules online. However, when filing such proposed rule changes and publishing such pricing schedules, they typically refrain from disclosing the number of members that qualify for their different tiers, information which would be useful to market participants. Knowledge of this would aid exchange members, other exchanges, and the public in considering and commenting on whether proposed volume-based pricing changes are equitable and not unfairly discriminatory. The Commission does not believe that the exchanges themselves can be expected to rectify the lack of tier transparency because doing so may reveal valuable information to their competitors as well as risk potential reputational costs.[96] Along with the proposed prohibition of volume-based pricing for agency-related order flow the Commission is proposing to require exchanges to disclose the number of members which qualify for each pricing tier. Given the proposed prohibition of volume-based tiers for agency order flow the proposed disclosures would relate to tiers that would only apply to principal order flow. The Commission expects that the proposed disclosures would provide important information to interested parties to provide comment on future proposed changes to an exchange's pricing schedule. Observing the distribution of principal volume tier qualification and its variation over time would allow interested parties to better assess if pricing tiers had been narrowly tailored for the benefit of some members and could be judged to be unfair. The disclosure of more information on how many members qualify for each principal pricing tier would add costs and could lead to reputational damage to an exchange if the exchange's pricing structure is publicly perceived to be unfair.

B. Baseline

1. Exchange Pricing

As discussed above in section I.B, many stock exchanges utilize a transaction pricing model that involves charging one party to a trade a per-share fee while offering the other party a per-share rebate. While exchange transaction pricing structures vary, with some exchanges charging both sides a fee or no fee at all, most of the on-exchange volume goes to exchanges which provide a rebate to the resting limit order and charge the fee to the marketable order. This type of fee structure is referred to as ''maker-taker'' pricing. Exchanges may employ maker-taker fees as a means of attracting competitively priced liquidity to post on an exchange, which, in turn, helps attract trading to the exchange.

Many exchanges incorporate volume-based transaction tiers into their pricing schedules, meaning that they offer improved pricing terms to members that execute more trading volume on the exchange, typically as a percent of total consolidated volume. These pricing tiers provide an incentive for exchange members to concentrate their order flow on a subset of exchanges, rather than route their orders more broadly across all competing exchanges, so as to increase their chances of qualifying for a higher tier on a specific exchange. In turn, this also helps to secure an exchange's share of the market, and in some cases may affect competition among exchanges.

a. Transaction Fees and Rebates

Exchanges generally seek to increase the amount of trading that occurs on their respective venue. Exchanges generate revenue, in part, from trade executions [97] by charging transaction fees net of any rebate they pay out, subject to a fee cap.[98] Because some market participants are sensitive to the level of fees and rebates, exchange fee schedules would affect an exchange's market share. Given that most exchanges set their access fees at or near the access fee cap it is particularly the variation in the rebates they offer which is more likely to influence an exchange's market share.[99]

A major component of the market to provide trade executions is the competition among exchanges in attracting competitively priced liquidity as a means of capturing more order flow.[100] Competitive quotes increase the likelihood that marketable orders will flow to an exchange which result in trades.[101] Exchanges aim to attract

[95] Agency-related order flow represents a substantial share of trading volume, comprising 56% of trading volume across the equities exchanges in Jan. 2023. *See* infra Table 4.

[96] *See* section IV.C.3.b.ii for a discussion of the potential reputational costs that the disclosure of tier qualification numbers may have.

[97] Exchanges also generate significant revenue from selling access to the data generated by the exchange as well by charging fees for connectivity.

[98] *See* 17 CFR 242.610 (Rule 610(c)), which prohibits trading centers from imposing a fee exceeding $0.0030 to access a quote in stock priced at or greater than $1.00. This level is commonly referred to as 30 mils with 1 mil defined as $0.0001. For quotes priced less than $1.00 the fee cap is at 0.3% of the quotation price.

[99] For instance, an exchange stated in a proposed rule change that ''[t]he Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient.'' *See* Securities Exchange Act Release No. 94252 (Feb. 15, 2022) 87 FR 9780 at 9781 (Feb. 22, 2022) (SR–CboeBZX–2022–008).

[100] Exchanges also compete with off-exchange trading venues such as ATSs and wholesaler broker-dealers to attract transactions.

[101] Exchanges can try to attract such quotes by paying rebates on limit orders. By offering to pay the market participant who sends a limit order to an exchange a rebate should the limit be hit, the exchange may be able to increase to total number limit orders sent to it. This may increase likelihood

competitively priced quotes because, holding other considerations constant, it is generally in market participants' interest to route their order to the venue with the best prices insofar as doing so would be consistent with the duty of best execution that broker-dealers have with regard to customer orders. In addition to these incentives, the Order Protection Rule also contributes to the competition for order flow by requiring that, with specified exceptions,[102] orders must execute at prices that are equal to or superior to the prevailing national best bid and offer (NBBO).

The competitive environment that has emerged from the desire to attract competitively priced liquidity contributes to the predominance of maker-taker pricing across exchanges.[103] In January 2023, 9 of the 16 exchanges employed maker-taker pricing and the trading volume on those 9 exchanges make up 89% of trading volume which occurred on the exchanges.[104] As discussed above in section I.B., exchanges typically adopt one of three different forms of transaction pricing models, including maker-taker, inverted, or flat.[105] The ''maker-taker'' pricing model encourages liquidity provision by paying rebates to limit orders (*i.e.,* the ''makers'') that the exchange funds by charging fees on marketable orders.

Outside of the maker-taker pricing model, other exchanges have adopted inverted or flat pricing models. These exchanges collectively represent a smaller portion of the overall market share. As reported in Table 4, inverted pricing venues, which charge a fee to passive limit orders and pay a rebate to marketable orders, accounted for only 6% of traded share volume in January 2023. Flat venues accounted for roughly 5% of traded share volume in January 2023.

It is likely that the lack of an incentive to post limit orders in the form of a transaction rebate contributes to the limited share of these non-maker-taker venues. Conditional on the quoted price on different exchanges being the same, a trader would be expected to prefer routing its marketable order to either an inverted or free venue over a maker-taker venue to avoid the access fee and potentially earn a rebate instead. However, a market observer has stated that the occurrence of equivalently priced quotes at the NBBO between maker-taker exchanges and non-maker-taker exchanges is an infrequent occurrence.[106] The infrequency of this occurrence may be due, in part, to the lack of rebates for limit orders on these non-maker-taker exchanges.

Three exchange groups together make up a large majority of the market share in the exchange landscape with the Nasdaq group (Nasdaq, BX, Phlx (PSX)) making up 30% of the market by trading volume, the Intercontinental Exchange group (NYSE, NYSE American, NYSE Arca, NYSE Chicago, NYSE National) making up 34% and Cboe Global Markets (Cboe BZX, Cboe BYX, Cboe EDGA, Cboe EDGX) making up 24%.

TABLE 4—EXCHANGE TRADING VOLUME AND SHARE BY LIQUIDITY TYPE, JAN. 2023

[The following table breaks apart the total buy and sell executed order flow from all exchange members using a sample of CAT data for the month of Jan 2023. Exchange members are identified as the set of unique CRD IDs in CAT which have directly routed orders to any of the national equities exchanges in the month. Exchange member CRDs are also verified in the CAT Industry Member Identifier List daily reference data. For each exchange the number of shares executed under the CAT allowable trade capacities of Agency, Principal, and Riskless Principal are reported. Trade capacity in CAT is defined by the exchange member for its side of a trade and represents the capacity in which the exchange member acted at trade time. Trades with the sale condition codes–M—Market Center Official Close, –Q—Market Center Official Open, –V—Contingent Trade, –7—Qualified Contingent Trade (QCT), –8—Placeholder for 611 Exempt, and –9—Corrected Consolidated Close (per listing market) were excluded. The share of total trading volume across all exchanges for orders of a specific capacity are reported under the trading volume. The fourth column, ''Total'' reports the total trading volume for each exchange with the exchange's volume-based exchange market share reported below.]

Exchange	Agency	Principal	Riskless principal	Total
Nasdaq[b] (Maker-Taker)	42,381,231,425 32.04%	26,084,186,949 24.37%	256,443,292 13.90%	68,721,861,666 28.50%
NYSE[a] (Maker-Taker)	23,578,087,344 17.82%	15,663,850,087 14.64%	145,114,774 7.86%	39,387,052,205 16.33%
NYSE Arca[a] (Maker-Taker)	19,581,312,954 14.80%	19,600,669,528 18.31%	129,269,046 7.00%	39,311,251,528 16.30%
Cboe EDGX[c] (Maker-Taker)	13,478,973,097 10.19%	12,512,933,159 11.69%	677,345,568 36.70%	26,669,251,824 11.06%
Cboe BZX[c] (Maker-Taker)	9,612,667,056 7.27%	10,242,339,878 9.57%	367,462 0.02%	19,855,374,396 8.23%
MEMX (Maker-Taker)	6,308,673,864 4.77%	6,746,470,107 6.30%	186,541,931 10.11%	13,241,685,902 5.49%
IEX (Flat)	6,860,652,435 5.19%	3,905,276,620 3.65%	7,011,129 0.38%	10,772,940,184 4.47%
Cboe EDGA[c] (Inverted)	3,401,951,122 2.57%	2,289,187,280 2.14%	109,407,328 5.93%	5,800,545,730 2.41%
Cboe BYX[c] (Inverted)	1,950,854,778 1.47%	2,582,413,642 2.41%	131,506,520 7.13%	4,664,774,940 1.93%

that the exchange ends up with the best-priced limit order in a given symbol.

[102] *See* 17 CFR 242.611 (Rule 611). The rule requires trading centers to ''establish, maintain, and enforce written policies and procedures that are reasonably designed to prevent trade-throughs on that trading center of protected quotations in NMS stocks'' (a trade-through occurs when one trading center executes an order at a price that is inferior to the price of a protected quotation). The prevention of trade-throughs means that marketable orders are more likely to be executed on trading venues with competitively priced quotations at the NBBO.

[103] *See supra* note 15.

[104] *See* Table 4.

[105] *See supra* section I.B (describing the different exchange pricing models).

[106] For a discussion of how long different exchanges spend quoting at the NBBO, *see* Phil Mackintosh, Three Charts That Show the Importance of a Competitive Bid/Offer NBBO (Dec. 4, 2018), available at *https://www.nasdaq.com/articles/three-charts-that-show-the-importance-of-a-competitive-bid-offer-nbbo-2018-12-04.*

TABLE 4—EXCHANGE TRADING VOLUME AND SHARE BY LIQUIDITY TYPE, JAN. 2023—Continued

[The following table breaks apart the total buy and sell executed order flow from all exchange members using a sample of CAT data for the month of Jan 2023. Exchange members are identified as the set of unique CRD IDs in CAT which have directly routed orders to any of the national equities exchanges in the month. Exchange member CRDs are also verified in the CAT Industry Member Identifier List daily reference data. For each exchange the number of shares executed under the CAT allowable trade capacities of Agency, Principal, and Riskless Principal are reported. Trade capacity in CAT is defined by the exchange member for its side of a trade and represents the capacity in which the exchange member acted at trade time. Trades with the sale condition codes–M—Market Center Official Close, –Q—Market Center Official Open, –V—Contingent Trade, –7—Qualified Contingent Trade (QCT), –8—Placeholder for 611 Exempt, and –9—Corrected Consolidated Close (per listing market) were excluded. The share of total trading volume across all exchanges for orders of a specific capacity are reported under the trading volume. The fourth column, ''Total'' reports the total trading volume for each exchange with the exchange's volume-based exchange market share reported below.]

Exchange	Agency	Principal	Riskless principal	Total
MIAX Pearl (Maker-Taker)	1,803,716,409	2,527,733,474	153,910,919	4,485,360,802
	1.36%	2.36%	8.34%	1.86%
NYSE National [a]				
(Inverted)	827,209,968	1,489,403,927	1,340,645	2,317,954,540
	0.63%	1.39%	0.07%	0.96%
Phlx (PSX) [b] (Maker-Taker)	877,534,988	1,342,954,596	53,580	2,220,543,164
	0.66%	1.25%	0.00%	0.92%
BX [b]				
(Inverted)	713,708,890	965,538,116	32,818,578	1,712,065,584
	0.54%	0.90%	1.78%	0.71%
NYSE American [a] (Maker-Taker)	712,130,625	818,767,495	14,185,250	1,545,083,370
	0.54%	0.77%	0.77%	0.64%
NYSE Chicago [a]				
(Flat)	177,946,002	254,499,006	120,789	432,565,797
	0.13%	0.24%	0.01%	0.18%
LTSE				
(Free)	10,749,491	1,411,063	0	12,160,554
	0.01%	0.00%	0.00%	0.01%
Total	132,277,400,448	107,027,634,927	1,845,436,811	241,150,472,186
	100.00%	100.00%	100.00%	.....
	54.85%	44.38%	0.77%	

[a] Part of NYSE/ICE Exchange group of exchanges.
[b] Part of the Nasdaq group of exchanges.
[c] Part of the Cboe group of exchanges.

The Commission estimates revenues generated from net transaction fees for the different exchange groups using volume-weighted average net capture rates which were made publicly available either through 10–Q filings or published online; the reported net capture rates are averages for all the different transactions occurring across the various equities exchanges in each exchange group.[107] The Commission estimates that one exchange group had revenue generated from net transaction fees in its US equities exchanges of approximately $37,347,258 in January 2023,[108] another exchange group had revenue of $46,498,861,[109] and a third exchange group had revenue of $10,828,089.[110]

The four exchanges outside of those three exchange groups made up the remaining 11.81% of the market in January 2023. One exchange is a free exchange, meaning that it does not charge access fees (nor does it pay out transaction rebates) and hence does not generate revenue from transaction net capture fees.[111] Another exchange charges a flat fee of $0.0009 per share to both liquidity providers and liquidity takers leading to net capture of $0.0018 and an estimated transactions revenue of $19,391,292 for January 2023.[112] The remaining two exchanges are not publicly-traded issuers and do not publicly disclose their net capture rates. The Commission understands based on Staff conversations with industry members that the net capture for non-auction trading in stocks is likely close to $0.0002 per share and uses this assumed net capture rate when estimating the transaction revenues for these exchanges.[113] Using the assumed net capture of $0.0002, or 2 mils, the Commission estimates the January 2023 transaction revenues for these two exchanges to be $2,648,337 and $897,072 respectively.[114]

The maker-taker transaction pricing model and higher rebates play an important role in attracting competitively priced quotes and capturing market share, as suggested by the market share statistics of Table 4.

[107] The Commission is making the assumption that the reported average net capture rates collected from public disclosure hold for the trading volume reported in Table 4. The publicly sourced data regarding average net capture rates for the exchanges which are publicly-traded issuers include the period of analysis, January 2023, as the disclosures pertain to Q1 2023. *See infra* notes 126, 127, 128.

[108] The revenue numbers are calculated as the sum of the total trading volume for the venues in an exchange group reported in Table 4 by their average net capture rate. Intercontinental Exchange, the parent firm of NYSE, reports on page 38 of its Form 10–Q filing for the three months ending Mar. 31, 2023 that its net capture for U.S. equities transactions was approximately 4.5 mils in Q1 2023.

[109] Nasdaq did not report its net capture in its Form 10–K filing, however, Nasdaq provides information on its investor relations web page which indicates that the average net capture across all Nasdaq platforms for U.S. equities transactions in Q1 2023 was 6.4 mils. *See* Nasdaq 2023/2022 Monthly Volumes, NASDAQ, available at *https://ir.nasdaq.com/static-files/465d2157-c476-4546-a9f7-8d7ad0c9be77.*

[110] Cboe reports in its Form 10–Q filing for the three months ending Mar 31, 2023, that its net capture for U.S. equities transactions was approximately 1.9 mils for Q1 2023.

[111] The exchange, LTSE does not charge fees to transact. *See supra* note 15.

[112] *See* IEX pricing schedule, *supra* note 15.

[113] The assumption that the remaining two exchanges (MEMX & MIAX Pearl) earn an estimated 2 mils net capture per transaction is in line with prior Commission discussions and would put them in line with the net capture rate reported by the Cboe group. *See supra* note 110.

[114] *See supra* note 98 defining the term ''mil''.

There are important factors which serve to limit the liquidity of lower volume exchanges; these exchanges are not the primary listing market for any securities as they are newer, and they also tend to be more specialized or structured to facilitate specific trading strategies.

The idea that the maker-taker transaction pricing model and rebates offered play an important role in exchange market share is also supported by the results of an experiment run by one maker-taker exchange, Nasdaq, in which it reduced both its fees and rebates. The experiment resulted in less competitive liquidity being supplied to the exchange along with a decrease in the exchange's market share in the treated stocks. That market share fell despite the reduction in transaction fees being greater than the reduction in rebates suggests that changes in the transaction pricing applicable to liquidity-providing order flow may have a greater effect on exchange market share than similar changes in the transaction pricing applicable to liquidity-demanding order flow. In this experiment, the exchange unilaterally reduced both access fees and rebates for a set of 14 stocks. Over the course of the experiment Nasdaq reported a significant drop in a number of liquidity provision measures.[115] Per the Nasdaq reports, the average number of shares displayed by Nasdaq at the NBBO in the experiment declined by 45%, average time at the NBBO declined by 4.7 percentage points from 92.7% to 88.0%, liquidity share[116] fell from 29% to 19%, and the share of liquidity provided by the exchange's top five liquidity providers prior to the experiment decreased from 44.5% to 28.7%. These changes align with the findings of one academic study (the ''Swan Study'') which also analyzed the Nasdaq experiment.[117]

Both the Nasdaq reports and the Swan Study found that Nasdaq's market share fell in traded stocks, with Nasdaq reporting an average decline of 1.8 percentage points. The Swan Study found that the Nasdaq share loss was captured by the two highest rebate-paying stock exchanges. As the experiment also reduced fees in addition to rebates, the reported reduction in market share was a net effect of both reductions, it is likely that the reduction in market share would be greater had access fees not also been reduced.[118] Other factors which may have contributed to the decrease in market share include the improved fill rates and fill times, as well as narrower effective and realized spreads net of transaction rebates and fees on competing exchanges which were reported in the Swan Study.

b. Volume-Based Pricing Tiers

Stock exchange transaction pricing schedules often operate with a tiered system that relies on the volume an exchange member brings to the exchange to determine its transaction pricing tier for a given month. Qualification to different rebate and fee tiers is determined at the end of each month and typically is based on a member's average daily share volume for the month as a percentage of the total consolidated volume that month.[119] This kind of pricing method where exchanges offer different fee and rebate levels to members based on the amount of trading volume each member executes on the exchange is referred to as volume-based exchange transaction pricing.[120] The tier threshold is often expressed as a percentage of the total consolidated volume reported by one or all consolidated tapes for the month.[121] It is common that tier thresholds are defined relative to the trading volume of the market as a whole; it is seldom the case that tier thresholds are set as an absolute number of shares.

The Commission understands that exchanges make use of volume-based tiers as a means of encouraging their members to execute orders on their venue. Volume-based tiers encourage exchange members to concentrate, or execute a larger share of their order flow, on the exchange in order to qualify for the higher rebates or lower fees offered by higher volume pricing tiers.[122]

The pricing terms of the tiers reserved for high volume exchange members may be subsidized through higher net capture rates of lower-volume members or via other lines of business such as those earned from providing connectivity and market data.[123] The fact that many exchanges offer high-tier rebates that exceed the Rule 610 access fee cap in magnitude implies a need for cross-subsidization to support these rebate tiers. In a 2018 roundtable on market data and market access, one exchange that participated in the roundtable stated that five out of their ten largest members by trading volume receive payment from the exchange even after factoring in the costs of connectivity and market data.[124] This suggests that the rebates an exchange pays to those members may be subsidized by the net transaction fees paid by other exchange members or the fees paid for other services such as data and connectivity.

Newer or smaller exchanges may find it difficult to attract order-flow away from the larger legacy exchanges given that a sizable portion of order flow is provided by the high-volume exchange

[115] Nasdaq produced two reports concerning their access fee experiment. *See* Frank Hatheway, Nasdaq Access Fee Experiment (Mar. 2015), available at *https://pages.stern.nyu.edu/~jhasbrou/SternMicroMtg/Old/SternMicroMtg2015/Supplemental/Access%20Fee%20Experiment%20-%20Month%20One%20Report%20Final.pdf. See also* Frank Hatheway, Nasdaq Access Fee Experiment Report II (Mar. 2015), available at *https://pages.stern.nyu.edu/~jhasbrou/SternMicroMtg/Old/SternMicroMtg2015/Supplemental/Access%20Fee%20Experiment%20-%20Second%20Report%20Final.pdf* (''Nasdaq Access Fee Experiment Report II'').

[116] ''Liquidity Share'' is a measure of an exchange's displayed liquidity, factoring in both the frequency it is at the NBBO and the size of its quote. The calculation involves weighing the average size quoted by an exchange that is concurrently quoting at the NBBO by the duration of time spent quoting at the NBBO to yield a quantity which is referred to as ''Average Liquidity.'' This value is then divided by the total average liquidity of all exchanges quoting the stock to compute the liquidity share. *See* Nasdaq Access Fee Experiment Report II, *supra* note 115.

[117] *See* Yiping Lin, Peter Lawrence Swan, and Frederick H. deB. Harris, ''Why Maker-Taker Fees Improve Exchange Quality: Theory and Natural Experimental Evidence'' (Mar. 14, 2019), available at *https://ssrn.com/abstract=3034901* (retrieved from SSRN Elsevier database).

[118] Conditional on compliance with Rule 611 and keeping all else equal, including other considerations of execution quality, traders typically would prefer to route their marketable order to a trading venue with a lower access fee. Thus, a reduction in access fees would help attract marketable orders and increase trading volume.

[119] *See supra* note 17 (discussing the Commission's Access Fee Proposal that would require exchanges to make the amounts of all fees and rebates determinable at the time of execution, which would require volume-based transaction pricing tiers to be applied prospectively rather than retroactively to the start of a month).

[120] Volume-based tiers in trading often have different qualifications. For instance, some tiers require adding Average Daily Volume (''ADV''), while others consider total ADV (both add and remove volume), and some tiers are tape dependent. There are also specific tiers for mid-point liquidity (''MPL'') orders, non-displayed limit orders, and opening/closing auction trading, to name a few.

[121] For example, an exchange may require a member to accumulate, on a specific tape, an amount of adding trading volume (trade volume from trades which executed against a member's liquidity providing order) greater than X% of the total consolidated trading volume for that specific tape.

[122] *See infra* section IV.B.2 for a discussion of the incentives introduced by volume-based pricing tiers.

[123] A flat pricing schedule does not allow an exchange to offer some traders a higher rebate (lower fee) by offering others a lower rebate (higher fee). In principle the cross-subsidization of rebates from other business lines could occur in the absence of pricing tiers though this is likely to be more costly since the flat nature of the pricing schedule would mean that the trading of all members would have to subsidized rather than, potentially, just the trades of the members which qualify for the preferential pricing tiers.

[124] *See* Remarks of Chris Concannon, *supra* note 3, Transcript at 74–75.

members which qualify for the top tiers and similar terms would have to be offered to those members to pull them away. As previously discussed, exchanges are able to use volume-based pricing as a means of increasing the rebates earned by a few high-volume exchange members often at the expense of members with less trading volume; the lack of a large trading base could make it difficult to profitably subsidize the top tiers from the trades of other exchange members. Smaller or newer exchanges looking to compete with larger exchanges would find it difficult to compete with larger exchanges by cutting transaction fees. In the case of a maker-taker exchange, cutting take fees may require lower rebates for liquidity provision by lowering the degree to which those rebates can be funded via take fees. Cutting make rebates relative to those offered on other exchanges would likely hamper an exchange's tendency to attract competitively priced limit orders putting the exchange in a competitively disadvantageous position. In the case of an inverted or flat venue, cutting make fees could help an exchange attract more liquidity however because these exchanges by their very nature, charge fees rather than pay rebates to liquidity providers, makes them less attractive as a venue to post a competitive quote, all else being equal. Alternatively, smaller or newer exchanges could try to compete with the larger maker-taker exchanges on the basis of offering larger make rebates, lacking substantial trading volume could make cross-subsidization of rebates difficult possibly meaning that the exchange may need to operate their trading business at a loss in order to match or beat the top rebates of other exchanges.[125] The lack of a similar membership base, trading volume, and data and connectivity subscribers make it difficult for smaller exchanges to sustainably provide volume-based tiers competitive with the top tiers offered by the largest exchanges.

An alternative view on the complexity of pricing schemes offered by the dominant exchange families [126] is to regard the range of volume-based discounts as a form of product proliferation, a preemptive strategy for limiting the range of profitable choices available for newer and smaller exchanges. Reminiscent of behavior by established firms when attempting to corner the market across other industry settings,[127] the range of pricing bundles offered by the dominant exchanges may likewise have partial exclusionary effects.

c. Tying Closing Auction Fees to Consolidated Volume

The daily closing price of NMS equities is typically established by means of the closing auction, which is run at the end of each trading day by the primary listing exchange for the respective equity. Because of the significance of the closing price to a variety of financial market functions, including the measuring of tracking error in index funds, many market participants are highly desirous of executing trades at precisely the daily closing price, an outcome that can be facilitated by participating in the closing auction on the listing exchange. Listing exchanges may be able to exploit this demand for participation in the closing auction by offering discounts on auction orders to members who send volume into the intraday trading sessions. This practice may help listing exchanges preserve or extend their market power, potentially at the expense of reducing the welfare of the exchange members.

A number of factors contribute to high and growing [128] demand for participation in closing auctions. One significant reason for this is that an important performance metric for passive funds, the tracking error, is tied to the daily closing price set by these closing auctions. For this reason, index funds and exchange-traded funds are motivated to concentrate flow in the closing auctions so as to minimize tracking errors.[129]

Listing exchanges operate closing auctions that set an official closing price for their listed securities.[130] This makes them an obvious means by which a market participant can get its trades executed at the official closing price. Some alternatives do exist, for example, some broker-dealers may offer to internalize customer orders at the closing auction price,[131] once it is determined on the listing exchange. Another example of an alternative is the pre-match close offered by one exchange for market-on-close orders.[132] However, if a market participant wishes to execute an on-exchange trade at the official closing price determined by the primary listing exchange, and use a limit-on-close order for that trade, the only option is to send that order to the listing exchange's closing auction.

Some primary listing exchanges implement closing auction pricing tiers that involve discounts which are based on the member's overall trading volume on the same exchange.[133] Specifically, the exchange pricing schedule is such that higher consolidated volume (overall volume from both auctions and regular trading hours) helps broker-dealers qualify for more favorable fees and rebates on auction orders. Industry practitioners refer to ''auction linked pricing'' as a discount on auction orders based on the continuous trading volume.[134] This practice is a form of tying or conditional pricing. The related literature, referenced in the following paragraph, has shown that tying can reduce competition and has potential

[125] For example, a new exchange in 2020 implemented a pricing schedule with high rebate tiers which would generate losses while the venue tried to establish market share. *See* Shanny Basar, New Exchange MEMX Details 'Smart' Pricing Structure (Sept. 15, 2020) available at *https://www.tradersmagazine.com/am/memx-unveils-smart-pricing-structure/.*

[126] Most of the public exchanges are organized based on families of affiliated exchanges, where the exchanges within a family are owned by the same holding company but may employ distinct business models (*e.g.,* charging a ''make'' fee on taker-maker exchanges or a ''take'' fee on maker-taker exchanges).

[127] *See* Jean Tirole, The Theory of Industrial Organization, 346–52 (1988) for a discussion of leading firms' incentive to pack the product space so as constrain the market niche for new or minor firms. A motivating example is ''the Swedish Tobacco Company, upon losing its legal monopoly position in 1961, reacted by offering twice as many brands.'' *Id.* at 346. Dominant firm's preemptive decision to introduce a menu of latent choices is also analyzed in Yong Chao, Guofu Tan, and Adam Chi Leung Wong, ''Optimal Nonlinear Pricing by a Dominant Firm under Competition'', 14 Am. Econ. J.: Microeconomics 240 (May 2022).

[128] For S&P 500 stocks, the daily average fraction of a stock's closing auction trades over total shares traded increased from 3.5% in 2010 to 10% in 2018. *See* Yanbin Wu, ''Closing Auction, Passive Investing, and Stock Prices,'' 9 (Aug. 2019), available at *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3440239.* Another source reports that the shares that the NYSE closing auctions commanded doubled over a five-year period to nearly 7% of NYSE-listed volume in recent years. *See* ''Behind the Scenes—An Insider's Guide to the NYSE Closing Auction,'' available at *https://www.nyse.com/article/nyse-closing-auction-insiders-guide.*

[129] Yanbin Wu, ''Closing Auction, Passive Investing, and Stock Prices,'' *supra* note 128.

[130] The exchanges that currently have listings are Nasdaq, NYSE, NYSE Arca, and Cboe's BZX. *See* Cboe's ''The Impact Closing Auctions Have on Volumes'' (Nov. 18, 2020), available at *https://www.cboe.com/insights/posts/the-impact-closing-auctions-have-on-volumes/.*

[131] Staff experience suggests that some broker-dealers aim to enhance their volumes and attract flow by guaranteeing the listing market's official closing price at no additional cost.

[132] *See https://www.cboe.com/us/equities/trading/offerings/cboe_market_close/.*

[133] *See* Nasdaq Rule 118(d)(2): Section 118. Nasdaq Market Center Order Execution and Routing for a description of Nasdaq closing auction tiers that include volume criteria based on continuous volume: *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules/Nasdaq%20Equity%207#section_118_nasdaq_market_center_order_execution_and_routing.*

[134] MEMX comment letter to Regulation NMS: Minimum Pricing Increments, Access Fees, and Transparency of Better Priced Orders, *https://www.sec.gov/comments/s7-30-22/s73022-20163328-333796.pdf.*

exclusionary effects. There is a lack of consensus within the economic literature on the anti-competitive potential of offering price discounts for allocating a target purchasing level in a bundled goods context. However, the theoretical literature has provided examples arguing that tying the sales of a monopolized or dominant product to other product(s) can be a profitable way for a firm to protect its market power, oftentimes through partially foreclosing the more competitive portion of the market to competitors.[135] In other imperfectly competitive market settings, offering more generous terms for purchasing a bundle of different goods can also result in greater producer surplus.[136] Bundling arrangements may have partial exclusionary effects when a dominant firm takes advantage of its captive (non-contestable) portion of demand and ties its captive demand with part of its contestable demand.[137] More generally, both the theoretical and empirical literatures have offered evidence that bundling, or offering discounts for purchasing a portfolio of different goods, can result in greater producer surplus,[138] but sometimes at the expense of consumer surplus.[139]

The same forces analyzed in the literature on bundling and tying may be present in the case of listing exchanges and their closing auction discounts. Because of the high value placed on executing in the closing auction described above, listing exchanges are able to offer a relatively unique trading mechanism. This is in contrast to intraday trading, where the orders may potentially interact with multiple trading platforms.[140] The use of volume discounts that apply across both mechanisms may enable the listing exchanges to leverage their position as the sole primary listing exchange and provider of a closing auction to increase order flow to their intraday trading.[141] As described above, the economic literature shows that this may reduce the welfare of the exchange members.

In addition to leveraging market power, the economic literature suggests that bundling can increase exchange profit by averaging (through aggregating) consumer preferences.[142] To the extent that broker-dealers differ in their willingness to participate in the closing auction and intraday trading, tying execution fees for the closing auctions to total volume may help the listing exchanges capture greater demand from a segment of the participants. By drawing in broker-dealers who might otherwise have little interest in participating on one of the venues (*e.g.,* closing auction or intraday trading), the listing exchanges may earn greater revenue than what would be possible with component (unbundled) pricing for closing auction and intraday trading.

To the extent exchanges are engaged in imperfect competition for order flow across heterogeneous broker-dealers, bundling as a product differentiation strategy could also help a listing exchange extract more order flow.[143] Auction linked pricing may be particularly effective in attracting order flow from broker-dealers who value gains from executing trades during the closing auction but who might otherwise have lower valuation for intraday trading on that exchange.

While the exchanges may benefit from auction-linked pricing, the impact on broker-dealers and their customers is ambiguous. In general, depending on the particular situation price discrimination can either increase consumer welfare or decrease it. Nevertheless, a significant number of academic studies have found that bundling decreases consumer surplus.[144] Consumer surplus (*i.e.,* consumer welfare), is typically defined as the net benefit the buyer derives from his optimal consumption bundle, after adjusting for the price he incurs from his preferred purchase.

2. Volume-Based Tiers and Order Routing Incentives

Volume-based tiering serves exchanges by incentivizing their members to concentrate their order-flow onto their platform. The following analysis presents evidence consistent with this notion.[145] Maker-taker exchanges with a higher number of pricing tiers are not only larger but have a higher proportion of their members execute a plurality of their order flow on their platform; plurality members are also responsible for a greater proportion of the trading volume executed on these exchanges. The analysis also finds that individual member order flows are on average more concentrated than they would be had their executed order flow been split in line with the relative market shares of the exchanges. Order flow deviations from the relative market weights which contribute to higher concentration measures tend to be those which place more weight on maker-taker exchanges with the most pricing tiers.

The use of volume-based pricing tiers by exchanges can affect the routing decisions of their members through the incentives it introduces. Volume-based pricing encourages members to concentrate their order flow on exchanges where members hope to increase their chances of qualifying for a preferential pricing tier. Qualifying for a better pricing tier can result in both

[135] Dennis W. Carlton and Michael Waldman, ''The Strategic Use of Tying to Preserve and Create Market Power in Evolving Industries,'' 33 Rand J. Econ. 194 (Summer 2002). Michael D. Whinston, ''Tying, Foreclosure, and Exclusion'', 80 Am. Econ. Rev. 837 (Sept. 1990). *See also* a discussion of tying from W. Kip Viscusi, Joseph E. Harrington, and David E. M. Sappington, Economics of Regulation and Antitrust, Chapter 7 Vertical Mergers and Vertical Restraints, 296–312 (5th ed. 2018). Yong Chao, Guofu Tan, and Adam Chi Leung Wong, ''All-Units Discounts as a Partial Foreclosure Device'', 49 Rand J. Econ. 155 (2018).

[136] For example, in the context of firms competing to attract demand from customers who differ in their preferences over different goods, some firms may use bundling as a way differentiate their products, and thereby soften price competition. For a numerical example of bundling as a way for firms to differentiate their products in a price discrimination context *see* Paul Belleflamme and Martin Peitz, Industrial Organization: Markets and Strategies, Chapter 11.3.1 Bundling as a Way to Soften Price Competition, 274 (2010).

[137] By tying part of the competitive portion to its captive portion, the dominant firm draws sales away from its capacity-constrained rival in Yong Chao, Guofu Tan, and Adam Chi Leung Wong, ''All-Units Discounts as a Partial Foreclosure Device'', 49 Rand J. Econ. 155 (2018).

[138] Katherine Ho, Justin Ho, & Julie Holland Mortimer, ''The Use of Full-Line Forcing Contracts in the Video Rental Industry'', 102 Am. Econ. Rev. 686 (2012).

[139] Yong Chao, Guofu Tan, and Adam Chi Leung Wong, ''All-Units Discounts as a Partial Foreclosure Device'', 49 Rand J. Econ. 155 (2018). Gregory S. Crawford, ''The Discriminatory Incentives to Bundle in the Cable Television Industry'', 6 Quantitative Mktg. & Econ. 41 (2008).

[140] The introduction of Reg NMS, in particular the Order Protection Rule, requires investors to interact with the exchange(s) offering the most favorable execution prices throughout the regular trading session.

[141] Specifically, tying closing auction fees to intraday trading encourages broker-dealers who value participation in the closing auction to direct more order flow to the primary exchanges, in order to benefit from volume-based discounts during the closing auctions.

[142] Chenghuan S. Chu, Phillip Leslie, and Alan Sorensen, ''Bundle-Size Pricing as an Approximation to Mixed Bundling'', American Economic Review 101, 263–303 (2011). Gregory S. Crawford, ''The Discriminatory Incentives to Bundle in the Cable Television Industry'', 6 Quantitative Mktg. & Econ. 41 (2008). Katherine Ho, Justin Ho, & Julie Holland Mortimer, ''The Use of Full-Line Forcing Contracts in the Video Rental Industry'', 102 Am. Econ. Rev. 686 (2012).

[143] For a numerical example of bundling as a way for firms to differentiate their products in a price discrimination context *see* Paul Belleflamme and Martin Peitz, Industrial Organization: Markets and Strategies, Chapter 11.3.1 Bundling as a Way to Soften Price Competition, 274 (2010).

[144] Consumer surplus is the analog of investor surplus from the exchange setting.

[145] Throughout this section the analysis relies on a population of only 16, a small sample reduces the statistical confidence (the probability that an estimated quantity is not the result of random chance) in the estimation of any relationships between variables. Despite this limitation, the evidence presented in this section is consistent with volume-based price tiering promoting the concentration of order flow rather than resulting from random chance.

saving on transaction costs (or even profiting from net rebates), and potentially obtaining a competitive advantage in the market to provide non-member customers access to the exchanges.[146]

The following table examines the relationship between market share, the average share of member order flow, and the number of tiers on an exchange. Panel A of Table 5 shows that the average share of member order flow which is directed to the exchange tends to be greater for exchanges with more tiers, in particular the maker-taker exchanges.

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[146] *See infra* section IV.B.4 (discussing the market to provide exchange access to non-members).

Table 5 - Exchange Tiers, Pricing, Market Share, and Plurality Members

This table lists out market share, # of tiers, base rebates and fees, and order flow concentration statistics for the 16 national equities exchanges using the total executed buy and sell order flow from all exchange members using a sample of CAT data for the month of Jan. 2023. Exchange members are identified as the set of unique CRD IDs in CAT which have directly routed orders to any of the national equities exchanges in the month. Exchange member CRDs are also verified in the CAT Industry Member Identifier List daily reference data. For each exchange the number of shares executed under the CAT allowable trade capacities of Agency, Principal, and Riskless Principal are reported. Trade capacity in CAT is defined by the exchange member for its side of a trade and represents the capacity in which the exchange member acted at trade time. Trades with the sale condition codes–M - Market Center Official Close, –Q - Market Center Official Open, –V- Contingent Trade, –7 - Qualified Contingent Trade (QCT), –8 - Placeholder for 611 Exempt, and –9 - Corrected Consolidated Close (per listing market) were excluded. Market share measures are pulled from Table 4 and the number of tiers correspond to the count of the number of tiers reported are collected from the exchange price schedules which were effective for the month of Jan. 2023 in the same method as for Table 1.

Panel A: Base Rebates and Average Member Order flow shares. Base Rebate and Fees correspond to the default pricing for orders which do not qualify for any tiers listed on an exchange's pricing schedule. Average member order flow share is a simple average of the proportion of trading volume that an exchange member executed on the exchange relative to the total trading volume across all the other exchanges they are a member of. Member order flow share is calculated as the number of shares executed by an exchange member during regular trading hours over the month of Jan. 2023 divided by the total number of shares the exchange member executed across all national stock exchanges during regular trading hours over the month of Jan. 2023.

	Exchange	Market Share	# of Tiers	Base Fee	Base Rebate	Avg Member Orderflow Share
Maker-Taker	Nasdaq	28.46%	74	-30	13	51.52%
	NYSE	16.45%	93	-30	12	35.43%
	NYSE Arca	16.28%	72	-30	20	31.59%
	Cboe EDGX	11.04%	19	-30	16	15.28%
	Cboe BZX	8.22%	26	-30	16	14.17%
	MEMX	5.48%	13	-30	20	8.59%
	MIAX Pearl	1.86%	8	-29	29	3.41%
	Phlx (PSX)	0.92%	4	-30	20	5.89%
	NYSE American	0.64%	10	-30	20	4.82%
Non-Maker-Taker	IEX	4.46%	0	-9	0	22.58%
	Cboe EDGA	2.40%	8	-30	16	7.59%
	Cboe BYX	1.93%	11	-20	2	3.88%
	NYSE National	0.96%	11	-29	0	1.30%
	BX	0.71%	20	-30	-7	0.94%
	NYSE Chicago	0.18%	0	-10	0	10.28%
	LTSE	0.01%	0	0	0	0.01%

Panel B: Plurality Members and Plurality Order flow. A plurality member for an exchange is any exchange member who executes the largest share of their order flow on that exchange. For each exchange member the member order flow share (described above in panel A) is computed for every exchange for which they are a member of, the member is considered to be a plurality member for the exchange for which their member order flow share is highest. Exchange members are identified as the set of unique CRD IDs in CAT which have directly routed orders to any of the national equities exchanges in the month. Exchange member CRDs are also verified in the CAT Industry Member Identifier List daily reference data. The "percent of plurality members" is computed as the proportion of exchange members who are plurality members. "Average plurality order flow share" is a simple average of the proportion of order flow executed on the exchange across plurality members only. "Volume Due to Plurality members" is the proportion of exchange total volume which is attributable to plurality members. The last column, average number of exchanges of plurality members ("Avg # of Exgs of Plurality Members"), is a simple average of the number of exchanges for which a plurality member is a member of.

	Exchange	Market Share	# of Tiers	Percent of Plurality Members	Average Plurality Orderflow Share	Volume Due to Plurality Members	Avg # of Exgs of Plurality Members
Maker-Taker	Nasdaq	28.46%	74	64.71%	70.35%	89.93%	5.9
	NYSE	16.45%	93	29.21%	91.47%	17.97%	2.7
	NYSE Arca	16.28%	72	31.48%	64.75%	15.98%	5.4
	Cboe EDGX	11.04%	19	11.76%	64.48%	11.83%	4.9
	Cboe BZX	8.22%	26	7.69%	89.79%	0.16%	2.3
	MEMX	5.48%	13	3.85%	52.53%	1.02%	9.5
	MIAX Pearl	1.86%	8	2.78%	30.48%	1.77%	10
	Phx (PSX)	0.92%	4	4.44%	100.00%	0.06%	1
	NYSE American	0.64%	10	3.70%	100.00%	0.49%	1
Non-Maker-Taker	IEX	4.46%	0	22.99%	79.08%	10.17%	4.5
	Cboe EDGA	2.40%	8	5.56%	98.46%	0.01%	1.3
	Cboe BYX	1.93%	11	1.41%	100.00%	0.01%	1
	NYSE National	0.96%	11	0.00%		0.00%	
	BX	0.71%	20	0.00%		0.00%	
	NYSE Chicago	0.18%	0	10.00%	100.00%	0.62%	1.0
	LTSE	0.01%	0	0.00%		0.00%	

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Panel A of Table 5 shows that an exchange's market share is more associated with the number of pricing tiers than they are with either the base fee or rebate. The coefficient of correlation between the number of tiers and market share is 0.87 whereas the coefficients of correlation of market share with the base fee and rebate are −0.34 and 0.20 respectively. Focusing on the maker-taker exchanges, the base take fees are all set at 30 mils with a single exception at 29 mils. Among the maker-taker exchanges there does not appear to exist a clear relationship between the base rebate paid out and an exchange's observed market share. The smallest three maker-taker exchanges, with a combined market share of 3.42%, have a volume-weighted average base rebate of 23.7 mils which is substantially larger than the 13.5 mil average base rebate for the three largest maker-taker exchanges which make up over 60% of the market. On the other hand, Table 5 shows a clearer correspondence between the count of tiers on a maker-taker exchange's price schedule and its market share with the three largest exchanges having a volume-weighted average of 61 tiers and the three smallest maker-taker exchanges having 3.4 tiers on average. To the extent that rebates may play a role in order-routing considerations, as discussed in section IV.B.1, the evidence presented here is consistent with the notion that tiered rebate rates are more important than the base rebates. This is not to suggest that merely having a greater number of pricing tiers would result in greater market share but rather that if the number of tiers serves as a viable proxy for how important tiering is for an exchange's pricing then the apparent association between the market share and number of tiers is consistent with the hypothesis that tiers incentivize the

concentration of order flow and increase market share.[147]

Consistent with the idea that price tiering incentivizes the concentration of order flow, there appears to be a positive association between the number of tiers on an exchange's pricing schedule and that exchange's share of members which execute at least a plurality of their trading volume on the exchange; the correlation coefficient between the two variables is 0.76. Panel B of Table 5 reports statistics regarding those exchange members which execute a plurality of their trading volume on each exchange. The three exchanges with the largest number of tiers on their pricing schedules have an average of 41.8% of their members executing at least a plurality of their trading volume on the exchanges. This is in contrast with the 3 exchanges with no tiering for which 11% of members, on average, execute a plurality of their orders on their exchanges. Restricting to those exchanges with price tiering, the three exchanges with the lowest number of tiers have an average of 4.26% of their members sending them a plurality of order flow. Three exchanges (NYSE National, BX, LTSE) did not have any members with a plurality of their trading volume on the exchanges and for three other exchanges (Phlx (PSX), NYSE American, and NYSE Chicago) the only members which execute a plurality of their orders on those exchanges do so only because they did not execute any order flow on any other exchange.[148] Moreover ''plurality members'' constitute a greater share of the total exchange trading volume for exchanges with more tiers relative to those with fewer tiers. The measure of correlation between the number of pricing tiers and the share of exchange volume from plurality members is 0.64. For exchanges with above median number of tiers (≤11) an average of 19.56% of their total trading volume originate from plurality members whereas for exchanges with less than/equal to the median number of tiers (<=11) is 1.46%. The average proportion of plurality member trading volume for the three largest exchanges by number of tiers, 41.8%, is roughly 20 times the average for every other exchange, 2.01%.

It is important to note that these observations do not prove a causal relationship between tiering and market share and the Commission acknowledges that there may exist other factors that could drive the patterns observed. For instance, it may be the case that maintaining a complex pricing schedule may be costly and, as a result, exchanges with larger market shares may find it more feasible to employ a pricing schedule with more tiers than an exchange with a smaller market share. Another reason for differences in market share across exchanges could be the widely documented fact that stocks trade more heavily on their primary listing venue particularly with respect to trading at the close.[149]

The following analysis directly measures the degree of concentration for the order flow of individual members and examines how they deviate from a market benchmark on average. The Herfindahl-Hirschman Index (HHI) is employed to gauge the degree to which each individual exchange member diversifies or concentrates its order flow across the exchanges of which it is a member. The HHI is widely used for measuring market concentration or dispersion.[150] Member HHIs are computed based on the relative order flow dispatched to the exchanges by the individual exchange member. This calculation is performed for each exchange member's principal orders, the combination of agency and riskless principal orders, as well as their overall order flow.

The concept of a ''pro-rata HHI'' is introduced to serve as a benchmark which encapsulates the inherent disparities in market shares among exchange. As with the member HHI, a pro-rata HHI is computed for each individual exchange member and category of order flow using the relative market shares of exchanges, this contrasts with the member HHI computation which is calculated with the relative share of the member's order flow. The pro-rata HHI has a straightforward interpretation; it reflects what an individual member's HHI would have been had it distributed its order flow across its member exchanges in proportion to their relative market shares.[151]

Deviations in the share of order flow routed to an exchange from the relative market weight can either contribute to increasing or decreasing member HHI relative to the pro-rata HHI.[152] Most order flow deviations which contribute to higher order flow concentration are associated with maker-taker exchanges with more pricing tiers and these deviations are positive and of larger magnitude relative to those of other exchanges. In contrast, deviations in order flow which contribute to lower HHI measures tend to be negative for the maker-taker exchanges with the highest number of pricing tiers and are positive for the other exchanges. This is to say that when broker-dealers concentrate their order flow, they tend to increase the share of order flow sent to those exchanges with more pricing tiers, consistent with the notion that tiering promotes the concentration of order flow. Table 6 reports each exchange's share of the total order flow deviations which either increase or decrease concentration and the volume-weighted average size of the deviation for each exchange.

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[147] Aside from order flow concentration, higher rebate/lower fee pricing tiers could increase trading volume and therefore market share by incentivizing the submission of limit orders which would have otherwise not been submitted absent the tiers.

[148] A plurality member is defined for a particular exchange as a member who executes the largest share (a plurality) of their order flow on that exchange. If a broker-dealer is a member of only one exchange they are necessarily a plurality member of that exchange since 100% of the order flow they execute across all the exchanges (for which they are a member) occur on that exchange.

[149] *See* Maureen O'Hara, and Mao Ye ''Is Market Fragmentation Harming Market Quality?'', 100 J. Fin. Econ. 459 (2011).

[150] The HHI is generally calculated as the sum of squared weights which normally add up to one. The HHI ranges from (0,1) with lower values indicating a more even split between the constituent weights and higher values indicative of a more uneven distribution with a max value of one indicative of a single entity with a 100% weight. Conditional on the number of entities N, the lowest possible HHI value is 1/N which corresponds to the case when all weights are equal to one-another (equal to 1/N).

[151] To illustrate the computation of member and pro-rata HHIs consider the case of a broker-dealer that directs principal orders to three different exchanges they are a member of. If the broker-dealer sends 60% of their principal order flow to one exchange and 20% to each of the other two, then the broker-dealer's member HHI for their principal orders be 0.44 ($0.60^2 + 0.20^2 + 0.20^2$). If the relative market share for the exchanges, using the executions of principal orders, are 30%, 30%, and 40% then the pro-rata HHI would be 0.34. In this case because the member HHI of 0.44 is greater than the pro-rata HHI of 0.34, then the member concentrates their order flow to a greater degree than would be expected had they routed their order flow in accordance to exchange size.

[152] Overall, the executed member order flow was more concentrated relative to the pro-rata HHI. For the month of Jan. 2023, the volume-weighted average pro-rata HHI was 0.18 whereas the volume-weighted average member HHI was 0.20.

Table 6 - Order flow deviation from relative market weights and shares of deviating order flow

The following table splits deviations in exchange member order flow from their relative market benchmark into those which increase or decrease member order flow concentration using the sample of CAT data for the month of Jan. 2023 described in Table 4.[a] Member order flow share is calculated as the number of shares executed by an exchange member in any capacity (e.g. principal, agency, riskless principal) during regular trading hours over the month of Jan. 2023 divided by the total number of shares the exchange member executed across all national stock exchanges during regular trading hours over the month of Jan. 2023. The share volume-weighted average deviation (in percentage points) for deviations which increase concentration and decrease concentration are reported under columns "Avg Deviation From Market", this is the difference between the percentage of order flow sent to the exchange by members and the relative market share of that exchange for that member. Columns titled "Share of Deviating Flow" denotes the share of total deviating order flow which either increases or decreases member concentration.

			Increase Concentration		Decrease Concentration	
	Exchange	# of Tiers	Avg Deviation From Market	Share of Deviating Flow	Avg Deviation From Market	Share of Deviating Flow
Maker-Taker	NYSE	93	13.2%	20.7%	-3.7%	15.3%
	NSDQ	74	19.2%	39.8%	-4.8%	50.6%
	ARCA	72	7.4%	13.4%	-3.3%	14.2%
	BZX	26	2.3%	3.9%	-1.6%	0.9%
	EDGX	19	9.3%	11.9%	-2.8%	6.8%
	MEMX	13	3.2%	3.7%	1.2%	0.6%
	AMER	10	-0.2%	0.0%	1.7%	0.4%
	PEARLEQ	8	2.3%	0.3%	2.9%	2.8%
	PSX	4	3.4%	0.3%	6.0%	1.9%
Non Maker-Taker	BX	20	-0.3%	0.0%	1.7%	0.5%
	NSX	11	-0.5%	0.0%	2.7%	1.2%
	BYX	11	-0.6%	0.1%	2.2%	1.8%
	EDGA	8	3.6%	1.2%	1.9%	1.2%
	IEX	0	7.4%	4.8%	1.9%	1.7%
	CHX	0	-0.1%	0.0%	1.0%	0.1%
	LTSE	0	0.0%	0.0%	0.0%	0.0%

[a] For each exchange member (index i) a deviation from the relative market weight for an exchange (index j) is defined by the difference $d_{ij}=S_{ij}-M_{ij}$ where S_{ij} denotes the share of member order flow and M_{ij} denotes the relative market weight. Share of member order flow S_{ij} is calculated as the order flow executed by the member i on exchange j divided by the total order flow executed by member i across all the exchanges they are a member of. The relative market weight M_{ij} is calculated as the total order flow executed on exchange j divided by the sum of total order flow executed across all the exchanges for which i is a member. N_i denotes the number of exchanges that the exchange member i is a member of. Conditional on $M_{ij}>1/N_i$, a deviation d_{ij} contributes to a decreased member HHI if $2(M_{ij}-1/N_i)<d_{ij}<0$ and increases it otherwise. Conditional on $M_{ij}<1/N_i$, a deviation d_{ij} contributes to a decreased member HHI if $0<d_{ij}<2(M_{ij}-1/N_i)$ and increases it otherwise. In the case $M_{ij}=1/N_i$ then any deviation $d_{ij}>0$ would contribute to a greater member HHI. The size of a deviation is calculated as the product between the deviation d_{ij} and total share volume member i executed on the exchange.

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3. Routing Incentives and Potential Conflicts of Interest

In the case of agency-related volume the use of volume-based pricing tiers by exchanges introduces a potential conflict of interest between exchange members and their non-member customers without exchange access.

Volume-based pricing for agency order flow may give exchange members an incentive to route customer order flow to certain exchanges for the purposes of tier qualification rather than maximizing other aspects of execution quality. The Commission finds evidence that agency and riskless principal order flow is overall more concentrated than principal order flow; however, relative to the relevant benchmark HHI, principal order flow is more concentrated.[153] However, Commission analysis suggests that the lower principal concentration is due in part to less concentration in marketable orders compared to similar agency-related order flow.[154] Additionally concentration of order flow may not always be contrary to customer interests. It is therefore unclear if differences in order flow concentration between principal and agency order flow are attributable to broker-dealers acting on the conflict of interest.

The potential for a conflict of interest emerges since broker-dealers can typically enjoy the benefits of the qualifying for a better pricing tier as a result of concentrating customer order flow without having to internalize the costs of that concentration.[155] Exchange members directly benefit from qualifying for a better tier since the preferential pricing would not only extend to their own principal orders but would also improve their ability to attract more customer flow by allowing them to pass through more savings. The concentration of agency order flow has the potential to be costly to the customers of exchange members if it comes at the cost of other factors of execution quality such as fill rates, time to execution, the availability of better-priced liquidity, and the likelihood of being adversely selected, each of which may vary across exchanges. However, it may not always be the case that concentration for the purpose of tier qualification comes at the expense of the customer, particularly if the member passes through large proportions of the cost savings from the tier qualification, then the reduction in costs for customers may on-balance leave the customer better off.

In contrast, when exchange members trade for their own account using principal orders, the incentives of the members are more straightforward. A member can choose to route an order to a particular exchange primarily out of a desire to make a profitable trade or to concentrate order flow and obtain a volume discount at its own discretion.[156]

Results from relevant academic research suggest that routing customer order flow in a rebate maximizing manner comes at the cost of execution quality. Brokers routing limit orders may also be motivated by liquidity rebates. Different sources document that limit order execution quality tends to be lower on exchanges with high take fees and low make rebates.[157] Execution quality can be measured along the different dimensions of fill rates, execution speeds, realized spreads, and adverse selection costs. Higher access fees tend to be associated with lower fill rates and execution speeds for non-marketable orders, and standing limit orders directed to high take-fee exchanges tend to face greater adverse selection costs.[158] One academic paper makes the claim that brokers typically route customer limit orders to exchanges where the broker will receive a rebate and that the rebate is typically not passed on to the customer.[159] Another study examining four high volume retail brokers which appear to route all nonmarketable limit orders in a manner consistent with maximizing rebates find that the expected rebate revenue offered by high take-fee venues may be insufficient to justify the opportunity cost, or potential loss in execution quality concurrently available on low take-fee venues.[160]

Member broker-dealers may have an incentive to profit to the detriment of the customer by choosing to concentrate agency orders onto a limited number of specific exchanges not because routing to those specific exchanges is necessarily in the interests of the customer but rather to increase the member's chances of qualifying for a particular volume-based pricing tier without necessarily passing some or all of the benefits of doing so back to the customer.[161]

There are forces in the market for equity brokerage services that serve to limit the extent to which this conflict of interest can alter behavior. For example, because of the Order Protection Rule, a broker-dealer looking to concentrate order flow on a particular exchange could not do so if doing so resulted in trading through the NBBO. In addition, the Commission understands that it is common for some institutional customers to monitor their broker-dealers on a trade-by-trade basis which would be expected to influence order routing decisions.

[153] The overall member HHIs for principal order flow is 0.21 whereas it is 0.24 for agency+riskless principal order flow; relative to their benchmark pro-rata HHI the principal member HHI is 31% greater whereas agency member HHI is 11% greater than its benchmark. *See infra* Table 7. The benchmark pro-rata HHIs differ between the two since the principal pro-rata HHI is computed using relative market weights taking only into account principal orders whereas the relative market weights used for the agency pro-rata HHI are computed using only agency or riskless principal order flow. For a more detailed discussion of the calculations of member and pro-rata HHIs *see supra* section IV.B.2.

[154] The Commission finds that the member HHI for principal order flow computed using only liquidity taking orders was 0.19 whereas it was 0.24 for agency order flow. When member HHI is calculated using only liquidity making orders it was 0.24 for principal order flow and 0.26 for agency order flow.

[155] Contracting solutions/payment arrangements between a broker and its customer may mitigate but not fully eliminate the incentive conflict. Investors may have difficulty in fully assessing execution quality, and broker-dealers may sacrifice execution quality on agency order flow, especially in situations where firms have concentrated sufficient principal order flow on an exchange to be near top-tier thresholds. If additional agency flow helps the broker-dealer cross the threshold for achieving a desirable tier, the broker-dealer has an incentive to direct agency orders to the exchange. In doing do, the broker-dealer could be trading off limit order execution quality for agency orders and potential rebate revenue for both agency and principal orders. Meanwhile, investors typically only partially accrue the rebates/transaction fees on agency orders under negotiated arrangements with their brokers.

[156] The member would still be subject to certain restrictions such as the Order Protection Rule.

[157] *See* Costis Maglaras, Ciamac Moallemi, and Hua Zheng, ''Optimal Execution in a Limit Order Book and an Associated Microstructure Market Impact Model,'' (working paper May 13, 2015), available at *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2610808* (retrieved from SSRN Elsevier database).

[158] Execution quality of non-marketable orders decreasing on exchanges with high take-fees is expected as liquidity takers tend to route their marketable orders to venues with the lowest take fees, all else equal.

[159] *See* James J. Angel, Lawrence E. Harris, and Chester S. Spatt, ''Equity Trading in the 21st Century'', 1 Q. J. Fin. 1 (2011).

[160] *See* Robert Battalio, Shane Corwin, and Robert Jennings, ''Can Brokers Have It All? On the Relation between Make-Take Fees and Limit Order Execution Quality'', 71 J. Fin. 2193 (Oct. 2016).

[161] *See supra* note 155.

TABLE 7—EXCHANGE MEMBER AND PRO-RATA HHI FOR OVERALL, AGENCY OR RISKLESS PRINCIPAL, AND PRINCIPAL ORDER FLOW

[This table uses a sample of CAT data of NMS stocks traded on the national equities exchanges for Jan. 2023 and reports share volume-weighted measures of market and member HHI values using all, agency-related, and principal order executions.[a] *See* Table 4 for a description of how exchange members are identified as well as how agency, riskless principal, and principal transactions are identified. The table also reports the percentage difference between member and pro-rata HHIs; this is calculated as the difference between the member HHI and pro-rata HHI divided by the pro-rata HHI. Also reported are the share volume-weighted average HHI measures for different order capacities using only liquidity taking orders (Remove) and liquidity making orders (Add). The CAT liquidity categories specify if the side of the trade was adding or removing liquidity. As the HHI measurement is influenced by the number of entities involved in its calculation, market and member HHIs are also separately calculated among broker-dealers who are members of many (>10) and few (<=10) exchanges.]

	Order capacity	Pro-rata HHI	Member HHI	% Difference	HHI (remove)	HHI (add)
Overall (100%)	All	0.18	0.20	16	0.18	0.23
	Agency Or Riskless Principal	0.22	0.24	11	0.24	0.26
	Principal	0.16	0.21	31	0.19	0.24
>10 Exchanges (95%)	All	0.16	0.18	14	0.16	0.20
	Agency Or Riskless Principal	0.18	0.20	11	0.19	0.22
	Principal	0.15	0.19	32	0.18	0.22
<=10 Exchanges (5%)	All	0.48	0.61	27	0.57	0.61
	Agency Or Riskless Principal	0.69	0.78	12	0.76	0.79
	Principal	0.38	0.48	29	0.45	0.49

[a] For a more detailed discussion of the calculations of member and pro-rata HHIs *see* section IV.B.2.

Table 7 reports the volume-weighted average market and member HHIs derived from the individual exchange members. Consistent with section IV.B.2, individual members appear to be more concentrated (0.20) than would be expected by the relative market shares of the exchanges (0.18). Both market and member HHIs computed using agency or riskless principal trades are greater than they are when using only principal order flow in absolute terms. However, when measured relative to their benchmarks, agency related member HHI is only 11% greater than the pro-rata HHI whereas principal member HHI is 31% greater.[162] Broker-dealers typically have more discretion when routing non-marketable orders since the routing of non-marketable orders is not directly constrained by the Order Protection Rule. Therefore, the fact that the difference between agency-related and principal HHIs appears to be smaller when only considering the execution of non-marketable limit orders suggests that the observed differences in concentration between agency-related and principal order flow may not be driven by routing decisions taken where broker-dealers have the most discretion.

As the HHI measurement is influenced by the number of entities involved in its calculation, market and member HHIs are separately calculated among broker-dealers who are members of many (>10) and few (<=10) exchanges. This approach ensures a more accurate representation of market concentration since the average HHI could be skewed by instances where the member HHI is calculated over a low number of exchanges. For instance, the HHI will, by definition, be equal to one when the broker-dealer is a member of a single exchange meaning that 100% of its order flow is executed on that single exchange.[163] Consistent with this, Table 7 shows that the various HHI measures are generally greater when calculated for broker-dealers with 10 or fewer exchanges of which they are a member. For the subset of broker-dealers with 10 or fewer exchanges the differences between principal and agency concentration measures are greater.

While agency-related order flow appears to be more concentrated than principal order flow it deviates less from its respective benchmark pro-rata HHI measure than principal order flow. This result suggests that the broker-dealers who concentrate their principal order flow do so on a greater variety of venues whereas agency order flow across broker-dealers should concentrate more on the same exchanges across broker-dealers.[164] As the pro-rata HHI encapsulates commonalities in the distribution of order flow, larger deviations from the pro-rata HHI suggest that distribution of order flow is less dependent on those commonalities. For this reason, the Commission believes principal order flows are likely to be more responsive to any changes in the market.

4. The Market To Provide Exchange Access

Broker-dealer exchange members compete to provide access to the exchanges for investors, as well as for proprietary traders and other broker-dealers who give up orders to an exchange member. There is significant variation in the size of the exchange members, as measured by total order flow. In each of these markets, volume-based transaction pricing for agency-related volume may provide a competitive advantage to the larger exchange members.

a. The Current Effect of Volume-Based Tiers on the Market for Broker-Dealer Services

The tiered transaction pricing schedules create competitive advantages for high-volume broker-dealers in the market to provider brokerage services to investors. These tiered schedules may also be contributing to a trend of increased concentration in the executing broker industry.

The current equities exchange tiered transaction pricing schedules create differences in the fees and rebates applied across members. Tiered transaction pricing currently affords high-volume broker-dealers substantially cheaper trading, placing them at a competitive advantage over the smaller firms. One commenter suggested that ''[a] smaller firm's trading costs for any given trade on an exchange may be 30% or more of the costs of a larger competitor—for the exact same trade.'' [165] Lower-volume exchange

[162] A possible explanation of this could be that there may be a greater degree of correlation between agency trading decisions than between trading principal trades.

[163] It is worth noting that a broker-dealer can still route orders through to an exchange of which it is not a member but would have to do so through an intermediary which is a member of the target exchange, and that order flow would count towards the trading volume of the intermediary member rather than the original broker-dealer.

[164] If broker-dealers all choose to concentrate order flow in the exact same proportions on the same choice of exchanges, then the market and member HHI would be equal. If instead broker-dealers chose to concentrate their order flow on different exchanges then the difference between market and member HHI would be large.

[165] Letter from Tyler Gellasch, President and CEO, Healthy Markets Association to Mr. Brent J. Fields,

members may be providing a subsidy for a handful of the high-volume members.[166] One exchange group suggested that its highest volume members receive rebates exceeding the trading fees, data, and connectivity fees combined.[167] A representative of one exchange group has stated that ''[there are just the] top 10 firms across our four exchanges by market share. [. . .] Five of the top 10 get a check from us after the costs of their connectivity and market data. So we are cutting them a check monthly after their costs. [. . . At the same time, the] top 10 firms on our exchange eat up 50 percent of the capacity on our exchanges.'' [168] While the highest volume traders are either trading at heavily discounted rates or making a profit from exchange transaction rebates, the revenue to supply such discounts may come, in part, from lower-volume broker-dealers who do not qualify for volume discounts.[169]

There has been increased concentration in the executing broker industry in recent years.[170] A number of factors may be contributing to this trend. According to an industry source, data and connectivity costs have been trending upwards,[171] which increases the fixed costs of being an executing broker. In contrast, broker commission pools and rates that have long been in decline because, as some broker-dealers have become more efficient through automating most trades, competition for customers forced other broker-dealers to streamline or offer price cuts.[172] In addition, high-volume broker-dealers may be better positioned to attract customers through performance along dimensions other than commission. For example, high-volume broker-dealers may be better equipped with algorithmic tools and other technologies that facilitate execution quality, or they may be better positioned to bundle execution services with other offerings, such as research. According to one survey from 2021, because of the large brokers' various perceived strengths, 28% of buy-side asset managers anticipate doing more business with high-volume brokers versus only 10% who expected less.[173] In sum, increasing concentration in the broker/dealer space hints at competitive pressure to constrain fees and ''barriers to entry based on necessary scale to be able to absorb the fixed costs of infrastructure, market data and connectivity.'' [174] The number of registered broker-dealers declined by over 20% between 2015 and 2022, or by close to 1,000 from an initial value of 4,450 in 2022.[175] The decline in the number of broker-dealers is consistent with the Commission's understanding that the broker-dealer community has seen no salient growth of nascent firms in recent years. Volume-based transaction pricing may further contribute to this trend of increased concentration. Under volume-based exchange transaction pricing, the top volume broker-dealers' lower trading costs give them an advantage when competing for customers against smaller members.[176] Specifically, investments in infrastructure (*e.g.,* trading algorithms), connectivity (low versus high latency), and market data tend to be fixed costs that do not scale in proportion of trading volume. High-volume broker-dealers tend to have lower trading costs, in part due to volume-based pricing, which better position them to offer lower commissions or fees.[177] If these lower fees allow them to attract greater order flow from customers and non-member broker-dealers, they will be able to attain more favorable pricing tiers. Thus, volume-based transaction discounts create a self-reinforcing cycle that amplifies the competitive advantage of the members with the highest existing volumes. This self-reinforcing cycle may be further exacerbated to the extent to which lower-volume exchange members, or their customers, find it more economically viable to route orders through a higher volume exchange member which can qualify for more preferential pricing tiers. Some observer(s) express concern that volume-based exchange transaction pricing that favors the high-volume broker-dealers helps to erect significant barriers to entry for lower-volume broker-dealers.[178]

Broker-dealers may be motivated to offer lower commission fees or partially pass through their transaction price advantages, in part because certain classes of investors are sensitive to changes in their trading costs or cum-rebate commission rates. Lower broker commission rates may provide incentives for sell-side institutional customers to place more orders through the broker-dealer providing liquidity, as opposed to pursuing other strategies such as taking liquidity, posting the same order on dark pools, or using special order types. Likewise, proprietary trading firms are known to change their trading patterns with

Secretary, Commission, dated Nov. 13, 2018, at 5 (''Healthy Markets 2018 Letter''), available at *https://www.sec.gov/comments/s7-03-20/s70320-7235195-217095.pdf*.

[166] *See, e.g.,* Chester Spatt, ''Is Equity Market Exchange Structure Anti-Competitive?'' at 7 (Dec. 28, 2020) available at *https://www.cmu.edu/tepper/faculty-and-research/assets/docs/anti-competitive-rebates.pdf* and at 5 (describing rebate pricing tiers based upon relative volume as ''advantaging large vs. small brokers'' and citing a letter from the Honorable Ted Budd, the Honorable Alex Mooney, and the Honorable Ann Wagner, Congress, to Chairman Jay Clayton, Commission, dated Jan. 31, 2020 for its criticism of the role of pricing tiers in disadvantaging small brokers), and Healthy Markets 2018 Letter, *supra* note 165, at 5, observing that as lower-volume and medium-sized exchange members pay relatively higher transaction fees (and receive relatively lower rebates), they may be cross-subsidizing the exchange transaction pricing benefits enjoyed by high-volume broker-dealers. The sentiment that the only high-volume exchange member's transaction prices are heavily subsidized is also expressed by IEX in ''Why Exchange Rebate Tiers are Anti-Competitive'', available at *https://www.iex.io/article/why-exchange-rebate-tiers-are-anti-competitive*.

[167] Chester Spatt, ''Is Equity Market Exchange Structure Anti-Competitive?'', *supra* note 166, at 7.

[168] Remarks of Chris Concannon, *supra* note 3, Transcript at 74–75.

[169] Healthy Markets 2018 Letter, *supra* note 165, at 5.

[170] Norges Bank comment letter ''Re: Notice of Proposed Rule on Market Data Infrastructure, Securities Exchange Act Release No. 88216 (Feb. 14, 2020) (File No. S7–03–20)'', dated July 15, 2020, at 3, available at *https://www.sec.gov/comments/s7-03-20/s70320-7422691-219826.pdf*.

[171] *See* Securities Industry & Financial Markets Association, An Analysis of Market Data Fees, available at *https://www.sifma.org/resources/general/an-analysis-of-market-data-fees/*.

[172] *See* U.S. Institutional Equity Trading Study (Feb. 2021), available at *https://assets.bbhub.io/professional/sites/10/2021_02-Market-Structure-Buyside-Survey-US.pdf*.

[173] *See id.*

[174] Norges Bank comment letter ''Re: Notice of Proposed Rule on Market Data Infrastructure, Securities Exchange Act Release No. 88216 (Feb. 14, 2020) (File No. S7–03–20)'', dated July 15, 2020, at 3, available at *https://www.sec.gov/comments/s7-03-20/s70320-7422691-219826.pdf*.

[175] *See* U.S. Securities and Exchange Commission Fiscal Year 2024 Congressional Budget Justification, available at *https://www.sec.gov/files/fy-2024-congressional-budget-justification_final-3-10.pdf,* which reports there being 3,538 registered broker-dealers in 2022 which is down from the 4,450 registered broker-dealers in 2015. *See* U.S. Securities and Exchange Commission Fiscal Year 2015 Congressional Budget Justification, available at *https://www.sec.gov/about/reports/secfy15congbudgjust.pdf*.

[176] The use of relative volume thresholds based on total consolidated volume reinforces the transaction pricing advantages of high-volume broker-dealers. If exchange transaction pricing qualifications were based on absolute volume thresholds, it could increase the number of lower-volume members that benefit from rebates. In contrast, relative volume qualifications effectively put broker-dealers in a race against each other.

[177] For example, hedge funds that trade large volumes would be directly impacted by the size of exchange transaction rebates if they have negotiated pass-through arrangements with the sell-side broker-dealers they use to access exchanges, through which they pay on a ''cost plus'' basis. Since the exchange transaction rebates would flow back to these investors, higher exchange rebates incentivize hedge funds to direct order flow to the top-tiered broker-dealers.

[178] One lower-volume broker-dealer's expressed concerns to the Commission that the decrease in the number of brokers is reflective of the lower-volume broker-dealers' inability to qualify for better volume discounts. Healthy Markets 2018 Letter, *supra* note 165, at 5.

changes in broker commission rates. One reason for their commission price responsiveness, the Commission understands, is that some active proprietary trading firms may profit from exchange transaction rebates on some exchanges. Comparing the relative sizes of exchange transaction rebates and broker commissions, average broker commissions tended to range from 0.65 to 2.67 cents per share in 2020.[179] Since the base tiers for exchange rebates tend to be capped at roughly 0.3 cents per share, exchange transaction rebates for high-volume broker-dealers could be more than 10 percent of average commissions. Considering that exchange transaction rebates from high-volume members can be non-trivial compared to the average broker commissions, high-volume broker-dealers may effectively attract order flow by sharing portion of the rebates or offering lower commissions. While the current trend of consolidation may be concurrent with lower prices for investors and better service, increased market power among the high-volume broker-dealers could eventually lead to increased costs for investors. When the dominance of high-volume broker-dealers becomes sufficiently heightened, it is conceivable that dominant broker-dealers may eventually choose to exercise market power more aggressively. As a manifestation of the more general principle that a monopoly (or players with market power) tends to charge prices higher than what is socially optimal, large broker-dealers may raise commission fees. Doing so may result in a decline of trading volume facilitated by broker-dealers and a shrinkage of total surplus across investors.

b. The Market To Provide Exchange Access to Non-Member Broker-Dealers

Substantial differences in the exchange transaction pricing applicable across members with different volume echoes in the dramatic difference in size across those members. One measure of the dispersion of trading activities across members on an exchange is the coefficient of variation, applied to shares executed or total dollar volume. The coefficient of variation for member-level shares summarizes the standard deviation of firm's total monthly shares relative to the average across members on an exchange. The coefficient of variation, or ratio of standard deviation to mean, ranges from 1.6 to 2.45 across the 16 exchanges for the month of January 2023. The coefficient of variation, applied to total dollar volume defined as shares times trade price, ranges from 1.48 to 3.11 across exchanges for the same month. For both measures of dispersion, the ratios suggest that the standard deviation of dollar volume is as large as the mean across all firms. Moreover, the standard deviation of dollar volume across members can be 3 times as large as within-exchange average.

Higher rebate earned enables the largest exchange members to attract a disproportionate share of order flow from non-members, further exacerbating their competitive advantage over smaller exchange members. Pricing arrangements for non-member's exchange access services can be ''cost plus'', meaning that all or a portion of the access fee and rebates get passed on to non-members, with an additional fee for connecting to an exchange. Competition among direct market access (''DMA'') providers constrains the fee for non-members' exchange access to a narrow band of 0.5 to 2 mils per share, and one source suggests that DMA providers may offer the service free.[180] Considering that top tiers across exchanges lead to rebates exceeding 3 mils, the cost for direct market access may be modest compared to the highest rebates and justifies non-members' decisions to route through the largest exchange members. Large exchange members' market power in DMA provision amplifies their competitive advantage over smaller exchange members, as the added liquidity accrued from non-members helps the exchange members achieve even more favorable tiers.

In addition to competing for order flow from investors, broker-dealers also compete to provide sponsored access to exchanges for other entities, such as broker-dealers or proprietary traders. Executing broker-dealers also compete to receive order flow from other brokers who do not interact with the exchanges themselves. Through direct market and sponsored access services, investors and other lower-volume broker-dealers choose to route orders through high-volume broker-dealers. Among the benefits from doing so,[181] the current exchange transaction price tiers allow the lower-volume broker-dealers to share in some or all of the volume-based tiers of high-volume broker-dealers if they receive pass-through exchange transaction pricing, subject to the costs they pay to the sponsor for those services. Thus, within these markets, high-volume broker-dealers have certain competitive advantages over lower-volume broker-dealers that helps to account for their size. While a number of factors are involved, volume-based transaction pricing for agency-related volume contributes to the competitive advantages of high-volume broker-dealers.

One reason that lower-volume broker-dealers and proprietary traders that are not broker-dealers may rely on the broker-dealers that are exchange members to provide access and connectivity to exchanges is the substantial fixed costs associated with exchange connectivity and data. Market data and connectivity fees, together with exchange membership, have increased substantially in recent years and can be significant enough to raise entry cost concerns.[182] While the cost to maintain exchange membership tends to fall between $5,000 and $10,000 on the exchanges with the largest market share, proprietary exchange market data fees and fees for the most closely-connected connectivity to the exchange's matching engine can range from thousands to tens of thousands or more per month.[183] One study reports that the fees for depth of book data on some exchanges have increased more than tenfold from 2010 to 2018,[184] while a commenter on a

[179] *See* U.S. Institutional Equity Trading Study (Feb. 2021), available at *https://assets.bbhub.io/professional/sites/10/2021_02-Market-Structure-Buyside-Survey-US.pdf.*

[180] *See* Daniel Aisen, ''Connecting to the Stock Market (Choosing a DMA Partner)'' (Mar. 2021), available at *https://medium.com/prooftrading/connecting-to-the-stock-market-choosing-a-dma-partner-9176ccd3ce84* (''[i]t's gotten to the point where if you trade a fair amount of volume, you can probably find a good DMA provider who will offer you the service for free [. . .]'').

[181] *See supra* section IV.B.4.b for a discussion of the benefits for small broker-dealers to send orders via high-volume exchange members.

[182] Norges Bank comment letter ''Re: Notice of Proposed Rule on Market Data Infrastructure, Securities Exchange Act Release No. 88216 (Feb. 14, 2020) (File No. S7–03–20)'', dated July 15, 2020, at 3, available at *https://www.sec.gov/comments/s7-03-20/s70320-7422691-219826.pdf.*

[183] Exchanges can extract more profits from data sales by offering ''low-latency'' access to data feeds, such as additional monthly fees for the opportunity to co-locate their computers in physical proximity to the exchange's own computer. This practice is known as ''co-location'', and co-location fees alone can cost traders tens of thousands per month. *See* New York Stock Exchange's Connectivity Fee Schedule, available at *https://www.nyse.com/publicdocs/Wireless_Connectivity_Fees_and_Charges.pdf.* Co-location fees are separate from fees for accessing individual exchange's proprietary data, which can amount to thousands per month. *See* An Analysis of Market Data Fees (Aug. 2018), available at *https://www.sifma.org/wp-content/uploads/2019/01/Expand-and-SIFMA-An-Analysis-of-Market-Data-Fees-08-2018.pdf.* According to IEX's description of its market data fees, the maximum monthly cost for ''low-latency'' (super-fast) data subscription is around $3,500. IEX's report on its market data fees is available at *https://www.sec.gov/rules/sro/iex/2022/34-96331.pdf.*

[184] *See* An Analysis of Market Data Fees (Aug. 2018), available at *https://www.sifma.org/wp-content/uploads/2019/01/Expand-and-SIFMA-An-Analysis-of-Market-Data-Fees-08-2018.pdf.*

proposed exchange fee stated in 2016 that fees for connectivity and co-location have also escalated during an overlapping time period.[185]

Moreover, high-volume exchange members' size and scale affords them the resources that permit them to hire the expertise required to develop and use the smart order routing technologies necessary to trade competitively in the NMS stock market. Lower-volume market participants may lack the economies of scale to operate their own smart order routers, and may need to purchase those services from the high-volume broker-dealers that are exchange members. Some proprietary traders and lower-volume broker-dealers, who may otherwise be deterred from becoming members of and trading directly on the exchanges, can benefit from the high-volume exchange members' access and sophisticated systems, and may otherwise find it difficult to grow their business or to compete on equal terms with those members.

Another reason behind lower-volume broker-dealers' and proprietary traders' reliance on exchange members may be that the smaller firms cannot individually qualify for the fee and rebate levels that exchanges offer to their high-volume exchange members. Rather than becoming members of and trading directly on exchanges, the smaller firms can benefit from sending orders to exchanges via high-volume exchange members to share in a portion of the larger members' volume-based pricing advantage, subject to any costs or commissions.[186] It is likely that volume-based transaction pricing creates an advantage for the high-volume broker-dealers in attracting such order flow. Because high-volume broker-dealers tend to qualify for the highest tiers, they effectively have lower costs when offering sponsored access or execution services to other brokers. Competition among these sponsored access and direct market access providers constrains the fee for non-member's exchange access to a narrow band of 0.5 to 2 mils per share, and some providers may offer the service for less.[187] Considering that top tiers across exchanges lead to rebates exceeding 30 mils, nonmembers' cost for direct market access may be modest compared to the highest rebates and potential cost savings achieved. As with the market to provide broker-dealer services to investors, these lower costs lead to more volume from non-members. The broker-dealer is more able to qualify for the best tiers, further lowering costs and exacerbating its competitive advantage over lower-volume exchange members.

c. The Dispersion of Member Broker-Dealer Size

The fact that there are a range of different sizes by order volume for exchange members is an assumption that enters into the analysis that the Commission is presenting on the economic effects of the proposed rule. In this section, the Commission presents analysis showing the existence of such a dispersion in broker-dealer size.

One measure of the dispersion of trading activities across members on an exchange is the coefficient of variation, applied to shares executed or total dollar volume. The coefficient of variation for member-level shares summarizes the standard deviation of firm's total monthly shares relative to the average across members on an exchange. The coefficient of variation, or ratio of standard deviation to mean, ranges from 1.6 to 2.45 across the 16 exchanges for the month of January 2023. The coefficient of variation, applied to total dollar volume defined as shares times trade price, ranges from 1.48 to 3.11 across exchanges for the same month. Both measures of dispersion suggest that the distribution of member's trading level has considerable variability about its exchange's mean, with the standard deviation of dollar volume being as large as the mean across all exchanges. Moreover, the standard deviation of dollar volume across members can be 3 times as large as within-exchange average.

For further evidence of the large disparities in trading activities across broker-dealers, one can compare order volume of exchange members at the 25th percentile and at the 75th percentile on each exchange. For trading activities measured by shares executed in the month of January 2023, shares from exchange members at the 25th percentile can be as little as less than 1% of the shares from members at the 75th percentile on a single exchange. The proportion of exchange order flow attributable to members between the 25th percentile and 75th percentile is no more than 12 percent on each exchange. Comparable ranges apply to trading activities measured by a member's total dollar volume defined as shares times trade price. Comparing the ratios of the 25th percentile to 75th percentile across exchanges, dollar volume from the exchange member at the 25th percentile is as small as less than 1% and no greater than 12% of dollar volume at the 75th percentile. When one restricts the analysis of order flow to liquidity-adding activities on maker-taker exchanges, order flow is similarly concentrated. On several exchanges, the member from the 25th percentile of the dollar volume (or shares) distribution executed trades that are less than 1% of the dollar volume (or shares) of the 75th percentile member on the same exchange. Across exchanges, the ratio of the 25th to 75th percentile trading activities is no more than 10%. The substantial differences in trading activities between high-volume and the tail of lower-volume exchange members are consistent with an earlier observation that the broker-dealer space is highly concentrated.[188]

5. Lack of Tier Transparency

There is no public transparency about the number of firms that qualify for the different tiers across exchange transaction pricing schedules. This lack of transparency may limit the ability of members, other exchanges, and the public to submit informed comment on exchange pricing proposals and draw conclusions about the effects of all exchange transaction pricing including volume-based transaction pricing tiers. Knowing how many exchange members qualify for different pricing tiers would provide interested parties with insight into how the costs and benefits afforded by volume-based tiers are distributed across exchange members. This knowledge would allow market participants to submit more informed comments to the Commission by allowing them to better compare the pricing they receive to their competitors and better ascertain if a pricing schedule disproportionately favors certain participants.

Exchanges are required to provide information on their websites that detail the pricing schedules for trading on the exchange.[189] These documents include

[185] *See* Letter from David L. Cavicke, Chief Legal Officer, Wolverine Trading LLC, Wolverine Execution Services LLC, and Wolverine Trading Technologies LLC to Mr. Brent J. Fields, Secretary, Commission, dated Dec. 23, 2016.

[186] For example, pricing arrangements between members and non-members for sponsored and direct market access services can be ''cost plus,'' meaning that the sponsoring broker-dealer passes through to the non-member customer all or a portion of the exchange transaction fees and rebates for which it qualifies, with an additional fee charged for connecting to an exchange. A sponsoring member whose total volume qualifies for a high tier would have more to offer through such arrangements than a lower-volume member. *See* Daniel Aisen, ''Connecting to the Stock Market (Choosing a DMA Partner)'' (Mar. 2021), available at *https://medium.com/prooftrading/connecting-to-the-stock-market-choosing-a-dma-partner-9176ccd3ce84*.

[187] *See id.*

[188] *See supra* section IV.B.4.a.

[189] *See supra* note 7 and accompanying text.

the various tiers that market participants might qualify for, along with the associated fee or rebate.

The current transaction pricing practices of the exchanges in the market for NMS stocks is characterized by a large number of different pricing possibilities. These possibilities arise, in part, because fees and rebates for trades are often contingent on multiple factors including, the order types used in the trade, and whether the trade takes place in opening or closing auctions with additional discounts for volume-based tiers. The combination of the large number of pricing contingencies on many of the exchanges and the number of different exchanges in the market creates a large number of different pricing possibilities for market participants to consider when choosing where to route orders.[190]

The volume-based tiers [191] used in many exchange pricing schedules are generally based on a member's trading volume relative to the market's total trading volume in the month in which the market participant's trades take place. This means that the member faces a degree of uncertainty during the month about the precise tier it will be able to achieve on the exchange during the month.

The complexity and number of the various tiers, along with the frequency with which they change,[192] creates the possibility that for some tiers, only a few market participants qualify in a given month. It may even be the case that some tiers only have a single market participant that ultimately qualifies for them in a given month on a specific exchange.[193] If only one or a small number of members regularly qualify for a particular pricing tier it may suggest that an exchange's pricing schedule is structured to reserve the tier for the benefit of particular members. Pricing tiers of this manner could serve to entrench the dominant position of some members and contribute to the competitive imbalances between exchange members. Because of the lack of transparency with regards to ex-post tier qualification, the public is unable to assess whether there are tiers for which only one or a few market participants qualify. The Commission believes that many market participants are not aware of whether such limited qualification for tiers occurs.

C. Economic Effects

1. Effect of the Proposed Ban on Volume-Based Tiers for Non-Principal Orders

a. Benefits

i. Benefits To Lower Volume Exchange Members

We expect the proposal to yield some benefits to lower-volume exchange members, some of which would be passed on to investors who are their customers. In particular, to the extent that the differences in transaction fees would be less extreme under the proposed prohibition on volume-based pricing for agency-related volume in proposed Rule 6b–1(a), the proposed volume-based ban would result in benefits to lower-volume exchange members in the form of lower transaction fees and higher rebates. In response to the proposed prohibition of volume-based pricing for agency-related order flow, exchanges could set fees on agency-related orders that are between the current highest fees charged in the lowest volume tiers and the lowest fees charged in the highest volume tiers paid by the high-volume broker-dealers. Such an outcome is supported by results from the price discrimination and mechanism design literatures,[194] applied to settings where trading platforms (*i.e.,* firms making pricing decisions) face heterogeneous customers and may offer different prices depending on observable choices or observable customer characteristics. For models where firms may potentially sort customers based on volume, when comparing firm's optimal choices under price discrimination and restricting to a uniform price, prohibiting price discrimination oftentimes results in the new, flat per unit fee falling within the current range of the lowest per unit fee and highest per unit fee.[195] The context of non-volume based pricing among exchanges is more complex, as exchanges can condition prices on other broker-dealer characteristics. However, similar findings from the price discrimination literature may prevail, and price differentials across broker-dealers may be diminished under a volume-based ban. The smallest and medium-sized members, who currently pay higher transaction fees, would likely benefit from these ''intermediate'' prices, or prices that are less extreme relative to a setting where exchanges target low net transaction fees to high-volume broker-dealers and high fees to lower-volume broker-dealers.[196]

The proposed prohibition on volume-based pricing may result in an increase in agency order flow to medium-sized exchange members, due to their ability to divert business from direct market access customers. Under the current tiered pricing schemes, lower-volume broker-dealers with limited or no ability to route directly to exchanges are most likely to take advantage of the high-volume members' connectivity and tiers. In particular, because direct market access (DMA) pricing tends to be ''cost plus,'' [197] lower transaction fees/higher rebates for the high-volume exchange members may translate into lower fees for sponsored broker-dealers. The proposed ban on volume-based tiers, which would limit transaction fee differentials between the high-volume broker-dealers and the remaining players, would also lessen the pricing advantage of high-volume members when competing for DMA customers. Hence one consequence of removing the high-volume exchange members' tiered pricing advantage is that agency flow from direct market access customers may shift from the high-volume

[190] *See* RBC Letter, *supra* note 19, at 8 (''Our analysis identifies at least 1,023 pricing paths across the exchanges.'').

[191] *See supra* sections I.B and IV.B.1 (discussing volume-based pricing tiers).

[192] *See supra* section I.B (discussing changes to, and general complexity of, pricing schedules).

[193] *See* Healthy Markets Letter, *supra* note 165, at 5.

[194] ''Price discrimination'' is a term of art in economics, meaning charging different prices to different segments of consumers, sometimes for identical goods or services. Under price discrimination, consumers could be segmented based on their choices of different goods or services. The practice of price discrimination is not equivalent to unfair discrimination in the legal sense. The welfare consequence of price discrimination is ambiguous and can vary across industry settings. However, a number of empirical papers have found that when restricting to a constant price, customers previously enjoying the lower prices are worse off and those enjoying higher prices are better off, relative to a world where firms can vary prices with the customers' price-sensitivity. *See, e.g.,* Igal Hendel, and Aviv Nevo, ''Intertemporal Price Discrimination in Storable Goods Markets'', 103 Am. Econ. Rev. 2722 (2013); Guillermo Marshall, ''Hassel Costs and Price Discrimination: An Empirical Welfare Analysis'', 7 Am. Econ. J.: Applied Econ. 123 (2015).

[195] It is worth acknowledging that while charging an ''intermediate'' price is a plausible outcome, it is by no means the only outcome. The Commission believes an ''intermediate'' price to be a likely outcome given the wide range of order volume across broker-dealers, described in *supra* section IV.B.4.c. *See* W. Kip Viscusi, Joseph E. Harrington, and David M. Sappington, Economics of Regulation and Antitrust 365–70 (5th ed. 2018), for a simple setting with a numerical example. Alternatively, when trading venues are optimally setting prices in standard screening settings with private ''types'' across customers, optimal contracts for trading venues implies price discrimination. *See Patrick Bolton and Mathias Dewatripont, Contract Theory* 47–52 (2005), for a general reference.

[196] This benefit may be, in part, a transfer from the large-volume broker-dealers, who would end up paying more under this pricing arrangement. *See infra* section IV.C.1.b.i (discussing costs to high-volume broker-dealers from this effect).

[197] *See* Daniel Aisen, Connecting to the Stock Market (Choosing a DMA Partner), *supra* note 180.

exchange members to the medium-sized exchange members.

ii. Benefits to Investors

Proposed Rule 6b–1(a) may benefit investors by increasing competition among exchange members. The advantages afforded to high-volume broker-dealers through volume-based exchange transaction pricing may favor a more concentrated market structure in the market for brokerage services in NMS stocks. The removal of volume-based pricing tiers for agency-related order flow would reduce the pricing advantage afforded to higher volume exchange members for having more customer order flow. Having the same pricing for agency-related order flow across differently sized members would allow lower-volume members to more effectively compete against higher-volume members on the basis of passing on a higher proportion of collected rebates. In contrast, the likely changes in transaction fees and rebates, previously discussed in section IV.C.1.a.i, suggest lower cum-rebate transaction fees for small and medium sized broker-dealers under the proposed ban on volume-based tiers for agency flow, which lead to higher profit margins for such firms.[198] Competition leading to a high proportion of rebates being passed through may benefit investors even in the scenario in which the proposed rule reduces the total amount of price-savings (higher rebates/lower fees) available to be passed through to investors.

The lower transaction fees for small and medium sized broker-dealers described in section IV.C.1.a.i might lead to higher profit margins for such firms. This in turn would lead to a lower propensity to exit the market for such firms, and a greater likelihood of new entrants. With more firms in the market for brokerage services in NMS stocks, competition to provide those services could increase, benefiting investors.

Following the proposed ban on volume-based tiers, medium-sized exchange members may be better positioned to gain DMA customers, compared to lower-volume exchange members who are not well-equipped with fast connectivity and trading infrastructure. Based on staff experience, the Commission understands that roughly 30 broker-dealers across exchanges, including the dozen or so largest exchange members, have functional smart order routers (''SORs''), dedicated cabinets at data centers, and enough technical staff to support their functionalities. Consistent with that understanding, the average exchange has 34 members who contribute up to 99% of its dollar volume, where the average is taken over the 16 exchanges for the month of January 2023.[199] This observation aligns with the fact that substantial economies of scale are required to build expensive SORs with significant operational and regulatory risks. Consequently, while there is gradation in execution quality among exchange members, the difference in capability is more pronounced between the 30 or so large or medium-sized exchange members with both functional SORs and fast connectivity and the remaining small players. Banning volume-based tiers for agency-related order flow, which is expected to level competition for direct market access would benefit investors.

The extent to which lower net transaction fees facilitate the survival of lower-volume broker-dealers a wider variety of broker-dealers may be available to investors. Some lower-volume broker-dealers may specialize in niche areas or be better positioned to provide personal attention to investors and the proposed rule could help prevent the loss of such firms, benefitting investor welfare.

The proposed prohibition on volume-based transaction pricing for agency-related trades may also result in the benefit of improved execution quality for some customers of broker-dealers by removing an incentive to concentrate agency order flow. Reducing the incentive to concentrate agency order flow may result in improved execution quality for the direct market access customers of broker-dealers particularly if the broker-dealer had previously routed customer orders in accordance with that incentive. How much the customers of exchange members would tend to benefit from reducing the conflict of interest is uncertain as it is dependent on the preferences and practices of each routing broker. Additionally, the proposed prohibition of volume-based pricing for agency-related order flow will not resolve all potential conflicts of interest between exchange members and their customers.

Currently, when exchanges offer volume-based transaction pricing to members in return for those members executing more orders on the exchange, this creates a financial interest that could incentivize a member to route orders, including customer orders, to certain exchanges to qualify for better tiered pricing on those exchanges.[200] A prohibition on volume-based transaction pricing would remove this incentive. As a consequence of the proposed rule, broker-dealers may focus on execution quality for their customers in making routing decisions without the influence of volume-based exchange transaction pricing, which may result in improved execution quality.

Lower exchange transaction fees[201] that could result from the proposed rule and that better facilitate the survival of smaller brokers may result in benefits to investors through increasing the variety of broker-dealers available. Although smaller broker-dealers may not have the scale economies of larger broker-dealers, they may have firm-specific expertise valued by particular investors. A brokerage's strength may lie in good research in a niche area or personal attention which contributes to a firm's perceived service quality. By preventing the loss of firm-specific advantages and increasing the overall variety of broker-dealers, lower exchange transaction fees and higher rebates for small broker-dealers may enhance investors' overall welfare under the proposed ban on volume-based exchange rebates for agency-related volume.

iii. Benefits to Lower Volume Exchanges

Based on analysis described in section IV.D.2 below, the Commission expects that the proposed rule may decrease the level of order flow concentration for agency and riskless-principal orders and increase the concentration of principal order flow, which would be likely to benefit some exchanges. In the analysis of the changes to competition among exchanges, the Commission considered four separate scenarios: (1) agency order flow concentration decreases by 100%, (2) agency order flow concentration decreases by 20%, (3) principal order flow concentration increases by 20%, and (4) agency order flow concentration decreases by 20% and principal order flow concentration increases by 20%.[202]

Lower volume exchanges would be most likely to benefit from a decrease in the concentration of agency order flow. In the upper bound case where agency order flow was maximally dispersed

[198] *See supra* note 194 and associated text.

[199] This calculation was performed by first tabulating the number of members contributing up to 99% of dollar volume for each exchange, and then takes the mean across exchanges. The counts are based on data from the Consolidated Audit Trail, for the month of Jan. 2023.

[200] *See supra* section IV.B.3 (discussing this conflict of interest in greater detail).

[201] *See supra* section IV.C.1.a.i discussing how the proposed ban on volume-based tiers for agency orders may reduce transaction fees paid by smaller executing brokers.

[202] *See infra* section IV.D.2.b and Table 9 (for detailed discussion of the different scenarios discussed here and the underlying assumptions made).

(agency order flow concentration decreases by 100%), 11 of the 16 exchanges that currently make up a combined 19.58% of the on-exchange market would experience a 2.38 percentage point increase in market share on average. Assuming that both volume and average net captures remain the same as those of January 2023, this would translate to a combined overall increase of $26,382,403 in net transaction fee revenue across the 11 venues.[203] In the less extreme scenario in which concentration of agency order flow decreases by 20%, the same smaller exchanges would still benefit, but with an average increase in market share of 0.47 percentage points and a combined overall increase of $5,276,481.

The Commission's competition analysis [204] also considers the possibility of an increase in the concentration of principal order flow. That analysis concludes that the highest volume exchanges would be more likely to benefit from an increase in the concentration of principal order flow. Using January 2023 market shares, the 5 largest exchanges would experience an average 0.50% percentage point increase in market share given a 20% increase in principal order flow concentration. Assuming that both volume and average net capture rates remain the same as those of January 2023, the increase in market share would translate to a combined overall increase of $2,900,853 in net transaction fee revenue across the 5 venues.

The Commission also considered a case in its competition analysis [205] where a 20% increase in principal order flow concentration is coupled with a 20% decrease in the concentration of agency order flow would result in increased market shares for the 12 smallest exchanges by trading volume, with the exception of a single exchange, which would lose market share. In this case, the eleven positively affected exchanges would experience an average percentage point increase in market share of 0.26% and a combined increase in net transaction fee revenues of $2,574,733. That exchanges could be negatively or positively affected when only one kind of order flow concentration changes, indicates that exchanges have different sensitivities to changes in order-flow concentration.

[203] *See supra* note 123 and the accompanying text (for a description of how net transaction fee revenue is estimated and the assumed average net capture rates).

[204] *See infra* section IV.D.2.b.

[205] *See infra* section IV.D.2.b.

b. Costs

i. Cost to High-Volume Exchange Members

To the extent that average exchange per unit trading fees become more expensive than the lowest per unit (*i.e.,* top tier) fees currently offered, the proposed banning of volume-based exchange transaction pricing for agency-related volume would result in costs for the high-volume exchange members and possibly the smaller non-members routing through them if they receive pass-through exchange transaction pricing. This increase in costs may in turn cause the commissions charged by such broker-dealers to increase, resulting in costs for their customers as well.

The proposed ban on volume-based exchange transaction tiers might impose costs on a handful of the high-volume members in the form of lower rebates/higher transaction fees for agency order flow, along with loss of customer flow due to the large members' reduced price advantage when competing for customers. Various sources suggest that lower-volume exchange members may be effectively subsidizing a handful of the high-volume members receiving net payments.[206] A ban on volume-based exchange transaction tiers that dampens the extent of cross-subsidization across broker-dealers may cost the large members their forgone net payments. A second source of cost is the loss of potential customer flow, order flow that may have otherwise streamed to the top broker-dealers. Under volume-based pricing, the top broker-dealers' lower trading costs may give them a price advantage when competing for customers against smaller members. As the high-volume broker-dealers can better afford lower commission fees, they attract greater order flow from investing customers and non-members, which enhances their ability to attain more favorable pricing tiers. The proposed ban on volume-based discounts removes the competitive advantage that the high-volume broker-dealers otherwise gain through this self-reinforcing cycle.

Tiered rebates that aid in the concentration of order flow among high-volume exchange members may be desirable from an allocative efficiency perspective. Due to their scale economies, the high-volume exchange members may be most efficient at executing. Alternatively, the high-volume exchange members may have technology, capital or service strengths arising from their scale economies. Directing order flow to the high-volume exchange members may better ensure that resources are utilized in a cost-effective manner. Conversely, under the proposed ban on volume-based pricing, dispersing order flow across broker-dealers may reduce allocative efficiency.

An indirect, negative effect on the high-volume broker-dealers would arise from removing direct market access services and sponsored access from the tier qualifications for the high-volume members. If exchanges did not adjust their pricing levels in response to the proposed ban on volume-based exchange transaction pricing for agency-related volume, then removing the sponsored customers' order flow from the tiers calculation would weaken their ability to obtain more favorable pricing on principal orders compared to lower-volume members, thus eroding this competitive advantage.

Exchange members with large principal order flow also tend to have large agency order flow which is consistent with greater liquidity provision of either kind encouraging liquidity provision from the other order type. The majority of exchange members with principal order flow also route agency orders to the same exchange. There are over a thousand exchange-member firm pairs from January 2023 across 16 exchanges, with a majority of exchange members engaged in principal trading. Among exchange members that handle both principal and agency trades, 79% of members with principal trading also routed agency orders. One can compare a firm's position within the distribution of principal volume against its rank among agency trading firms on the same exchange. Conditional on executing both agency and principal orders on the same exchange, 83% of members whose principal trading was above an exchange's median dollar volume also ranked in the top half of agency trading dollar volume. Again, among members routing both types of orders, approximately 61% of members that ranked in the top quarter in terms of principal dollar volume also qualified for the top quarter of agency dollar volume on the same exchange. Thus, high relative principal flow is imperfectly associated with high relative agency flow. One plausible underlying force is that top-tier exchange transaction pricing (notably, rebates) earned from large principal flow provide incentives for non-members to direct their agency-related order flow through high-volume members to take advantage of a portion of that better exchange transaction

[206] *See* Healthy Markets 2018 Letter, *supra* note 165, at 5; Chester Spatt, ''Is Equity Market Exchange Structure Anti-Competitive?'', *supra* note 166, at 7.

pricing that may not otherwise be available to them. For these sponsoring members that already are rewarded preferred pricing for their principal flow, orders routed through them from non-members further contributes to the firm's larger agency and overall presence.

While the direct effect of the proposed banning of volume-based exchange transaction fee tiers could raise transaction costs on the high-volume broker-dealers' agency orders, the overall effect on the high-volume broker-dealers' trading activities and total welfare [207] depends on how exchanges respond to the proposed ban, especially through adjusting volume-based tiers for principal order flow. Offering a steeper volume-based pricing discount, or lower per-unit prices for greater utilization, has been documented as a means to attract demand to platforms in other market settings.[208] Likewise it is conceivable that while a ban on agency-related volume discounts could weaken the incentive to extract increasing levels of agency order flows if exchanges chose not to offer their best transaction pricing to all members equally, exchanges might respond with an increased rate of discounting for principal order flows. More generally, with the proposed ban on agency-related price tiers, the exchanges might re-adjust pricing schedules within each family of affiliated exchanges. Enhancing principal order flow enhances the liquidity externality across exchanges within a family, thereby increasing the value of keeping agency order flow on exchanges.

For high-volume broker-dealers trading in a principal capacity, the exchanges might re-adjust price schedules in a way that leaves the current high-volume firms with no substantial drop in profitability. While the proposed ban on agency-related volume transaction pricing tiers would weaken the competitive advantage of high-volume broker-dealers over smaller ones, the exchanges may attempt to offset the potential loss of agency order flow by either lowering the agency base fee or offering even steeper volume-based discounts for principal order flow. Deeper discounts for high principal volume may even enhance the profitability of these high-volume members with high amounts of principal trading. In addition, many high-volume broker-dealers engage in both proprietary trading and in a customer brokerage business. As discussed earlier in this section many firms with high levels of principal order flows also tend to achieve high levels of agency order flow on the same exchange. In the scenario with a ban on volume-based exchange transaction pricing for agency-related flow, better pricing for principal order flow may favor many of the same high-volume members as are favored under current volume-based pricing schedules. If deeper discounts on principal order flow for high-volume players helped to retain substantial principal order flow, then agency order flow may also tend to coalesce on the same exchange due to the order flow externality. Changes in volume discount transaction rates for principal order flow, combined with possible fee cuts on agency order flow, may counter the profit losses from forgoing previous subsidies on agency-related order flow for the high-volume broker-dealers.

ii. Cost to Investors With Trades Intermediated by High-Volume Exchange Members

Investors and other market participants that send exchange orders through large exchange members, which currently likely benefit from the volume-based transaction tiers of their sponsors, may experience costs in the form of higher fees from their executing broker-dealers under the proposed rule. In the absence of the ability of exchanges to use volume-based transaction pricing for agency-related flow, investors which rely on high-volume exchange members for market access may be left with relatively more expensive exchange transaction fee options. The transition from volume-based tiers to a flat fee that could result from the proposed rule is expected to lead to fees and rebates that are between the current values for the highest and lowest tiers.[209] This would lead to large-volume broker-dealers who qualify for the best tiers to be worse off, and low-volume broker-dealers to be better off. Because the changes for these broker-dealers would be to the marginal costs of their trading, the Commission expects this to impact the prices charged to their investor customers in the same direction. That is, when considered in isolation, this effect would tend to make customers of large broker-dealers worse off and customers of small broker-dealers better off. One potential response to limiting volume-based pricing for agency-related order flow would be for the exchanges to set intermediate transaction pricing for agency-related orders that are between the current highest fees charged in the lowest volume tiers and the lowest fees charged in the top-tiers.[210] To the extent that average exchange pricing on agency-related orders become more expensive than the previous top-tier pricing, investors and any intermediating broker-dealers who previously benefitted from the high-volume broker-dealers' passing through the volume-based exchange transaction pricing may be worse off.

Another category of trading activity that would no longer benefit from the tiered pricing advantages of high-volume broker-dealers would be sponsored and direct market access. Because proprietary traders using such access trade through the exchange member's connectivity to the exchange, orders directly routed to a trading center through sponsored access are marked as agency orders. These orders would no longer count towards volume-based tiers of the sponsoring member. Consequently, some sponsored traders may face higher net fees, compared to a setting where (1) the sponsored traders benefit from being the customers of top-tiered broker-dealers and (2) incorporating orders from sponsored traders reinforces the broker-dealers' ability to achieve higher rebates. The proposed ban on volume-based tiers may have a particularly adverse effect on the smaller traders that use these arrangements. Without the ability to tailor agency-related transaction fees to trading volume, some exchanges may not find it worthwhile to lower average fees in order to retain the order flows of the smallest traders.

The Commission also believes that the proposed banning of volume discounts, when considered in isolation, may have the effect of reducing efficiency if high-volume exchange members reduce the amount of order flow which they execute on the exchanges, something which could harm investor welfare.[211] As high-volume exchange members likely contribute substantially more to the depth of book on an exchange, a withdrawal of agency order flow on exchanges by these members may lower the overall displayed liquidity provision

[207] Here ''total welfare'' is defined as profitability summed across exchanges and broker-dealers with trading activities facilitated by exchange members.

[208] Meghan Busse and Marc Rysman, ''Competition and Price Discrimination in Yellow Pages Advertising'', 36 RAND J. Econs. 378 (2005).

[209] *See supra* section IV.C.1.a.i for discussion of this point.

[210] *See supra* section IV.C.1 for additional discussion on effect of the tiering ban on transaction pricing.

[211] *See* section IV.C.1.b.iii for a discussion of the costs to high-volume exchange members.

imposing a negative externality on other exchange members.[212]

iii. Costs to Higher-Volume Exchanges

Based on the analysis described in section IV.D.2 below, the Commission expects that the proposed rule may decrease the level of order flow concentration for agency and riskless-principal orders and increase the concentration of principal order flow, which would result in costs for some exchanges. The Commission considers four separate scenarios: (1) agency order flow concentration decreases by 100%, (2) agency order flow concentration decreases by 20%, (3) principal order flow concentration increases by 20%, and (4) agency order flow concentration decreases by 20% and principal order flow concentration increases by 20%.[213]

Larger exchanges would be most likely to bear a cost in the form of lost market share and net transaction cost revenue from an expected increase in the dispersion of agency order flow across more competing exchanges. Per Table 9, in the extreme case where broker-dealers decrease their agency order flow concentration by 100%, 5 of the 16 exchanges that currently make up a combined 80.42% of the on-exchange market would experience a 5.24 percentage point decrease in market share on average. Assuming that both volume and average net captures remain the same as those of January 2023, this would translate to a combined overall decrease of $32,720,244 in net transaction fee revenue across the 5 venues. In the scenario under which agency order flow concentration decreases by 20%, these 5 exchanges would also be adversely affected, though not as much as in the case of even re-distribution of agency flow across exchanges, with an average decrease in market share of 1.05 percentage points and a combined overall decrease in trading revenues of $6,544,049.

Smaller exchanges may lose market share from a given increase in the concentration of principal order flow. Using January 2023 market shares, the 11 smallest exchanges by trading volume would experience an average 0.23% percentage point decrease in market share given a 20% increase in principal order flow concentration. Assuming that both volume and average net capture rates remain the same as those of January 2023, the decrease in market share would translate to a combined overall decrease of $3,356,751 in net transaction fee revenue across the 11 venues.

In the case where a 20% increase in principal order flow concentration is coupled with a 20% decrease in the concentration of agency order flow, it could result in decreased market shares for the four largest exchanges. In addition, one smaller exchange could also lose market share in this case. In this case the five negatively affected exchanges would experience an average percentage point drop in market share of 0.58% and a combined decrease in net transaction fee revenues of $4,298,199.

iv. Increase in Principal Trades

The Commission recognizes that the proposed prohibition of volume-based pricing for only agency and riskless-principal orders would likely increase the benefits of principal trading which may increase systemic risk across broker-dealers. Without being able to count on agency order flow to help qualify for a volume-based tier exchange members may have to increase the concentration of their principal order flow in order to qualify for a preferred pricing tier. This effect likely would be exacerbated should exchanges adopt pricing schedules with more attractive volume-based pricing tiers for principal orders.[214]

One way market participants could increase their principal order flow would be to increase proprietary trading operations. Proprietary trading can increase market instability if the positions of different traders are correlated as correlated trading can amplify price movements and quickly deplete available liquidity.[215]

Some exchange members might adopt an inventory-based model to manage to effectively substitute what would have been agency or riskless principal orders with principal orders. Under an inventory model the broker dealer would aim to uphold a target inventory level in its traded securities which they could thereby use to internalize their customer trades. After internalizing the customer trade the broker-dealer could offset any changes in their inventory by executing an identical order on an exchange. The offsetting order, since it would be to manage the broker-dealer's inventory, would be a principal order. If the off-setting principal order is executed on exchange at the same price at which the customer order was previously internalized at, then the internalize-then-offset process would effectively transform what would have otherwise been an agency or riskless-principal order into principal order. The member broker-dealer would however risk that the offsetting principal trade would be executed at a worse price than what it had internalized the customer order at.

Maintaining an inventory position is both costly and risky. Holding inventory involves the investment of capital, broker-dealers have to purchase the shares needed to have a sufficient supply of stock in order to fill marketable buy orders as well as sufficient cash to handle marketable sell orders. Exchange members looking to transition to an inventory model may also have to maintain specific net capital levels as required by regulations to maintain solvency.[216] It is risky because holding non-zero inventory exposes the member broker-dealer to losses due to price fluctuation. This risk could lead to correlated trading among inventory-holding broker-dealers if price changes cause some to liquidate their inventory positions. This kind of correlated trading can exacerbate systemic risk among broker-dealers, as the liquidation of inventory by some can trigger further liquidations by others forming a self-reinforcing cycle. In the case that following this proposed rule exchanges would adopt pricing schedules that would make the transition to an inventory model worthwhile, larger broker-dealers would likely have a competitive advantage in absorbing the costs and managing risk given their greater resources. The Commission expects the costs associated with a shift in business model to limit the increase in principal trading due to broker-dealers taking on inventory for internalization.

v. Migration to Off-Exchange Venues

The proposed prohibition of volume-based pricing for agency-related order flow by exchanges would risk exchanges losing market share to off-exchange venues. In addition to competing with other exchanges, exchanges also use volume-based pricing tiers as a means of competition for order flow with off-exchange market centers such as wholesalers and ATSs. Lacking the ability to offer volume discounts on agency-related order flow may make exchanges less competitive. Not being able to realize preferential pricing offered by the highest volume-based tiers for the agency portion of their

[212] *See* section IV.D.1 for additional discussion of the effects of lower agency order flow on investor welfare and of the effects on efficiency that the costs to high-volume broker-dealers could have.

[213] *See* section IV.D.2.b and Table 9 (for detailed discussion of the different scenarios discussed here and the underlying assumptions made).

[214] *See* section IV.D.2.a.

[215] *See* Malceniece, Laura, Kārlis Malcenieks, and Tālis J. Putniņš. ''High frequency trading and comovement in financial markets.'' Journal of Financial Economics 134.2 (2019): 381–399.

[216] *See* 17 CFR 240.15c3–1.

order flow higher volume exchange members may instead face less attractive pricing thereby making off-exchange venues relatively more attractive.

Freeing up agency flow from the effects of volume-based tiers could result in fewer agency orders routed to exchanges. This view is manifested by both standard screening games from the mechanism design literature and price discrimination models, which suggest that volume-based price discrimination, particularly those based on absolute pricing tiers, can increase total demand for the platforms.[217] On the other hand, shutting down quantity discount schemes would remove a way for individual exchanges to better retain order flow from migrating to competing venues. This may lead to both greater dispersion of order flow across exchanges and a decline in trade volume among exchanges. Either (1) total order flow across exchanges may decrease or (2) a portion of that flow moves off-exchange, which in turn would harm on-exchange liquidity and increase trading costs.

Applying the insights from the price discrimination literature to the exchange setting suggests that the proposed ban on volume-based pricing may decrease both overall order flow across exchanges and overall efficiency, defined in terms of profit summed across broker-dealers and the exchanges. Standard theoretic models suggest that price discrimination can be a natural consequence of the trading venues' profit-maximizing incentive schemes (*i.e.,* contracts with customers), in setting with incomplete information present. Incomplete information could denote a setting with variation in valuation for execution/gains to trade across broker-dealers. Because the exchanges cannot perfectly ascertain each broker-dealer's intrinsic preference for trades, exchanges cannot condition transaction fees on broker-dealers' (private) valuations for order execution. Offering volume-based price discounts, compared to a regime prohibiting pricing tiers, can encourage broker-dealers with the most to gain from trade to better express their higher willingness to participating on an exchange. Tiered pricing can heighten the incentive to add liquidity to exchanges, enhancing not only total order flow and profit summed across the exchanges but also total broker-dealers' welfare. Prohibiting tiered pricing may shrink exchanges' overall profitability, to the detriment of broker-dealers as well.

Effectiveness of using price discrimination to increase total surplus, relative to a world absent of volume-based discounts, depends on sufficient heterogeneity across exchange members. Higher valuation, or greater gains from execution, could originate from the lower cost of operating broker-dealer businesses for high-volume exchange members. While the range of data products and co-location services offered by exchanges present substantial fixed costs for exchange participants, fees for proprietary data and connectivity do not increase proportionally with trading activity. As the per-share cost falls with increases in the exchange's trading volume, high-volume broker-dealers may find the value of trading greater than lower-volume exchange members. Another feature of standard screening models is that the participant's intrinsic value is revealed by the exchange member's self-selected quantity. The broad range of trading quantities across agency broker-dealers suggests a large degree of heterogeneity across agency broker-dealers. Across the 16 exchanges in January 2023, the coefficient of variation for dollar volume among exchange members' agency order flow ranges from 1.3 to over 3.3. Fixing an exchange, the exchange member at the 25th percentile has agency dollar volume that is as little as less than 0.1% and no more than 12.5% of the dollar volume coming from the 75th percentile exchange member.

One difference between the conventional nonlinear pricing/screening framework and the exchanges' price tiering setting is the use of relative volumes in the rebate formulae. Broker-dealers have an incentive to commit volume to an exchange so that their accumulated liquidity outcompetes rivals' liquidity and satisfies the threshold for higher rebates. The use of relative volumes in the rebate formulae may further reinforce the exchanges' ability to concentrate volume on their venue.

Market shrinkage and fragmentation of agency orders may have negative effects on transaction costs and undercut the internalization of the liquidity externality, potentially resulting in further loss of both principal and agency order flow. Coalescence on the larger exchanges is not only desirable for the exchanges but also increases the value of participating on each exchange, as trades are easiest to arrange on good terms in liquid markets. Having more consolidated markets under volume-based price tiers makes it easier for liquidity demand to meet liquidity supply on the same platform, lowering transaction costs. Conversely, loss of agency order flow from shutting down volume-based pricing could make the search for best price more costly for the remaining participants (both agency and principal) on an exchange, who might in turn decide to redirect orders away from dominant exchanges. Order flow externality reinforces the initial loss of surplus from shutting down volume-based price discrimination, resulting in further loss in efficiency, for dominant exchanges and their participants alike. Finally, as off-exchange market centers such as wholesalers often benchmark trades (and price improvement) to the NBBO, the withdrawal of a portion of on-exchange order flow may potentially result in wider (NBBO) spreads thereby harming execution quality in the market as a whole.[218]

Following the proposed ban, exchanges might adjust so as to ameliorate the loss of order flow and efficiency from reduced participation across exchange venues. In particular, one predicted response of the proposed ban is that some exchanges might try to retain agency order flows by offering steeper volume-based tiers for principal order flows. Deeper discounts that attract the largest proprietary traders and increase principal order flow on exchanges also benefit agency traders due to liquidity externality. More generally, exchanges might attempt to price discriminate along other dimensions not directly related to agency trading volume. As one source reports at least 3,762 separate pricing variables across exchanges, fees charged and rebates offered are based on an intricate array of other quality metrics, some of which are likely correlated with trading volume.[219] It is conceivable that exchanges might continue to ''lock in'' order flow by offering discounts for broker-dealers' percentage of time spent at the NBBO, among other measures of trading activities.

[217] *See* Hall R. Varian, ''Price Discrimination and Social Welfare,'' 75 Am. Econ. Rev. 870–75 (1985).

See W. Kip Viscusi, Joseph E. Harrington, and David M. Sappington, Economics of Regulation and Antitrust 365–70 (5th ed. 2018), Chapter 8 ''Monopolization and Price Discrimination'', pp 365–370 for a simple setting with a numerical example. *See also* Hall R. Varian, ''Price Discrimination and Social Welfare,'' 75 Am. Econ. Rev. 870–75 (1985).

[218] This is assuming that volume-based rebates to liquidity providers contribute to narrowing the NBBO, this particular increase in transaction costs may be limited to the extent to which such rebates do not influence the NBBO.

[219] *See* RBC Letter, *supra* note 19, at 1 (''In total, we found at least 3,762 separate pricing variables across the exchanges—that is, 3,762 factors that ultimately determine the fees charged and rebates offered by exchanges'').

2. Effects of Proposed Requirement of Rules and Policies and Procedures To Prevent Evasion

a. Benefits

Proposed Rule 6b–1(b)(1) would require national securities exchanges offering volume-based transaction pricing in connection with the execution of proprietary orders in NMS stocks for the account of a member to impose rules to require members to engage in practices that facilitate the ability of the exchange to comply with the prohibition in proposed Rule 6b–1(a). Proposed Rule 6b–1(b)(2) would require national securities exchanges offering such volume-based pricing for NMS stocks to establish, maintain, and enforce written policies and procedures reasonably designed to detect and deter members from receiving volume-based transaction pricing in connection with the execution of agency or riskless principal orders in NMS stocks. These requirements would increase the likelihood that the benefits of Rule 6b–1(a) would materialize. It is possible that exchange members would attempt to recover volume discounts for their agency-based order flow by trying to obtain volume discounts offered for principal-based order flow for their agency-based order flow. To the extent this happens, the benefits associated with prohibiting volume discounts for agency-based flow [220] would be less likely to materialize. Exchange rules requiring members to engage in practices that facilitate the exchange's ability to comply with proposed Rule 6b–1(a) and exchange policies and procedures reasonably designed to detect and deter members from receiving volume-based transaction pricing in connection with the execution of agency-related orders would reduce the likelihood that such attempts would happen, or would be successful if they did happen. The Commission is unable to quantify the size of this benefit because it is not feasible to determine the propensity of exchange members to attempt evasion without such measures in place.

b. Costs

The requirements of proposed Rules 6b–1(b)(1) and 6b–1(b)(2) would result in costs for those national securities exchanges for NMS stocks that choose to offer volume-based transaction pricing for a member's proprietary order flow after the implementation of the prohibition in proposed Rule 6b–1(a). Specifically, any national securities exchanges for NMS stocks that offers such volume-based transaction pricing would incur the legal and administrative costs to revise its rules to include the rules required by proposed Rule 6b–1(b)(1), and to develop and implement the policies and procedures required by proposed Rule 6b–1(b)(2), as well as the costs to maintain and enforce these rules and policies.

Table 8 provides the Commission's estimates of the PRA costs associated with developing the required written policies and procedures. The Commission estimates that there would be 13 [221] exchanges that would incur these costs.

TABLE 8—COMPLIANCE COSTS ESTIMATES

Description	Initial (one-time)	Ongoing (annual)
Review & revise price schedule + supplement anti-evasion rules	[222] $23,945.00	[223] $8,949.00
Collect, compile, and submit required disclosures to the Commission	[224] 21,758.00	[225] 37,488.00
Total (per exchange)	45,703.00	46,437.00
× 13 Exchanges with volume-based pricing	594,139.00	603,681.00

The requirements of proposed Rules 6b–1(b)(1) and 6b–1(b)(2) to revise exchange rules and implement anti-evasion policies and procedures would also impose costs by increasing the likelihood that the effects of Rule 6b–1(a), the prohibition of volume-based pricing to agency-related order flow, are realized. The Commission believes the proposed prohibition on volume-based transaction pricing for agency-based order flow would result in costs.[226]

3. Effects of the Transparency Provisions

a. Benefits

i. Increased Transparency

Proposed Rule 6b–1(c) would require equities exchanges to make monthly submissions to the Commission concerning how many members qualify for their volume-based pricing in connection with the execution of proprietary volume in NMS stocks, among other things.[227]

Knowing the number of exchange members that qualify for the different tiers will provide additional information to exchange members who would be concerned with which tiers they qualify for per their principal trading. While exchange members already know the tier qualification criteria or many volume-based tiers knowing the tier qualification criteria does not mean that

[220] *See supra* section IV.C.1.a (discussing the benefits associated with the prohibition on volume-based transaction pricing in agency-related volume for NMS stocks).

[221] This estimate is based on the assumption that the 13 national securities exchanges for NMS stocks currently offering volume-based tiers would continue to offer such tiers for principal related order flow after the implementation of proposed Rule 6b–1(a). *See supra* section III.D.

[222] The Commission derived the total estimated burdens from the following estimates: (Attorney at 30 hours * $462 per hour) + (Compliance Counsel at 10 hours * $406 per hour) + (Chief Compliance Officer at 5 hours * $542 per hour) + (General Counsel at 5 hours * $663 per hour) = $23,945 per exchange in initial costs. $23,945 per exchange × 13 respondents = $311,285 total initial costs. *See supra* note 84. The Commission derived the hourly rate figures from SIFMA's Management & Professional Earnings in the Securities Industry 2013, modified to account for an 1,800-hour work-year and inflation, and multiplied by 5.35 to account for bonuses, firm size, employee benefits, and overhead.

[223] The Commission derived the total estimated burdens from the following estimates: (Compliance Attorney at 12 hours * $406 per hour) + (Compliance Manager at 8 hours * $344 per hour) + (Business analyst at 5 hours * $265 per hour) = $8,949 per exchange in ongoing annual costs. $8,949 per exchange × 13 respondents = $116,337. *See supra* note 85.

[224] The Commission derived the total estimated burdens from the following estimates: (Sr. Programmer at 25 hours * $368 per hour) + (Sr. Systems Analyst at 10 hours * $316 per hour) + (Compliance Manager at 10 hours * $344 per hour) + (Director of Compliance at 5 hour * $542 per hour) + (Compliance Attorney at 8 hours * $406) = $21,758 per exchange in initial costs. $21,758 per exchange × 13 respondents = $282,854. *See supra* notes 85, 106, and accompanying text.

[225] The Commission derived the total estimated burdens from the following estimates: (Compliance Attorney at 6 hours * $406 per hour) + (Compliance Manager at 2 hours * $344 per hour) = $3,124 per monthly filing. $3,124 × 12 months = $37,488 per respondent. $37,488 per exchange × 13 respondents = $487,344. *See supra* note 89.

[226] *See supra* section IV.C.2.b (discussing costs associated with proposed Rule 6b–1(a)).

[227] *See supra* section II.D, discussing the full requirements of proposed Rule 6b–1(c).

an exchange member can with certainty know which tier it would qualify for a given absolute amount of trading volume. For example, many volume-based pricing tiers set the volume threshold needed for tier qualification as a percentage of aggregate measures such as the total consolidated trading volume [228] which is dependent on the trading of other market participants and not just that of the member itself. The disclosures of how many members qualify for their volume-based pricing in connection with the execution of principal flow would help resolve uncertainty regarding the distribution of tier qualification.

The Commission expects that the main benefit from the disclosure provisions of the proposed rule would be to improve the comments provided by members and other interested parties by providing information on the distribution of member tier qualification. As previously mentioned,[229] the monthly disclosures would identify the different transaction pricing tiers at each exchange and provide a breakdown of how many members qualified for the various tiers each month. The enhanced transparency would increase the ability of the exchange members, other exchanges, and other interested parties to assess how many members qualify for specific transaction pricing on an exchange and better understand the effect of exchange fee tiers which may enable more detailed comment. The Commission expects that by helping interested parties in providing more detailed comment on future fee filings the required disclosures would enhance the information available to the Commission and improve regulatory efficiency.

Disclosure of the number broker-dealers qualifying for each tier across all NMS stock exchanges would enable investors to learn the distribution of transaction fee-related costs across broker-dealers.

The proposed rule would also require the exchanges to disclose the number of members that executed principal orders in NMS stocks for each month as well as provide a table enumerating each volume-based tier along with basic information regarding the tier and its qualification criteria. While the Commission does not expect these other items to provide new benefits, since total membership numbers and detailed pricing schedules are already publicly accessible, the proposed rule would also require that these data be submitted to EDGAR in Inline XBRL, which would be a benefit as we discuss below.

ii. Benefits of EDGAR and Inline XBRL Requirements

Under proposed Rule 6b–1(c)(3), exchanges would provide the monthly disclosures in EDGAR in Inline XBRL. Requiring equities exchanges to present this information in a machine-readable, structured data language—namely, Inline XBRL—rather than an unstructured format (*e.g.,* HTML, ASCII, PDF) would further heighten transparency around exchange fee tier structures by facilitating more efficient retrieval, comparison, aggregation, and other analysis of fee tiers data on specific exchanges as well as across different exchanges and time periods. The use of Inline XBRL tags for proprietary volume-based pricing disclosures would thus make the disclosures more easily accessible to, and usable by, the Commission, exchange members, and the public, which in turn should allow for more efficient review of the impact of volume-based exchange transaction pricing.

Inline XBRL is an open, nonproprietary standard overseen by a not for profit consortium that includes a community of service providers and software tools.[230] Exchange members and market participants could leverage this existing infrastructure to readily compile, compare, and analyze the number of tiers at different exchanges, the number of members in various tiers at different exchanges, and the financial benefits attributable to different tiers within and across exchanges. Thus, the Inline XBRL standard could help the public more efficiently assess the effects and application of exchanges' volume-based pricing for NMS stocks for proprietary volume.

In addition, requiring exchanges to file the disclosures with the Commission would allow the Commission, the public, or exchange members to access the disclosures directly from a central, publicly accessible location, thus enabling efficient access and retention of the number of exchange members that qualify for each volume-based pricing tier on their proprietary volume. Centralized filing of the proposed disclosures would assist members, other exchanges, and the public in analyzing and commenting on volume-based exchange transaction pricing schedules that apply to proprietary volume. Additionally, centralized filing of the tiers disclosures with the Commission could, by making it easier for the Commission and the public to retrieve the exchange fee tiers disclosures over time from a single source, facilitate assessment of the level of competition and the impact of pricing tiers on intermarket competition.[231] The EDGAR system also would enable technical validations (*i.e.,* programmatic data error checks) on the disclosures, thus potentially improving data quality by reducing the incidence of non-discretionary errors (*e.g.,* including text for a disclosure that should contain only numbers).

iii. Impact on Exchange Price Schedules

The proposed transparency provisions would publicly reveal the number of exchange members which qualify for different pricing tiers on each exchange. If publicized, this information could prompt exchanges to reconsider their pricing structures, especially if they could give the appearance of disproportionately favoring a small number of exchange members. A possible effect of this kind of disclosure could be for exchanges to voluntarily adopt price schedules with fewer pricing tiers that end up applying to a few select exchange members in order to not give the appearance of disproportionately favoring a small number of exchange members. If exchanges adopt pricing schedules which result in a more even distribution of tier qualification as opposed to pricing schedules where more members qualify for lower volume tiers and few qualify the top tiers it could result in a benefit to the small to medium-sized exchange members who, under the current price schedules, may struggle to qualify for the best pricing tiers.

Such a shift in pricing structure would enable a broader range of members to qualify for improved pricing terms which in turn could help level the competitive field in the market between exchange members to provide direct market access to non-member customers insofar as members subsidize the terms

[228] For example, one exchange defines total consolidated volume as ''the total consolidated volume reported to all consolidated transaction reporting plans by all exchanges and trade reporting facilities during a month in equity securities, excluding executed orders with a size of less than one round lot.'' *See https://listingcenter.nasdaq.com/rulebook/nasdaq/rules/nasdaq-equity-7.*

[229] *See supra* section II.D.

[230] *See* About, *XBRL.org,* available at *https://www.xbrl.org/the-consortium/about;* Tools and Services, available at *https://www.xbrl.org/the-standard/how/tools-and-services/.*

[231] *See supra* section II.D (establishing the more effective assessment of whether pricing tier changes are reasonable, equitably allocated, not unfairly discriminatory, and do not impose a burden on competition as an objective of proposed Rule 6b–1(c)).

offered to their agency customers with the savings realized from hitting higher pricing tiers with their principal order flow.

b. Costs

i. Implementation Costs

With respect to the Inline XBRL requirement for the proposed fee tiers disclosures, equities exchanges would incur both initial Inline XBRL compliance costs, such as the cost of training in-house staff to prepare filings in Inline XBRL, and the cost to license Inline XBRL preparation software from vendors, and ongoing Inline XBRL compliance burdens that would result from the proposed tagging requirements. The proposed Inline XBRL requirements for the proposed fee tiers disclosures would result in compliance costs for equities exchanges relative to the current baseline, because equities exchanges would be newly required to apply Inline XBRL tags to the proposed disclosures before filing the fee tiers disclosures with the Commission (or pay a third-party tagging service provider to do so).

Because Inline XBRL tagging compliance software has already been developed and is already in use by public reporting companies to fulfill Inline XBRL requirements, the Commission expects that vendors would update their tagging software to accommodate the proposed Inline XBRL requirement for the proposed fee tiers disclosures if such a requirement is adopted. Equities exchanges currently are not subject to Inline XBRL requirements to comply with their legal requirements as exchanges. That said, most equities exchanges are affiliated with public reporting companies that are subject to existing Inline XBRL requirements. For example, 12 of the 16 equities exchanges are affiliated with public companies that are required to file financial statements and other disclosures in EDGAR in Inline XBRL.[232] To the extent that an equities exchange shares compliance systems with an affiliated entity that is required to submit Inline XBRL structured filings in EDGAR, or could otherwise leverage the affiliated entity's processes, licenses, service agreements, and expertise in complying with Inline XBRL requirements, the exchange's compliance costs could be partially mitigated.

The Commission believes the compliance costs associated with the proposed requirement to structure the proposed fee tiers disclosures in Inline XBRL likely would decrease over time because equities exchanges likely would comply with structuring requirements more efficiently after gaining experience over repeated filings, although such an effect could be diminished for equities exchanges affiliated with public reporting companies that already have experience structuring filings in Inline XBRL.

Because national securities exchanges are not currently subject to EDGAR filing requirements,[233] equities exchanges would incur a one-time compliance burden of submitting Form ID to access EDGAR as a result of the proposed requirement to submit the fee tiers disclosure via EDGAR.[234] While there are no fees associated with registering as an EDGAR filer, the Commission recognizes that the proposed requirement to submit the proposed fee tiers disclosures in EDGAR would impose compliance costs on equities exchanges in order to make limited changes to their systems, policies, and procedures to comply with the EDGAR filing requirement. These costs could be mitigated by the fact that many equities exchanges have affiliated entities that provide disclosures in EDGAR in Inline XBRL, and therefore employees of the equities exchanges could leverage the knowledge and experience about EDGAR and Inline XBRL possessed by staff within those affiliates.

ii. Reputation Costs & Changes in Exchange Price Schedules

The proposed transparency provisions which require the monthly public disclosure of the number of exchange members which qualify for different pricing tiers with their principal order flow has the potential to impose reputational costs on the exchanges. As the proposed rule would prohibit the application of volume-based tiers to agency-related order flow any qualification to a volume-based tier would have to be a function of non-agency related volume and the pricing of those tiers would only apply to non-agency related orders. The fact that the disclosure would only apply to principal trades limits the extent to which the information would be useful for market participants other than proprietary traders.

While exchanges currently are required to disclose their pricing schedules by publishing them online,[235] the number of members which qualify for each tier is not known to the public.[236] Some exchanges could suffer reputational costs if the distribution of members over the tiers for which they qualified for is perceived to be unfair. For instance, if only a few exchange members qualify for the most advantageous pricing tiers, the potential perception that these select few members receive advantages not available to a wider group could harm the reputation of the relevant exchange, especially if it appears as if the exchange is subsidizing the top pricing tiers at the expense of lower tiers.

The Commission believes that the risk of such reputational costs may induce exchanges to change their price schedules. Such changes would result in costs for those exchanges who undertake them, in the form of costs to alter existing price schedules, and through the possibility that such changes in price may reduce the incentive for their members to concentrate their principal order flow. Having to adopt a pricing schedule with a more even distribution of tier qualification, one where more members qualify for the different tiers, may only be possible by offering less attractive pricing across the top tiers. Trading off the pricing terms of high volume tiers in order to adopt a pricing schedule which may be perceived as more equitable could cause the exchange to lose trading volume or liquidity provided as high volume members may find other venues as more attractive following the change. As discussed in sections IV.D.2 and IV.D.1 the Commission cannot establish a reliable estimated range for the extent of these costs and which exchanges would be affected given that exchanges

[232] *See, e.g.,* Cboe Global Holdings, Inc. 2022 Form 10–K, available at *https://www.sec.gov/ix?doc=/Archives/edgar/data/0001374310/000155837023008202/cboe-20230331x10q.htm;* Intercontinental Exchange, Inc. 2022 Form 10–K, available at *https://www.sec.gov/ix?doc=/Archives/edgar/data/1571949/000157194923000006/ice-20221231.htm;* NASDAQ, Inc. 2022 Form 10–K; available at *https://www.sec.gov/ix?doc=/Archives/edgar/data/0001120193/000112019323000014/ndaq-20221231.htm.*

[233] The Commission recently proposed that national securities exchanges and exempt exchanges, including the equities exchanges that would be covered by proposed Rule 6b–1(c), file certain forms in EDGAR in structured data languages. *See* Electronic Submission of Certain Materials Under the Securities Exchange Act of 1934; Amendments Regarding the FOCUS Report, Securities Act Release No. 11176; Exchange Act Release No. 97182; Investment Company Release No. 34864 (Mar. 22, 2023) 88 FR 23920 (Apr. 18, 2023).

[234] Form ID must be completed and filed with the Commission by all individuals, companies, and other organizations who seek access to file electronically in EDGAR. *See* 17 CFR 232.10(b); 17 CFR 249.446. Accordingly, a filer that does not already have access to EDGAR must submit a Form ID along with the notarized signature of an authorized individual to obtain an EDGAR central index key and access codes to file on EDGAR.

[235] *See supra* note 7 and accompanying text.

[236] *See supra* section IV.B.5 (discussing the current state of price tier transparency).

may modify their pricing schedules in response to many factors, including the proposed rule.

D. Effect on Efficiency, Competition, and Capital Formation

1. Efficiency

The Commission anticipates that the proposed rule would result in most exchanges that trade NMS stocks significantly adjusting their transaction pricing schedules. By prohibiting one form of transaction pricing (volume-based) for trades of agency and riskless principal, the proposed rule would allow exchanges to apply different fees or rebates to principal trades. An example of one such case could entail offering fixed transaction fees and rebates to agency and riskless-principal trades but offering volume-based tiered prices to principal trades. While current pricing tiers may effectively differentiate between agency-related and principal trades it is often as a by-product of the tier categorization rather than an explicit condition of the application of the tier. An example of such an instance would be pricing tiers reserved for exchange members that are registered with the exchange as a market-maker and whose market-making orders would all be principal trades. However, this pricing would not apply to other exchange members that exclusively trade in a principal capacity if they are not registered market makers; so while all orders in such a tier may be of the same capacity categorization, qualification to such a market-maker tier does not universally apply to all principal capacity trades. The proposed rule would not prohibit exchanges from proposing transaction pricing where qualification is predicated on the capacity of the order as long as they are not based on volume to any extent.

The potential for exchanges to offer distinct pricing to principal and agency-related order flow introduces the possibility for greater market segmentation. This could arise if exchanges chose to tailor their transaction pricing schedule to favor one type of order flow over another.[237] Such segmentation could negatively impact overall transaction costs by resulting in wider spreads being quoted on the exchanges. By their very nature agency orders have to be handled by an intermediary before being able to reach one of the exchanges, which leaves agency traders with a latency disadvantage relative to principal traders that can access the exchanges directly.[238] If such a concentration of agency orders on certain exchanges occurs it would result in traders having a higher degree of certainty as to whether they are trading against an agency order or not based on which exchange the transaction is occurring. Understanding that their orders are more likely to be routed to some exchanges over others and hence more readily identified as an agency order, agency traders could elect to provide liquidity at a wider spread as a means of compensation for the increased risk of being adversely selected by a principal trader. While the latency disadvantage exists in current markets, exchanges that have a mix of agency and principal orders may see less likely adverse selection for agency orders because principal orders face more uncertainty about the capacity of their counterparty. The relative scarcity of agency order flow on exchanges that become dominated by principal trading following the implementation of the proposed rules could also result in wider spreads on those exchanges. These dynamics could be even more pronounced in the presence of additional discrepancies between the informativeness or adverse selection risk of agency and principal orders. This phenomenon further underscores the potential implications of distinct pricing mechanisms for different types of order flow on market efficiency and transaction costs.

The effects of the proposed elimination of volume-based transaction pricing tiers for agency-related trades could improve transaction quality and market efficiency by alleviating an impediment to switching the routing of orders from one exchange to another. As previously discussed, volume-based transaction price tiering effectively makes it more difficult for market participants to justify partially switching trading venues by increasing the opportunity costs of doing so, because switching the venue to which agency orders are routed to makes it less likely that the market participant will end up qualifying for a preferential pricing tier. The elimination of volume-based transaction price tiering for agency-related trades would alleviate this worry of missing out on preferential pricing and allow broker-dealers to route orders more readily to a variety of exchanges on the basis of execution quality. While variation in rebates and fees across exchanges would likely continue to exist and be one factor that influenced the routing decisions of brokers, the lack of volume-based transaction tiering would mean that brokers could route agency orders to a different exchange without jeopardizing the average net per-share costs of their overall trading.

While welfare for different customer segments may increase or decrease under the proposed ban, the overall welfare effects of banning price discrimination are ambiguous and can vary across market settings.[239] Nevertheless, standard intuition derived from economic theory suggests that when heterogeneity across customers exists, price discrimination may increase total welfare (*i.e.,* welfare summed across firm(s) and their customers who derive utility from the purchased goods) if the quantity sold increases under discrimination.[240] The analog of ''customers'' in the exchange setting is a combination of broker-dealers and their customers. Broker-dealers and the end investors share in gains from executing trades. As the intermediaries, to the extent the broker-dealers share the rebates with their investors, the end investors benefit from both the fulfilled trades and rebate pass-through. To the extent that broker-dealers' responsiveness to volume-based discounts is driven by the end investors' responsiveness to cost savings, volume-based discounts may expand overall liquidity across exchanges. Not only might volume-based discounts help the dominant exchange extract more order flow and revenue, but the pricing schemes could also increase broker-dealers' and their customers' total surplus.

Evaluation of price discrimination from other market settings provides the insight that volume-based pricing that attracts more agency business from high-volume exchange members may benefit both the high-volume exchange members and the exchanges, possibly at the cost of lower-volume exchange members. However, in the context of

[237] A broker-dealer solely looking to minimize transaction fees and maximize transaction rebates would concentrate their principal order flow on the exchange(s) with the most attractive principal volume tiers and concentrate their agency flow on the exchange(s) with the best agency order pricing. Markets are more likely to fragment if the set of exchanges with the best agency order pricing differ from the set with the best principal order pricing.

[238] With the exception of sponsored access trades under which the exchange member's sponsored customer can directly access the exchanges using the member's infrastructure, although sponsored access trades comprise a small portion of total agency flow.

[239] Igal Hendel and Aviv Nevo, ''Intertemporal Price Discrimination in Storable Goods Markets,'' 103 Am. Econ. Rev. 2722 (2013); Guillermo Marshall, ''Hassel Costs and Price Discrimination: An Empirical Welfare Analysis,'' 7 Am. Econ. J.: Applied Econ. 123 (2015); Sofia Berto Villas-Boas, ''An empirical investigation of the welfare effects of banning wholesale price discrimination.'' 40 RAND J. Econ. 20 (2009).

[240] *See* Hall R. Varian, ''Price Discrimination and Social Welfare,'' 75 Am. Econ. Rev. 870–75 (1985).

trading platforms with liquidity externality, additional order flow from high-volume exchange members may ultimately be beneficial to lower-volume broker-dealers. High-volume exchange members likely contribute substantially more to the depth of book on an exchange. When volume-based discounts induce additional order flow from high-volume broker-dealers to convene on a dominant exchange, more liquidity reduces the cost of searching for the best execution and benefits the lower-volume broker-dealers. This order flow externality, which is absent in many traditional price discrimination settings, provides a benefit that partially countervails the potential negative impact of volume-based tiers on the lower-volume broker-dealers.

2. Competition

a. Broker-Dealer Competition

To the extent that such increased costs for investors caused them to send order flow to other, lower-volume exchange members, allocative efficiency in the market for NMS stock brokerage services might be reduced. The high-volume exchange members might be most efficient at executing trades due technology, capital or service strength arising from their scale economies. Directing more order flow to the lower-volume exchange members might result in resources being inefficiently utilized. The effects of the proposed rule on the competition among broker-dealers are discussed in sections IV.C.1.a.i and IV.C.2.b.i.

b. Changes in Order Flow Concentration

The Commission expects that the proposed prohibition for volume-based exchange transaction pricing on agency-related order flow would be likely to increase the dispersion of agency flow and increase the concentration of principal order flow across exchanges.

The reason that agency-related volume might be impacted in this way is that volume-based transaction pricing incentivizes the concentration of order flow and, all else being equal, the removal of this incentive should result in less concentration of that flow. Under the assumption that some variant of volume-based transaction pricing remains in place for principal orders, the concentration of principal order flow on exchanges that previously used tiered transaction pricing would be expected to increase since the absence of agency volume counting towards tier qualification could lead to a higher degree of concentration of principal flow that would be needed to qualify for pricing similar to what they realized prior to the proposed rule. As reported in Table 5 the members of exchanges with more price tiering are more likely to concentrate their order flow onto those exchanges as illustrated by higher average share of member trading volume and a greater proportion of members executing a plurality of their order flow on the exchange. This suggests that exchanges might adjust their pricing schedules to confer greater rewards to the execution of principal trading volume as a means of competing for principal trading flows. This effect would not be present if exchanges instead offered their best transaction pricing to all members equally.

The extent to which the different order flows become more or less dispersed under the proposed prohibition is uncertain as it depends on the changes of a multitude of other factors and their interactions which are infeasible for the Commission to reliably forecast. For instance, many exchange transaction pricing schedules would be likely to significantly change as a result of the proposed rule, which would likely affect broker-dealer routing decisions and could possibly increase principal trading.[241] In light of these difficulties, rather than providing a single point estimate, the following analysis will present expected effects on the exchanges that a variety of hypothetical changes in order flow concentration are likely to have.

Table 9 reports the expected trading volumes and market shares for the 16 exchanges under different changes in order flow concentration. The analysis uses the January 2023 on-exchange trading volume as a baseline. Implicit in the analysis is the assumption that the various exchange members execute the same trading volume on-exchange as they did in January 2023 baseline.[242]

TABLE 9—EXCHANGE POSITIONS GIVEN CHANGES IN ORDER-FLOW CONCENTRATION

The following table reports the total amount of executed orders (panel A) and the changes in executed orders (panel B), measured in number of shares, that were executed during regular trading hours across the 16 national stock exchanges under different scenarios using the total buy and sell executed order flow from all exchange members using a sample of CAT data for the month of Jan. 2023 from Table 4 as a baseline. Exchange members are identified as the set of unique CRD IDs in CAT which have directly routed orders to any of the national equities exchanges in the month. Exchange member CRDs are also verified in the CAT Industry Member Identifier List daily reference data. For each exchange the number of shares executed under the CAT allowable trade capacities of Agency, Principal, and Riskless Principal are reported. Trade capacity in CAT is defined by the exchange member for its side of a trade and represents the capacity in which the exchange member acted at trade time. Trades with the sale-condition codes–M—Market Center Official Close, –Q—Market Center Official Open, –V—Contingent Trade,–7—Qualified Contingent Trade (QCT), –8—Placeholder for 611 Exempt, and –9—Corrected Consolidated Close (per listing market) were excluded. ''Agency −100% Concentration'' corresponds to the scenario under which every exchange member sends an equal proportion of its agency-related order flow (orders of capacity code of agency or riskless principal) across all the exchanges they are a member of. ''Agency −20% Concentration'' corresponds to the case where the proportion of agency-related order flow executed by each exchange member is adjusted to be 20% closer to the equal proportion levels. ''Principal +20% Concentration'' corresponds to the case where the proportion principal order flow executed by each exchange member is adjusted to be 20% further from the equal proportion levels. ''Agency −20% Concentration & Principal +20% Concentration'' corresponds to the case where the proportion of principal order flow executed by each exchange member is adjusted to be 20% further from the equal proportion levels and the proportion of agency-related order flow executed by each exchange member is adjusted to be 20% closer to the equal proportion levels. *See* note 243 and the associated text for a detailed description of the calculations.

Panel A: Trading Volume and Market Share Levels. Below the total order flow, measured in number of shares, for each of the four scenarios and the baseline for each exchange is reported. The percentage share of total trading volume between each of the four scenarios and the baseline for each exchange are reported under the trading volume.

[241] *See supra* section IV.C.2.b.iii (discussing how the proposed rule is expected to increase the incentive to increase the concentration of principal order flow).

[242] *See supra* section IV.C.1.b.v (discussing how the proposed rule may increase the amount of trading which may migrate to off-exchange market centers).

Exchange	Baseline	Agency −100% concentration	Agency −20% concentration	Principal +20% concentration	Agency −20% & principal +20%
NYSE American	1,545,083,370 0.64%	9,014,311,364 3.74%	3,038,928,968 1.26%	925,779,162 0.38%	2,419,624,761 1.00%
NYSE Arca	39,311,251,528 16.30%	28,194,801,883 11.69%	37,087,961,599 15.38%	40,979,313,252 16.99%	38,756,023,323 16.07%
BX	1,712,065,584 0.71%	10,202,384,309 4.23%	3,410,129,329 1.41%	954,950,476 0.40%	2,653,014,221 1.10%
Cboe BYX	4,664,774,940 1.93%	10,767,820,881 4.47%	5,885,384,128 2.44%	3,996,852,852 1.66%	5,217,462,040 2.16%
Cboe BZX	19,855,374,396 8.23%	18,464,904,008 7.66%	19,577,280,318 8.12%	20,177,425,112 8.37%	19,899,331,035 8.25%
NYSE Chicago	432,565,797 0.18%	6,732,028,311 2.79%	1,692,458,299 0.70%	271,874,586 0.11%	1,531,767,089 0.64%
Cboe EDGA	5,800,545,730 2.41%	10,492,471,510 4.35%	6,738,930,886 2.79%	5,050,458,361 2.09%	5,988,843,517 2.48%
Cboe EDGX	26,669,251,824 11.06%	21,126,143,742 8.76%	25,560,630,207 10.60%	27,337,564,263 11.34%	26,228,942,646 10.88%
IEX	10,772,940,184 4.47%	12,475,034,616 5.17%	11,113,359,070 4.61%	10,073,270,498 4.18%	10,413,689,385 4.32%
LTSE	12,160,554 0.01%	6,380,358,525 2.65%	1,285,800,148 0.53%	10,749,491 0.00%	1,284,389,085 0.53%
MEMX	13,241,685,902 5.49%	14,925,744,644 6.19%	13,578,497,650 5.63%	12,975,451,264 5.38%	13,312,263,013 5.52%
Nasdaq	68,721,861,666 28.50%	36,597,959,759 15.18%	62,297,081,284 25.83%	71,138,284,292 29.50%	64,713,503,911 26.84%
NYSE National	2,317,954,540 0.96%	9,158,405,160 3.80%	3,686,044,664 1.53%	1,708,621,212 0.71%	3,076,711,336 1.28%
NYSE	39,387,052,205 16.33%	26,406,685,490 10.95%	36,790,978,862 15.26%	40,310,486,972 16.72%	37,714,413,629 15.64%
MAX Pearl	4,485,360,802 1.86%	9,986,884,064 4.14%	5,585,665,454 2.32%	3,863,443,029 1.60%	4,963,747,682 2.06%
Phlx (PSX)	2,220,543,164 0.92%	10,224,533,912 4.24%	3,821,341,313 1.58%	1,375,947,356 0.57%	2,976,745,506 1.23%

Panel B: Changes in Trading Volume and Market Share. Below the difference in total order flow, measured in number of shares, across each of the four scenarios and the baseline for each exchange is reported. Differences in the percentage share of total trading volume across each of the four scenarios and the baseline for each exchange are reported under the trading volume. The number of tiers for each exchange from Table 5 are also reported for each exchange.

NYSE American	10	7,469,227,994 3.10%	1,493,845,598 0.62%	−619,304,208 −0.26%	874,541,391 0.36%
NYSE Arca	72	−11,116,449,645 −4.61%	−2,223,289,929 −0.92%	1,668,061,724 0.69%	−555,228,205 −0.23%
BX	20	8,490,318,725 3.52%	1,698,063,745 0.70%	−757,115,108 −0.31%	940,948,637 0.39%
Cboe BYX	11	6,103,045,941 2.54%	1,220,609,188 0.51%	−667,922,088 −0.27%	552,687,100 0.23%
Cboe BZX	26	−1,390,470,388 −0.57%	−278,094,078 −0.11%	322,050,716 0.14%	43,956,639 0.02%
NYSE Chicago	0	6,299,462,514 2.61%	1,259,892,502 0.52%	−160,691,211 −0.07%	1,099,201,292 0.46%
Cboe EDGA	8	4,691,925,780 1.94%	938,385,156 0.38%	−750,087,369 −0.32%	188,297,787 0.07%
Cboe EDGX	19	−5,543,108,082 −2.30%	−1,108,621,617 −0.46%	668,312,439 0.28%	−440,309,178 −0.18%
IEX	0	1,702,094,432 0.70%	340,418,886 0.14%	−699,669,686 −0.29%	−359,250,799 −0.15%
LTSE	0	6,368,197,971 2.64%	1,273,639,594 0.52%	−1,411,063 −0.01%	1,272,228,531 0.52%
MEMX	13	1,684,058,742 0.70%	336,811,748 0.14%	−266,234,638 −0.11%	70,577,111 0.03%
Nasdaq	74	−32,123,901,907 −13.32%	−6,424,780,382 −2.67%	2,416,422,626 1.00%	−4,008,357,755 −1.66%
NYSE National	11	6,840,450,620 2.84%	1,368,090,124 0.57%	−609,333,328 −0.25%	758,756,796 0.32%
NYSE	93	−12,980,366,715 −5.38%	−2,596,073,343 −1.07%	923,434,767 0.39%	−1,672,638,576 −0.69%
MIAX Pearl	8	5,501,523,262 2.28%	1,100,304,652 0.46%	−621,917,773 −0.26%	478,386,880 0.20%
Phlx (PSX)	4	8,003,990,748 3.32%	1,600,798,149 0.66%	−844,595,808 −0.35%	756,202,342 0.31%

Changes in concentration are calculated by either increasing or decreasing the distance between the proportions of order flow individual broker-dealers allocate to the different exchanges and an even split. For a given percentage increase in concentration, the distance between the relative share of a broker-dealer's order flow sent to an exchange and 1/N, where N denotes the number of exchanges it is a member of, is increased by that percentage amount.[243] The effect of this is to increase a member's HHI measure by reducing the share of order flow sent to exchanges for which the exchange member allocated a smaller proportion of its original order flow and increase the share sent to those exchanges for which it was already allocating larger shares of its order flow. Similarly, a percentage decrease in concentration would manifest in a lower HHI value.[244] A 100% decrease in concentration corresponding to the case when an exchange member evenly splits its order flow and the member HHI is equal to the minimum achievable value.[245]

The first non-baseline column of Table 9 shows what the on-exchange market would look like if all exchange members evenly split their agency flow across the exchanges they are member of while not changing the distribution of principal order flow. This case serves as an upper limit of the potential effect of the proposed rule's effect on agency-related order flow concentration. The reason why this case reflects an upper bound is because while the Commission expects agency order flow concentration to decrease as a result of the proposed rule, it believes that it is highly unlikely that the resulting market landscape would result in individual broker-dealers evenly distributing their agency-related order flow.[246] The case of an even distribution of agency-related order flow across exchanges would result in a more fragmented market with the overall pro-rata HHI falling from 0.16 to 0.08.[247]

Aside from the upper bound case of an even distribution of agency flow, a case where there would be a 20% reduction in agency flow concentration, a case where there would be a 20% increase in principal flow concentration, and a case with the combination of the two are also reported Table 9. While the case of a 100% reduction in agency-related flow concentration serves as an upper bound of the potential effects on order flow, other scenarios serve as an exercise in comparative statistics to illustrate the effects of more modest changes in concentration. For the cases of a 20% decrease in concentration of agency-related order flow and a 20% increase in principal order flow concentration, the overall pro-rata HHI would be 0.14 and 0.17, respectively. For the combined case of both a 20% decrease in agency-related flow concentration and 20% increase in principal flow concentration the resulting pro-rata HHI would be 0.15. Compared to the January 2023 HHI of 0.16, these changes suggest that the distribution of trading volume across the market is slightly more sensitive to decreases in agency-related order flow concentration than to similar increases in principal order flow concentration. As a result, a reasonable expectation for the likely effect of the proposed rule would be to result in a marginally more even distribution of market share across stock exchanges, which may be representative of a more competitive market.[248]

c. Tying Closing Auction Fees to Consolidated Volume

As discussed in section IV.B.1.c, tying closing auction fees to broker-dealers' overall volume helps the primary listing exchanges extend their market power and softens inter-exchange competition. For listing companies and index funds with strong interests in closing auctions, the current pricing structure heightens their incentive to divert order flow to the primary exchanges in order to qualify for lower fees during the closing auctions. The proposal would prohibit exchanges from offering volume-based pricing in connection with the execution of agency-related order flow in NMS stocks. The proposal would thus prohibit exchanges from offering transaction pricing on any orders if that pricing is determined, in part, by the execution of agency-related trading volume. Accordingly, the proposal would prohibit exchanges from tying transaction pricing on orders executed during closing or opening auctions to a member's agency-related trading volume in NMS stocks during regular trading hours. Limiting the listing exchanges' ability to tie prices for the closing auctions to intraday agency-related trading volume may benefit smaller exchanges without listing capabilities.

A more level playing field for intraday trading across exchanges will likely benefit broker-dealers for two reasons. First, the absence of tying that protects the primary listing exchanges may result in more intense competition for order flow across exchanges during the regular hours. This may in turn result in lower transaction fees/more generous terms for broker-dealers for order executed. Second, the primary exchanges' closing auction pricing structure tends to partially foreclose broker-dealers' order flow that may have otherwise gone to whichever exchange offering the best execution quality or more generous rebates. Broker-dealers' welfare may be higher under ''unbundling'', if changes in choice sets result in broker-dealers choosing superior products.

3. Capital Formation

The Commission believes the proposed rules would have a modest impact on capital formation. The proposed rules may lower transaction costs for investors through their effect on exchange transaction pricing schedules,[249] broker-dealer competition,[250] and the broker-dealer conflict of interest.[251] However, the net effect is difficult to determine. For example, some broker-dealers' transaction costs may increase,[252] which could then increase the transaction costs of investors to the extent these increases are passed through to them.

To the extent the proposed rules reduce transaction costs, they would increase the efficiency of trading, which may lead to better capital allocation.

[243] Suppose that a broker-dealer allocates, for each exchange *i*, a share s_i such that the sum of s_i's across exchanges indexed by *i* (''sum of shares'') equals one. Given a percentage change *p* in concentration, the broker-dealer shares are transformed to an updated $s_i^* = \max[s_i + p(s_i - 1/N), 0]$, where *N* denotes the count of exchanges over which the broker-dealer allocates order flow. When $p > 0$, member HHI increases, since the sum of the updated $(s_i^*)^2$'s is greater than the sum of the $(s_i)^2$'s. In cases where $s_i + p(s_i - 1/N) < 0$, the updated sum of shares would be greater than 1. In these cases the new shares are recalculated as the ratio of s_i^* to the updated sum of shares, in order to ensure that the shares sum to one; whenever this occurs the number of exchanges receiving non-zero order flow decreases.

[244] To illustrate, if a broker-dealer distributed their order flow 70%/30% across two exchanges a 50% increase in concentration would result in a 80%/20% split (0.8 = 0.7 + *p*(0.7–0.5), and 0.2 = 0.3+*p*(0.3–0.5) for *p = 50%*). A 50% decrease in concentration would result in a 60%/40% split (0.6 = 0.7—*p*(0.7–0.5), and 0.4 = 0.3 − *p*(0.3–0.5) fir *p = 50%*).

[245] This is the case when $p = -1$, and $s_i = (1/N)$ for each exchange *i*.

[246] *See* section IV.B.2 (discussing non-tier factors that may influence order routing decisions).

[247] Overall pro-rata HHI is calculated as the sum of squared market shares reported in Table 6.

[248] It is important to note that the basis for the statement relies on the assumption that agency-related order flow concentration would decrease at least as much as principal order flow concentration increases. More importantly the analysis assumes that exchange membership and exchange pricing schedules do not change (outside of the prohibition of applying volume-based pricing on agency or riskless principal order flow).

[249] *See supra* section IV.C.1.a.ii.

[250] *See supra* section IV.C.2.a.i.

[251] *See supra* section IV.C.2.a.iii.

[252] *See supra* section IV.C.2.b.ii.

E. Reasonable Alternatives

1. Ban Volume-Based Pricing for All Orders

As an alternative to the proposed prohibition of volume-based transaction pricing for agency-related orders in NMS stocks, the Commission might instead prohibit exchanges from offering volume-based transaction pricing for all volume in NMS stocks.

The Commission believes that much of the baseline regarding the effects of volume-based transaction pricing on agency-related volume is relevant to principal-based volume. One difference in the baseline for principal order flow from proprietary trading is that such order flow does not have the potential for a conflict of interest between members and customers with respect to routing. Because the member trades for its own account when routing in a principal capacity, only its own interests are at stake in the routing decisions. Currently, the transaction fees that a member pays and the rebates that it receives apply to both the member's agency-related volume and its proprietary volume, as exchanges generally do not distinguish their pricing tiers for orders solely on the basis of whether the order was filled in a principal or agency capacity. However, some tiers, such as those reserved for registered market makers, effectively only apply to principal orders. In addition, the incentives, in the form of lower transaction pricing, that volume-based exchange transaction pricing create to attract members to route their orders to particular exchanges also apply to principal orders in the same way that they do for agency-related orders.[253] Further, the potential for burdens on competition between members associated with volume-based exchange transaction pricing exist for proprietary volume in a similar manner as for agency-related volume. Even though unlike for agency-related volume there are no third-party customers involved in or directly impacted by exchange transaction pricing for principal orders, volume-based pricing tiers still present issues related to competition by granting those exchange members with a high degree of principal trading a competitive advantage in attracting customer order flow.[254]

High-volume exchange members' current tiered pricing advantage also helps them attract customer order flow from non-members and other members. The same pricing advantage applies to members engaged in both agency and principal trading because a member's combined agency-related and principal activity is counted towards its total volume to qualify it for higher tiers, which benefits the member when competing for customers in the market to provide exchange access to others. To the extent that broker-dealers engage in principal bidding to fill customer orders,[255] principal trading may still be related to the market to provide exchange access to investors, albeit in an indirect manner. In this case, the barriers to entry in the brokerage business, including the contribution of volume-based transaction pricing, would continue to apply to principal-based trading.

Whether or not exchange members compete for customer orders or primarily trade in a principal capacity, they face the same fixed costs described in section IV.B.4 for data, hardware, connectivity including co-location services, and other inputs. While these fixed costs may create a substantial barrier-to-entry, volume-based discounts that lower variable costs for trades may increase trading activities and variable profits for the high-volume members. Higher variable profits for high-volume members help to offset the fixed costs of trading. Hence volume-based transaction pricing that lowers trading costs for higher volume exchange members may amplify the market shares of those higher volume exchange members. Unlike the proposal which is more likely to adversely affect exchange members with a high volume of agency-related order flow, a ban on volume-based pricing for all orders may also affect exchange members with a high volume of principal order flow.[256] Prohibiting volume-based pricing for principal order flow could lead to a more level competitive environment between exchange members which primarily trade in a principal capacity, including amongst market makers, as differences in fees paid and rebates collected may meaningfully affect the competitive position of the higher volume firms which qualify for more preferential pricing tiers.[257] Moreover, conditional on the extent to which volume-based pricing increases trading volumes, the prohibition of volume-based pricing under this alternative may decrease the investment in faster connectivity and technological prowess (*e.g.,* trading algorithms) that contribute to the competitive edge of principal traders by lowering the value of such investments.

A full ban on volume-based transaction pricing would result in a number of differences in benefits and costs.

Under a full ban on volume-based transaction pricing, there would be no need, and therefore no requirement, for disclosures regarding the number of exchange members qualifying for volume-based tiers, as there would be no volume-based tiers left. Therefore, under this alternative there would be no need for the disclosures required under proposed Rule 6b–1(c) nor would the anti-evasion provision in proposed Rule 6b–1(b) be needed because members would not be able to evade a broad prohibition through activity such as mismarking orders to qualify for tiered pricing because volume-based tiered transaction pricing would no longer be permitted. As described in sections IV.B.1 and IV.B.5 volume-based pricing tiers contribute to a highly complex trading environment and by banning volume-based pricing for all orders, this alternative may result in simpler markets. Volume-based pricing tiers allow for significant variation across exchanges in the volume-based tiers offered to principal orders, and a prohibition of volume-based price tiering would greatly limit the degree of variation in pricing schedules across exchanges. This lack of variation would make the various trading venues look more similar in terms of the fees charged facilitating the comparison of transaction pricing across exchanges and could lead trading to increasingly congregate on a smaller number of exchanges, those with the highest rebates and lowest fees. Relative to this alternative, the proposal would still allow for a greater variation between exchange pricing schedules since it would continue to allow the application of volume-based pricing tiers to principal order flow. On the other hand, contrary to the proposal, this alternative would be simpler for exchanges to

[253] *See* section IV.B.3 for a discussion of the additional incentives introduced by volume-based pricing tiers to order routing decisions.

[254] Exchange members compete for the agency-related order flow of non-exchange member customers. Volume-based pricing tiers present a network effect, or positive feed-back loop, in that exchange members with large amount of trading volume find it easier to qualify for higher volume tiers which in turn allows them to attract more customer volume by offering more attractive terms than lower volume competitors.

[255] For example, a broker, instead of working a sell order as an agent for the customer, might just offer the customer a price to buy the shares outright from the customer.

[256] *See* section IV.C.1.b.i for a discussion of how the proposed rule could adversely affect exchange members with a high volume of agency-related order flow.

[257] *See* Letter from John Ramsay, Chief Market Policy Officer, Investors Exchange LLC to Vanessa Countryman, Secretary, Commission (Sept. 20, 2023) (''IEX Letter'') (comment letter on File No. S7–30–22), available at *https://www.sec.gov/comments/s7-30-22/s73022-262059-619382.pdf.*

implement than a ban on only tiered transaction pricing for agency-related volume in at least one sense: exchanges would not have to ascertain order capacity codes to separate agency-related orders from proprietary orders when computing member transaction invoices.

The Commission believes that the benefits to lower-volume exchange members described in section IV.C.1.a.i could be increased and extended. In that section, the Commission describes how, consistent with the relevant economic literature, exchanges could set new prices that are between the current lowest and highest prices offered for transactions, benefiting those broker-dealers that currently pay the highest prices. To the extent that these broker-dealers have principal order flow, the change in transaction pricing would apply to that order flow as well, further reducing these broker-dealers' transaction costs.

Similarly, the costs to broker-dealers that currently qualify for the highest tiers, described in section IV.C.1.b.ii would be increased and extended. Banning volume-based exchange transaction tiers would likely impose costs on high-volume exchange members in the form of lower rebates/higher transaction fees. The expanded ban may also contribute to a loss in the competitive advantage of the high-volume members in competing for customers, particularly if the member would have otherwise leveraged discounts on principal volume to attract customers and qualify for higher volume tiers. The number of broker-dealers affected would be greater under this alternative relative to the proposal.[258] If exchanges set transaction fees and rebates for all orders that are between those offered at the highest and lowest volume tiers then exchange members, including those which primarily trade with principal orders would be affected. If exchanges respond to the full ban by offering a new price schedule in which rebates of the lowest tier are increased or transaction fees are decreased, those broker-dealers whose principal-related volume would have continued to qualify for discounts would be subject to higher trading costs for this principal volume.

A broad ban on the application of volume-based transaction pricing might also reduce excessive intermediation, *i.e.,* excessive quoting from high-frequency traders looking to earn rebates, which may be exacerbated through the offer of large rebates, particularly amongst higher volume exchange members.[259]

A broad ban would fully prohibit volume-based discounts in the closing auctions, where the tiers are based on a member's overall trading volume, which may benefit both high- and low-volume exchange members if this unbundling results in a more level playing field for intraday trading. As a consequence of unbundling, broker-dealers may be less constrained by the incentive to direct intraday order flow to a primary listing exchange so as to qualify for higher discounts for their principal order flow during the closing auctions. Instead, the broker-dealer may place greater weight on execution quality or rebates received, to the ultimate benefit of the broker-dealer and the customer. Unbundling that weakens primary listing exchanges' market power over intraday trading may also lead to lower average transaction fees for intraday trading, further benefitting broker-dealers.

Banning volume-based transaction fees for both principal and agency-related order flow may expand the range of profitable opportunities for new and smaller exchanges while limiting persistent concentration across the largest exchanges. A ban on volume-based transaction pricing is likely to reduce the degree to which exchange members concentrate their order flow on exchanges by removing the incentive to concentrate order flow caused by volume-based pricing which is discussed in section IV.B.3. As also discussed in section IV.B.3 it is likely the case that principal order flow is more responsive to changes in transaction pricing and so extending the prohibition of volume-based pricing to principal order flow would likely result in less order flow concentration. Compared to the volume-based transaction pricing ban for agency-related volume under the proposal, a full ban on volume-based transaction pricing may result in greater dispersion of order flow across the exchanges, potentially leveling the playing field among larger and smaller exchanges in this regard, since a full ban would also remove the incentive to concentrate principal order flow on exchanges offering volume tiers.[260] Unlike the proposal, eliminating volume-based pricing for all orders would reduce the incentive to concentrate order flow for all orders rather than potentially increase the concentration of principal order flow as a means of offsetting the effects of prohibiting volume-based pricing for agency-related order flow.[261]

Banning the tying of volume-based tiering in the closing auctions for both agency-related and principal order flow may further contribute to a dispersion of order flow across exchanges, to the benefit of the less dominant exchanges. Tying execution costs in the closing auction to the firm's overall trading volume on the same platform can alter the level of competition for intraday trading across exchanges.[262] It provides a way for primary listing exchanges, which facilitate closing auctions with large-scale liquidity, to extend their market power to intraday trading. Prohibiting tiers for both agency-related and principal order flow in the closing auctions may further contribute to a shift in order flow towards non-listing exchanges.

A ban on both principal and agency-related flow would constrain the exchanges' ability to adjust their pricing schedules for principal flow in a way that preserves their existing competitive advantages. Shutting down volume-based tiers for both agency-related and principal order flow would limit the potential for exchanges to employ strategic behavior under a ban on only agency-related order flow, since this behavior may otherwise serve to preserve the competitive advantage of the largest exchanges.[263] For example, to counter the potential loss of agency volume, the higher-volume exchanges may re-adjust their pricing schedules for principal order flow. For instance, deeper discounts for increases in principal order flow may serve to both (1) further incentivize the submission of inframarginal principal limit orders and (2) constrain the newer, smaller

[258] Exchange members which currently qualify for the best volume-based pricing tiers may be worse off whilst those which fail to do so may be better off.

[259] Excessive intermediation here refers to excessive quoting in sufficiently liquid securities in order to earn rebates, which crowds out investors from being able to supply liquidity. Large rebates can increase quoting activity from high-frequency traders looking to earn rebates. Because rebates are paid when a quote is hit by a marketable order, obtaining high priority in the queue at each tick is essential to such strategies. High-frequency, proprietary traders are generally better able to obtain such priority, and consequently investors may have less opportunity to profitably fill their trades using limit orders.

[260] Broker-dealers seeking to execute a proprietary order may choose to route it to an exchange for the purpose of increasing the likelihood of qualifying for a volume tier even if, absent tier considerations, they would choose to route to another exchange. Extending the prohibition of volume-based pricing to principal orders would remove this effect and could result in a greater dispersion in order flow over exchanges, which might increase the competitiveness of less dominant exchanges. *See* section IV.C.1.a.iii for a discussion of how increased order flow dispersion might benefit lower-volume exchanges.

[261] *See* section IV.D.2.b.

[262] *See* section IV.D.2.c.

[263] *See* section IV.D.1 for discussion of how exchanges may adjust their price schedules.

exchanges' ability to effectively compete with the dominant exchanges. The dominant exchanges' ability to consolidate principal flow increases the attractiveness of their exchange services, which in turn helps the exchanges better attract agency order flow. Exchanges may adapt to the proposal in a way that not only preserves their dominance over the smaller exchanges but also confers even more favorable rebates for top-tiered principal order flow. As previously noted, aside from high-frequency trading firms and market-makers, exchange members with the largest principal order flow also tend to be high-volume players in terms of their agency order flow. Consequently, increased discounts for principal trading activities may potentially offset some of their profit loss from higher transaction fees on agency order flow. The possibility of cross-subsidization where transaction fees on agency-related trading are used to subsidize better pricing for principal trading activities, along with the possibility that broker-dealers may effectively transform agency trades into principal trades if they switch from an agency model to a principal model, means that the high-volume broker-dealers' competitive advantage may persist even under a ban on pricing tiers for agency flow.

A by-product of the full ban on volume-based transaction pricing would be to dampen the possibility that broker-dealers transition to an inventory-holding model, thereby reducing systemic risk associated with holding inventory.[264] A full volume-based ban may not only lessen the high-volume broker-dealers' tier advantages from principal trading but also limit the increase in inventory risk across these players that shift towards greater reliance on principal trading.

To the extent that volume-based transaction pricing helps exchanges better retain order flow, a ban on both agency-related and principal order flow may increase cost to exchanges in the form of forgone revenue and the cost to broker-dealers in the form of forgone surplus. Section IV.E.1 discusses how volume-based pricing, viewed as a price discrimination mechanism or in a mechanism-design (screening) context, can be an effective way for exchanges to extract increasing levels of order flow and expand total surplus. Some of the forgone order flow loss under a full ban would be order flow streamed to off-exchange venues, as volume-based transaction pricing may help exchanges compete with off-exchange venues.[265] The additional loss of such order flow would increase the costs of the rule for those exchanges, but this change in order flow would be a benefit to the off-exchange venues that receive it instead.

2. Ban Volume-Based Pricing for All Orders Except Registered Market Makers

As an alternative to the proposed prohibition of volume-based transaction pricing for agency-related orders in NMS stocks, the Commission might instead prohibit exchanges from offering volume-based transaction pricing for all volume in NMS stocks, but subject to a carve-out only for displayed liquidity providing orders from exchange registered market makers in their registered or appointed symbols where the registered market maker is subject to minimum continuous quotation and minimum quote width standards that meet or exceed the highest such standards in place among national securities exchanges.[266]

In the current trading environment, many stock exchanges also offer separate volume-based rebates to their registered market makers as a means of incentivizing additional liquidity provision in the form of displayed quotations. For example, one exchange has rebate tiers for its market makers with qualification based on the percent of time the registered market maker quotes at the NBBO and the average size of those quotes in addition to the volume of liquidity provided.[267] Similar to the volume-based pricing tiers offered to non-market-maker exchange members these volume-based market maker pricing tiers are designed to attract the order flow of high-volume market makers who contribute significantly to the overall liquidity on the exchange.[268] As described in section IV.B.1.a, exchanges compete to attract competitively priced liquidity and they do so, in part, by offering variable pricing terms to their registered market makers which award them with better rebates/fees.

This alternative would allow exchanges to incentivize their registered market makers, through transaction pricing incentives, to maintain displayed quotations. It would not permit volume-based exchange transaction pricing incentives for non-displayed quoting activity, including non-displayed orders, orders not in the market maker's assigned or registered symbols (which would not be subject to the quantitative and qualitative market making standards under an exchange's rules). It also would not allow exchanges to determine volume-based transaction fees based on total orders or customer orders. Rather, the carve-out would allow volume-based transaction pricing only for the types of orders specified above.

Allowing exchanges to incentivize displayed quotations from their registered market makers allows exchanges to continue to reward members for becoming, and remaining, registered market makers and for posting displayed quotations that are visible to and accessible by all market participants. Those displayed quotations provide an important and central public source of price transparency that can directly benefit investors, as displayed quotations are used for many purposes including informing trading decisions, establishing security valuations, and performing index calculations. Allowing exchanges to continue to offer transaction pricing incentives to encourage public displayed quotes, where those quotes are subject to quantitative and qualitative standards contained in exchange rules, could benefit the public interest.

Because this alternative would involve a prohibition on volume-based exchange transaction pricing for all NMS stocks, the discussion and analysis above about extending the prohibition to also include proprietary volume, including the baseline, the costs and benefits, and the effects, applies equally to this alternative and is hereby incorporated by reference. This ban might also reduce excessive intermediation, *i.e.,* excessive quoting from high-frequency traders looking to earn rebates, which may be exacerbated through the offer of large rebates, particularly amongst higher volume exchange members, though not from registered market makers.

A prohibition on volume-based exchange transaction pricing for both agency-related and principal order flow that carves out displayed liquidity adding orders submitted by exchange

[264] For a discussion concerning the incentive broker-dealers may have to carry larger inventory position with which to internalize customer orders see section IV.C.1.b.iv.

[265] *Id.*

[266] *See, e.g.,* NYSE Rule 104 (for an example of a rule that concerns quotation requirements). Such exchange rules would typically impose, for example, maximum quotation widths (*i.e.,* the spread between the bid to buy and the offer to sell) as well as time at the inside requirements (*i.e.,* time where the market maker must be quoting at least as good as the national best bid and offer).

[267] *See* NYSE pricing schedule, available at *https://www.nyse.com/publicdocs/nyse/markets/nyse/NYSE_Price_List.pdf.*

[268] For additional discussion regarding the incentives introduced by volume-based pricing tiers *see* section IV.B.3.

registered market makers in their registered or assigned symbols, where the registered market maker is subject to minimum continuous quotation and minimum quote width standards that meet or exceed the highest such standards in place among national securities exchanges, would result in a number of differences in benefits and costs compared to the proposal. Those differences are identical to the differences discussed above for the alternative involving a prohibition on volume-based exchange transaction fees for both agency-related and principal order flow without a carve out, except where otherwise discussed directly below.

Under a ban on volume-based exchange transaction pricing with a registered market maker displayed quote carve out, there would be less need for disclosures regarding the number of exchange members qualifying for volume-based tiers, as fewer members would be eligible for volume-based tiers and it would only apply to displayed quotes. This alternative could be implemented with a transparency measure for those tiers eligible for the displayed quote carve-out, or with no additional disclosures. We request comment on these different possibilities below. While this alternative would allow some volume-based exchange transaction pricing for displayed quoting activity of exchange registered market makers, that is only a subset of principal trading. Under this alternative, volume-based exchange transaction pricing would not be available for liquidity removing orders, non-displayed orders, or orders not in one of the registered market maker's assigned or registered symbols because those are not liquidity-adding quotations for which the registered market maker is subject to the exchanges' quotation requirements. The significantly narrowed scope of what would be subject to the disclosures under Rule 6b–1(c), and the limited subset of members and trading activity to which they would apply, could significantly limit the usefulness of the disclosures to a point where the benefits may not justify the costs. Accordingly, this alternative would not require the proposed transparency disclosures.

Under this alternative, there would be no anti-evasion provision because members would not be able to evade a broad prohibition through activity such as mismarking orders to qualify for tiered pricing because volume-based tiered transaction pricing would no longer be permitted except for orders that exchanges closely track because exchanges need to identify, monitor, and count that activity for compliance with the applicable exchange market making requirements, including quantitative quotation standards. Thus, the same activity that counts towards the registered market maker's quotation would be eligible for tiered pricing under the carve out.

For the same reason, under this alternative, exchanges would not be required to have policies and procedures reasonably designed to detect and deter members from engaging in practices that evade the prohibition because the only type of activity that would be eligible for tiered pricing would be the specially designated activity that counts towards the market maker's displayed quotation requirement.

The Commission does not expect that there would be a substantial increase in the number of exchange registered market makers under this alternative even though the continued allowance of volume-based transaction pricing for exchange registered market makers could make becoming one attractive. The requirements and obligations associated with being a registered market maker likely make the prospect of becoming a registered market maker for the purpose of receiving volume-based pricing on liquidity providing orders not economically viable.[269] Further, because the activity that would be subject to the carve-out would be subject to those exchange market making requirement rules, any attempt to evade the prohibition would result in members engaging in trading activity that would become subject to those market making quoting requirements. Accordingly, an anti-evasion provision would not serve a comparable purpose and would not be necessary with a broad ban that has a limited carve-out for registered market makers.

Similar to the alternative discussed in section IV.E.1 featuring a prohibition on volume-based exchange transaction pricing for both agency-related and principal order flow, this alternative may result in less market fragmentation and simplify markets and that discussion applies equally to this alternative.

As exchanges would continue to be able to offer volume-based transaction pricing to market makers in their registered or appointed symbols where the registered market maker is subject to qualitative and quantitative quotation standards that meet or exceed the highest such standards in place among national securities exchanges, exchanges would be incentivized to adopt more rigorous quantitative and qualitative market making requirements. Consequently, competition could increase for the provision of displayed quotes, which should promote price discovery and liquidity provision to the benefit of investors and the public interest.

For a ban with a limited carve-out for registered market maker quoting, exchanges should readily be able to ascertain the applicable market-making activity because it is subject to existing quantitative exchange quoting requirements. Exchanges would not need to ascertain the capacity of other interest because those would be subject to the broader prohibition. Accordingly, a prohibition with a limited carve-out for registered market makers should also be simpler for exchanges to implement than a prohibition on tiered transaction pricing for agency-related volume.

As discussed in the alternative for a prohibition on volume-based exchange transaction pricing for both agency-related and principal order flow, the prohibition with a limited carve out for registered market makers could also provide benefits to lower-volume exchange members that currently pay the highest prices if exchanges respond by offering lower fees and higher rebates for non-market making order flow. In turn, that could reduce these members' transaction costs. However, members that receive the highest rebates and pay the lowest fees may see their transaction costs increase if exchanges reduce those incentives when they discontinue offering volume-based transaction pricing. A ban with a limited carve-out for registered market makers could preserve some, or all, of the incentivized fee and rebate levels that a registered market maker currently receives.

A ban with a limited carve-out for registered market makers also would prohibit volume-based discounts for both agency-related and principal order flow in the closing auctions except for the registered market maker limited carve out. Similar to the first alternative, members who are not market makers may be less constrained to direct intraday order flow to a primary listing exchange so as to qualify for higher discounts during the closing auctions. Instead, the member may place greater weight on execution quality or rebates received for just intraday order flow, to the ultimate benefit of the broker-dealer and the customer. Unbundling that weakens primary listing exchanges'

[269] In particular, being a market maker involves regulatory, technology and operational burdens such as having algorithmic trading strategies and servers in order to meet the quoting requirements, and other affirmative obligations of a registered market maker, while doing the fewest possible unwanted trades.

market power over intraday trading may also lead to lower average transaction fees for intraday trading, further benefitting broker-dealers that are not market makers.

The distortions in intraday routing decisions faced by principal traders, as mentioned in section IV.B.3, do not apply in the same manner to registered market makers, for whom market making requirements can provide incentives to concentrate order flow on particular exchanges.

Because registered market maker quoting currently involves passive displayed liquidity provision, registered market makers cannot direct flow to an exchange intraday in the same manner that a non-market making member can, though they can increase their quoting activity in the expectation that they would receive more executions. Some types of exchange registered market makers face more significant quoting obligations and trading volume requirements than other types of exchange registered market makers. To meet stringent obligations, those types of market makers might be more reluctant to reroute orders to exchanges for which they are not designated market makers. Compared to non-market making broker-dealers, tying discounts in the closing auction on intraday volume might not have as large an effect at reducing market makers' surplus. While a full ban could result in greater dispersion in trading activities across exchanges and a loss of order flow to off-exchange venues, a limited carve-out for registered market makers could induce these members to concentrate more quoting activities on certain exchanges. Under this alternative, new and lower-volume exchanges could offer incentives to attract registered market maker members and could combine that with higher market making standards. The adjustments in market makers' obligations and benefits might result in the exchange more frequently setting the best prices and having more available liquidity, which would attract liquidity-removing order flow and increase the exchange's market share.

Under the ban with a limited carve-out for registered market makers, competitive advantages for high-volume broker-dealers might still exist, but the advantage would be largely limited to registered market makers. Unlike ordinary principal trading that only involves the proprietary trading member, displayed liquidity providing orders from exchange registered market makers in their registered or appointed symbols benefits investors and markets by contributing to price formation and liquidity provision. Accordingly, a limited carve-out for registered market makers could allow exchanges to continue to incentivize their members to become and remain registered market makers and quote and thereby confer a broader benefit to the market generally compared to an incentive on non-market-making principal trading.

To the extent that volume-based transaction pricing helps exchanges better retain order flow, a prohibition on volume-based exchange transaction fees for both agency-related and principal order flow with a limited carve out for registered market makers may, as is the case for the first alternative, increase costs to dominant exchanges in the form of forgone revenue and the cost to high-volume members in the form of forgone surplus. A ban with a limited carve-out for registered market makers would mitigate these increased costs by allowing exchanges to offer volume-based pricing to their registered market makers on their displayed liquidity-adding volume in their registered or assigned symbols where applicable market making standards apply, thus potentially retaining some of that transaction volume.

3. Proceed With Transparency Provisions for All Orders Without Tiers Prohibition

The proposal would prohibit volume-based transaction pricing for agency-related flow and would mandate transparency for principal-flow. Alternatives 1 and 2 would broaden the volume-based transaction pricing prohibition, making transparency irrelevant for Alternative 1, though possibly relevant for Alternative 2. Alternatively, the Commission could opt not to prohibit volume-based tiers for either agency or principal-related volume in NMS stocks, but rather expand the disclosures under proposed Rule 6b–1(c) to all orders.[270] Specifically, under this alternative, the Commission would require exchanges to disclose periodically certain information if they offer volume-based transaction pricing for any NMS stocks, for both principal and agency-related orders.[271]

Expanding the disclosure under proposed Rule 6b–1(c) to all volume in NMS stocks, the added transparency would have benefits similar to those of Rule 6b–1(c) described in the proposal.[272] It would allow interested persons greater access to information about the eligibility of each exchange's members for its volume-based transaction pricing tiers. It would improve the information set for those commenting during the SRO filing process. These comments, in turn, might assist the Commission in determining whether a filing is consistent with the Exchange Act. As the impact of their transaction pricing schedules would become evident to other members and the commenting public, greater transparency could perhaps place pressure on exchanges to adopt less ''bespoke'' volume-based transaction pricing.[273] It is possible that the appearance of a pricing scheme which appears to disproportionately favor a small number of exchange members might make an exchange more likely to voluntarily adopt price schedules with a more even distribution of tier qualification.

One issue that is unlikely to be addressed by transparency alone would be the self-reinforcing competitive advantage for high-volume exchange members, including high-volume firms that trade in a principal capacity. Among lower-volume broker-dealers, those who route some or all of their orders through higher-volume exchange members serve to reinforce the competitive advantage of high-volume exchange members. Compared to Alternatives 1 and 2, transparency alone might not help level the playing field between exchanges that employ volume-based tiers and those that do not.[274] In

[270] The SEC Investor Advisory Committee previously recommended that the Commission enhance disclosures to provide transparency about rebate tier practices at exchanges. Specifically, it recommended that the Commission receive monthly disclosures from exchanges concerning the volume of trades that receive a rebate and the rebate amounts broken down by volume ranges. In addition, it recommended public disclosure on an aggregated basis of rebate information broken down by tiers. *See* Recommendation of the SEC Investor Advisory Committee Regarding Exchange Rebate Tier Disclosure (Jan. 24, 2020), available at *https://www.sec.gov/spotlight/investor-advisory-committee-2012/exchange-rebate-tier-disclosure.pdf. See also supra* Request for Comment No. 24 (requesting comment on additional items for the monthly transparency disclosures, including the volume of shares qualifying for each tier, the dollar amounts involved, and the average transaction fee paid and rebate received by members).

[271] The Commission also could expand the disclosures to all NMS securities, which would include listed options in addition to NMS stocks.

[272] *See supra* section IV.C.3.a.

[273] *See supra* section IV.C.3.b.ii for additional discussion of the possible effect that the proposed disclosures may have on exchange pricing.

[274] As discussed in sections IV.B.1.b and IV.B.2, it would be more difficult for exchanges that do not employ volume-based pricing to effectively compete against those that do, since without volume-based pricing exchange members would not be incentivized to concentrate their order flow on those exchanges. Additionally, lower volume exchanges that are newer also face competitive hurdles because it would be more costly for them to offer higher tier rebates similar to the higher

Continued

addition, the transparency-only alternative might not address the incentive for members of more than one exchange to concentrate their trading, particularly agency-related orders, on one particular exchange in order to qualify for that exchange's volume-based tiers, so as to achieve lower fees and higher rebates. Likewise, this alternative would be unlikely to address the related conflict of interest between members and customers that can arise when the member executes an agency-related order (*i.e.,* the incentive for a member to route the order to one particular exchange over others and retain the benefit for itself, assuming it does not pass through that better exchange transaction pricing to its customer). Finally, this alternative is unlikely to address the incentive for a listing exchange to exploit demand for participating in the closing auction by offering discounts on auction orders to members who send volume, particularly agency-related volume, into the intraday trading session—a practice that may contribute to listing exchanges preserving or extending their market power at the expense of non-listing exchanges and potentially exchange members. However, compared to the proposal, this alternative would not lead to an advantage of principal brokerage models over agency ones. We request comment below on the relative benefits of the proposed ban versus transparency and mechanisms through which transparency would address the problems identified in the proposal.

4. Banning the Linking of Volume-Based Tiers for Closing Auctions to Consolidated Volume

The Commission might ban conditioning closing auctions' transaction fees on consolidated volume. Under this alternative, current volume-based discounts for trading during regular hours would continue, but execution costs for the closing auction would no longer be based on a member's continuous order book volume. Offering discounts for closing auction pricing linked to overall volume is a practice known as ''auction linked pricing.''

This ban would likely alter the level of inter-exchange competition, diverting more intraday order flow to small, non-listing exchanges. Conditional pricing, or qualifications for price discounts on one product depending on the purchase levels of other products, has been shown to harm competition when firm(s) with market power are able to foreclose rival(s) from a portion of the market or drive rivals out of the market entirely.[275] Similar intuition may apply to an exchange context under the current baseline, where price discounts for participation in the closing auctions are conditioned on consolidated volume. Because conditional pricing for closing auctions provides incentive for broker-dealers to stream intraday volume to the same listing exchanges, tying provides a way for listing exchanges with market power over their closing auctions to partially expand their dominance to intraday trading. A ban on conditional pricing may provide a more level playing field for inter-exchange competition and result in lower transaction fees for the average broker-dealer participating during regular trading hours.

The ban would likely benefit small, non-listing exchanges at the cost of primary listing exchanges. Tying provides a way for listing exchanges to soften competition and potentially charge higher transaction fees for trading during regular hours, compared to a regime where exchanges compete for order flow for the ''standalone'' market for intraday trading. Un-tying execution cost in the closing auction to total volume reduces a broker-dealer's incentive to route to a primary listing exchange during regular hours, in anticipation of participating in the closing auction on the same platform. Unbundling the auction and continuous order book trading decisions could increase non-listing exchanges' profits at the expense of the listing exchanges' profits.

Prohibiting tying auction fees to broker-dealers' overall volume may alter consumers' choices in a way that leads to improvement of broker-dealers' welfare. To qualify for lower fees during closing auctions, broker-dealers may make intraday order routing decisions that are suboptimal. Unbundling the closing auction trading decisions and order routing choices during regular hours may ultimately be in the broker-dealers' best interests, especially in combination with the fact that competition across exchanges may lower average transaction fees during regular trading hours.

Removing the conditioning of closing auction tiers on consolidated volume removes an additional pricing advantage for high-volume broker-dealers, who may already be trading at dramatically reduced prices because of their tier qualifications from intraday trading. Tiers applied to trading volume from broker-dealers' continuous order book confers an outsized pricing advantage to the high-volume broker-dealers. One concern is that the interaction of the high-volume broker-dealers' tiered pricing advantage and high fixed market data and connectivity costs creates significant disadvantage for lower-volume firms.[276] Pricing tiers for the closing auctions may accentuate the barrier-to-entry for lower-volume firms, in an industry that has seen no salient growth of nascent firms in recent years. Prohibiting volume-based pricing for the closing auctions removes one potential source of barrier-to-entry for lower-volume broker-dealers.

Among incumbent exchange members participating in the closing auctions, prohibiting ''auction linked pricing'' may increase low-volume broker-dealers' profits derived from closing auctions while decreasing high-volume broker-dealers' profits. Unlinking transaction fees for closing auctions to member's overall trading volume may induce exchanges to reduce the execution cost differentials between high- and low-volume participants in the closing auctions. Because the execution cost for low-volume members may be reduced, these members who share their reduced input costs with customers can better attract agency order flow from investors and non-members. On the other hand, prohibiting ''auction linked pricing'' may lessen high-volume members' advantage in directing agency order flow to the closing auctions.

Removing only the closing auctions' volume criteria that are tied to overall trading volume preserves the volume-based pricing schemes for intraday trading, a potential dimension along which firms compete and a practice that may be welfare-enhancing. For a different market setting where the authors examine pricing schedules that embody discounts for greater demand or utilization, the authors find that firms compete more aggressively to offer size discounts in response to increased competition from rivals.[277] The paper highlights volume-based discount as a channel through which newspaper firms compete with one another as means to retain orders for advertising. This

volume exchanges due to their lower trading volume.

[275] Dennis W. Carlton and Michael Waldman, ''The Strategic Use of Tying to Preserve and Create Market Power in Evolving Industries'', 33 RAND J. Econ. 194(Summer 2002). Michael D. Whinston, ''Tying, Foreclosure, and Exclusion'', 80 Am. Econ. Rev. 837 (Sept. 1990). *See also* a discussion of tying from W. Kip Viscusi, Joseph E. Harrington, and David E. M. Sappington, Economics of Regulation and Antitrust, Chapter 7 Vertical Mergers and Vertical Restraints, pages 296–312 (5th ed. 2018).

[276] *See supra* section IV.B.4.a.

[277] Meghan Busse and Marc Rysman, ''Competition and Price Discrimination in Yellow Pages Advertising'', 36 Rand J. Econs. 378 (2005).

observation, along with the fact that price discrimination schemes may enhance both the price-setting firms' and the customers' overall welfare if they lead to greater demand,[278] suggests that volume-based tiers may potentially be a welfare-enhancing outcome of competition across exchanges. Despite the caveat that high-volume broker-dealers may disproportionately benefit from volume-based discounts, pricing tiers for intraday trading may be worth preserving because of their welfare-enhancing potentials. On the other hand, a number of studies have shed light on ways in which tying prices for complementary goods (or markets) can be effectively used by firms to (1) extract more surplus from customers [279] or (2) expand its market power from a dominant market to complementary markets.[280] Without salient cost synergies from bundling (*i.e.,* concentrating limit book order flow and participation in closing auction on the same listing exchange) or an enhancement in overall demand for broker-dealers, welfare-reducing tying justifies a ban on linking tiers for closing auctions to intraday trading volumes.

5. Require Disclosures of Volume-Based Pricing in Proprietary Volume in NMS Stocks To Be Posted on Exchange Websites or Submitted Through a Different System

The Commission considered requiring equities exchanges post the fee and rebate tiers disclosures in Inline XBRL on their websites, either in addition to, or instead of, filing the disclosures in EDGAR.[281] Requiring exchanges to place the structured fee tiers disclosures only on exchange websites would relieve exchanges of the need to apply for EDGAR filing access and adjust their compliance systems to submit the disclosures in EDGAR, thus reducing costs on exchanges. However, a website posting requirement would also decrease the ease of retrieving and consolidating the new disclosures, because data users would need to visit each equities exchange's website to retrieve the disclosed information and manually incorporate those disclosures into datasets (or pay a third party to do so). In addition, the data quality associated with the disclosures could decrease under a website-only requirement, because website postings would not be subject to programmatic checks for nondiscretionary errors (such as text where there should only be numbers). Such accessibility and data quality issues could impede the objective of the proposal, which is to provide the Commission and the public with insight into the application of an exchange's volume-based transaction pricing schedule and to provide information that could facilitate assessment of the level of competition among exchanges and the impact of pricing tiers on intermarket competition. Requiring exchanges to place the structured fee tiers disclosures only on exchange websites would relieve exchanges of the need to apply for EDGAR filing access and adjust their compliance systems to submit the disclosures through EDGAR, thus reducing burdens on exchanges.

Requiring exchanges to place the structured disclosures both on exchange websites and on EDGAR would not relieve exchanges of the need to apply for EDGAR filing access and adjust their compliance systems to submit the disclosures in EDGAR, and thus would not reduce costs on exchanges. In addition, while adding a website disclosure requirement may make it likelier that investors accustomed to accessing exchange websites for transaction pricing schedules would access those disclosures, the Commission believes the fee and rebate tiers information, when submitted electronically to the Commission, likely would be equally accessible to the parties most likely to access the information on a regular basis (*e.g.,* broker-dealer exchange members, financial data aggregators and other market participants).[282]

Alternatively, the Commission could require the disclosures to be submitted through another filing system, specifically the Electronic Form Filing System (''EFFS'') through which exchanges presently file their proposed pricing changes on Form 19b–4. Using EFFS would reduce the burdens on exchanges by relieving them from the need to apply for EDGAR filing access and adjust their compliance systems to submit the disclosures using EDGAR. Use of EFFS would allow the Commission to centralize the collection of the disclosures and could still allow for the application of programmatic checks for nondiscretionary errors. However, EFFS would need to be expanded to accept the disclosures in Inline XBRL format, and a mechanism would need to be implemented to make the disclosures available to the public.

6. Require a Different Structured Data Language for the Disclosures of Volume-Based Pricing in Proprietary Volume in NMS Stocks

The Commission also considered requiring that exchanges make the disclosures in a different machine-readable structured data language than Inline XBRL. The Commission considered requiring equities exchanges to submit the proposed disclosures in an eXtensible Markup Language (''XML'')-based data language specific to that form (''custom XML'' or, here, ''Tiers-specific XML''). Currently, certain registrants make filings in EDGAR in custom XML data languages that are specific to particular forms.[283] For custom XML filings, filers typically are provided the option to either submit the filing directly to the EDGAR system in the relevant custom XML data language, or to manually input the information into a fillable web-based form developed by the Commission that converts the

[278] *See supra* section IV.D.1.

[279] Gregory S. Crawford, ''The Discriminatory Incentives to Bundle in the Cable Television Industry'', 6 Quantitative Mktg. & Econ. 41 (2008).

[280] *See* Katherine Ho, Justin Ho, & Julie Holland Mortimer, ''The Use of Full-Line Forcing Contracts in the Video Rental Industry'', 102 Am. Econ. Rev. 686 (2012), for an empirical analysis. *See* Dennis W. Carlton and Michael Waldman, ''The Strategic Use of Tying to Preserve and Create Market Power in Evolving Industries'', 33 Rand J. Econ. 194 (Summer 2002), for theoretic analysis. Michael D. Whinston, ''Tying, Foreclosure, and Exclusion'', 80 Am. Econ. Rev. 837 (Sept. 1990). *See also* a discussion of tying from W. Kip Viscusi, Joseph E. Harrington, and David E. M. Sappington, Economics of Regulation and Antitrust, Chapter 7 Vertical Mergers and Vertical Restraints, 296–312 (5th ed. 2018).

[281] Certain Commission rules require registrants to post structured disclosures on their individual websites. For example, market centers (including equities exchanges) are required to post order execution disclosures on their websites in pipe-delimited ASCII. *See* 17 CFR 242.605(a)(1) and (2); Securities and Exchange Commission File No. 4–518 (National Market System Plan Establishing Procedures Under Rule 605 of Regulation NMS). Broker-dealers are required to post order routing disclosures on their websites using a custom XML schema designed by the Commission for those disclosures. *See* 17 CFR 242.606. Nationally recognized statistical rating organizations are required to post credit rating history disclosures on their websites in XBRL. *See* 17 CFR 240.17g–7(b)(3).

[282] The Commission recently proposed rules to require certain registered entities, including exchanges, to file new cybersecurity risk and incident history disclosures in EDGAR and post copies of those disclosures on their individual websites. *See* Cybersecurity Risk Management Rule for Broker-Dealers, Clearing Agencies, Major Security-Based Swap Participants, the Municipal Securities Rulemaking Board, National Securities Associations, National Securities Exchanges, Security-Based Swap Data Repositories, Security-Based Swap Dealers, and Transfer Agents, Securities Exchange Act Release No. 97142 (Mar. 15, 2023), 88 FR 20212 (Apr. 5, 2023). In the proposing release, the Commission stated its belief that retail investors (as well as other market participants) would have an interest in accessing the cybersecurity disclosures. *See id.* at 20308.

[283] For example, security-based swap entities file Form SBSE in a custom XML language specific to that form. *See* section 8.2.19 of the EDGAR Filer Manual (Volume II) version 66 (Jun. 2023).

completed form into a custom XML document.

As with the proposed Inline XBRL requirement, a custom XML requirement would allow the Commission to download the proposed information in a structured, machine-readable form, facilitating efficient access, organization, and evaluation of the disclosed information. Furthermore, if any filers were to use the fillable web-based form to provide their information under a custom XML requirement, those filers would forgo the compliance costs related to structuring their fee and tier-based disclosures.

However, the Commission believes the use of Inline XBRL for the fee and rebate tiers disclosures would provide advantages that the use of Tiers-specific XML would not. First, XBRL uses and implements existing accounting and reporting standards,[284] which facilitates the coordination and sharing of financial information. Thus, Inline XBRL would be well-suited to handle data about proprietary volume-based pricing tiers on equities exchanges. Second, the Commission believes creating a custom XML schema for the fee and rebate tiers disclosures would be less efficient than leveraging the existing Inline XBRL architecture, because doing so would involve re-creating features that XBRL already offers through its taxonomies and related data elements within those taxonomies.[285] Lastly, the use of a standard structured data language such as Inline XBRL would allow equities exchanges and market participants to leverage an existing ecosystem of software tools, service providers and related infrastructure that support XBRL tagging.[286] Thus, the Commission believes the use of a custom XML schema designed specifically for a particular regulatory form, while an improvement over unstructured forms, would not provide the same level of benefit as the use of a global, interoperable standard data language such as Inline XBRL.

7. Remove Structured Data Language Requirement for Disclosures of Volume-Based Pricing in Proprietary Volume in NMS Stocks

The Commission also considered not including the proposed requirement that exchanges submit the disclosures in a structured data language. Such an alternative would result in an incremental reduction in cost to equities exchanges associated with filing the fee tiers disclosures. However, the absence of any structured data language requirement would significantly reduce the benefits of the proposal because the fee tiers data would be more difficult for the Commission and market participants to assemble, review, and analyze. The use of HTML, ASCII, PDF, or another unstructured format for the proposed disclosures would force user of the data, including Commission staff and market participants, to manually transcribe information from the disclosures into datasets for aggregation, analysis, and comparison of the proprietary volume-based pricing data, or pay a third party to do so. This would impede data users such as financial analysts from producing reports and analyses about equities exchange fee tiers practices and trends that market participants could find useful.

F. Request for Comment

The Commission is sensitive to the potential economic effects, including costs and benefits, of the proposed rule. The Commission has identified certain costs and benefits associated with the proposal and requests comment on all aspects of its preliminary economic analysis, including with respect to the specific questions below. The Commission encourages commenters to identify, discuss, analyze, and supply relevant data, information, or statistics regarding any such costs or benefits. In addition, the Commission has the following specific requests:

31. Is there a lack of transparency for exchange price schedules? Does a lack of information on how many exchange members qualify for each volume-based tier in a given month inhibit public comment on exchange fees?

32. The Commission discussed above how the presence of volume-based transaction pricing on exchanges introduces a potential conflict of interest, because it gives broker-dealers an incentive to route agency-based volume in a way that minimizes exchange fees for the broker-dealer. Is such a conflict of interest present? The Commission requests comment on the impact of such potential conflicts of interest.

33. Does volume-based transaction pricing promote concentration in the broker-dealer business? Specifically, does it offer an advantage to larger broker-dealers that makes it harder for small broker-dealers to compete? Does this make it more difficult for new broker-dealers to enter the NMS equity brokerage business than it would be without volume-based transaction pricing?

34. Do commenters believe that there are relevant factors which were not discussed in the Commission's characterization of the relevant baseline for the proposed rule? Please describe any additional baseline details that you believe are relevant for understanding the impact of the proposed rule.

35. Is the Commission's description of current exchange pricing accurate, including the practice of volume tiering and using auction linked pricing to attract volume outside of the auction? Are there additional details about these practices which you believe are relevant to understanding their impact?

36. Do fees and rebates play a role in attracting order flow to exchanges? How sensitive are market participants to fees and rebates when making decisions about where to route orders? Do transaction fees and rebates significantly influence an exchange's market share?

37. What is the role of volume-based transaction pricing and its impact on what different market participants pay?

38. Does tying closing auction prices to intraday volume have an impact on the market share exchanges are able to obtain for intraday volume?

39. How does volume-based transaction pricing impact order routing incentives for broker-dealers? Does the impact involve a potential conflict of interest?

40. Is the Commission's characterization of the market to provide access to exchanges to non-members through things like sponsored access and direct market access accurate? Are there any relevant factors which were not discussed in the Commission's characterization of the

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[284] *See* Donna Johaneman & Louis Matherne, Harmonizing Accounting and Data Standards, XBRL.us, Dec. 23, 2019, available at *https://xbrl.us/harmonizing-accounting-data-standards/* (''As a data standard, [XBRL] is designed to support an existing accounting standard by unambiguously conveying details about that accounting standard reporting requirement.''). For example, the Financial Accounting Standards Board assumed the ongoing development of the Generally Accepted Accounting Principles (''GAAP'') Taxonomy from the SEC in 2010 to keep it current with GAAP. *XBRL:* What Is it? Why the FASB? Who Uses It?, *FASB.org*, available at *https://www.fasb.org/page/PageContent?pageId=/staticpages/what-is-xbrl.html&isstaticpage=true; see also* IFRS Accounting Taxonomy 2023, *XBRL.org*, available at *https://www.xbrl.org/news/ifrs-accounting-taxonomy-2023/*.

[285] *See, e.g.,* Standard Taxonomies, *SEC.gov*, available at *https://www.sec.gov/info/edgar/edgartaxonomies; Taxonomies, XBRL.us*, available at *https://xbrl.us/home/filers/sec-reporting/taxonomies/*.

[286] XBRL International is a global, nonprofit consortium that oversees the XBRL standard. Introduction to XBRL, *XBRL.org*, available at *https://www.xbrl.org/the-standard/what/an-introduction-to-xbrl/*. XBRL US is a jurisdiction of XBRL International. *See also* Membership Organizations, *XBRL.us*, available at *https://xbrl.us/join-us/membership/xusmembers/;* Membership List, *XBRL.org*, available at *https://www.xbrl.org/the-consortium/about/membership-list/*.

baseline for the market to provide exchange access?

41. What is the current effect of volume-based tiering on broker-dealer services? Does current volume-based tiering create a barrier to entry in the market for NMS equity brokerage services?

42. Is there substantial dispersion in the size of broker-dealer exchange members? What effect does such dispersion have on the market to provide exchange access and the role of volume-based transaction pricing in that market?

43. What is the current level of tier transparency? Does the lack of public knowledge of the number of exchange members that qualify for each tier affect the ability of the public to submit informed comments on exchange fees?

44. Are there any additional benefits from increased transparency the Commission did not discuss?

45. Is the Commission's assessment of the benefits of EDGAR and Inline XBRL requirements accurate?

46. What other benefits or costs to investors may arise from exchanges voluntarily adopting different price schedules after the implementation of the transparency provisions?

47. Do commenters agree with the Commission's assessment of the implementation costs associated with the transparency provision of the proposed rule? Are there any technical aspects which were not discussed which would affect any implementation costs? Do commenters agree with how the Commission has characterized the costs associated with the requirement for structured data, and the EDGAR filing requirement?

48. Will there be reputation costs and other monetary costs related to changes exchanges may make to their tiered pricing in response to the transparency requirements, as the Commission describes above?

49. Are there any additional benefits or costs of the transparency provisions that the Commission did not discuss?

50. Do commenters agree with the Commission's assessment of the benefits stemming from the effects of the volume-based prohibition on agency-related order pricing and competition among broker-dealers? In particular, would lower-volume exchange members end up with lower fees and higher rebates under such a ban? Would a flat fee and rebate for agency-related volume increase competition among broker-dealers to provide exchange access? Would investors benefit from the lower prices for lower-volume exchange members and lower barriers to entry in the NMS equity brokerage business?

51. Would prohibiting the application of volume-based pricing for agency-related order flow and the proposed disclosure provisions promote or impede competition between exchanges? Does the Commission adequately capture the costs and benefits resulting from the effect of the proposed rule on competition among exchanges?

52. What impact would an elimination of volume-based pricing on agency-related order flow have on the NBBO, including the spread width and depth of displayed interest at the NBBO?

53. Would the prohibition of volume-based pricing for agency-related order flow affect order-routing decisions by reducing the conflict of interest between members and customers in agency order routing?

54. Would the execution quality of agency-related orders improve by reducing the incentive to concentrate order flow on a small number of exchanges?

55. Do commenters agree with the Commission's assessment of the costs from the effect of the rule on competition among broker-dealers? Do you agree that the rebates earned will likely decrease and the fees paid will increase for the higher-volume broker-dealer members? Would these costs also affect non-members that work with higher-volume exchange members to trade?

56. Do commenters agree with the Commission's description of the indirect costs and reduction in efficiency which may result from a reduction of order-flow executed by higher-volume exchange members on exchanges?

57. How likely is the proposed prohibition of volume-based pricing for agency-related order flow to result in broker-dealers moving to an inventory model? Do commenters agree with the Commission's assessment of the costs of the proposed rule resulting from increased principal trading?

58. Would the proposed rule affect the ability of exchanges to compete with off-exchange venues? Do commenters agree with the Commission's assessments of the costs from order flow potentially moving to off-exchange venues?

59. Are there any additional benefits or costs from the prohibition of volume-based transaction pricing for agency-related volume that you believe the Commission did not discuss?

60. Do commenters agree with the Commission's assessment of the benefits and costs from the proposed rule's requirements that exchanges adopt rules and policies and procedures to prevent evasion?

61. Do commenters agree with the Commission's assessment of the impact of the proposed rule on efficiency, competition, and capital formation?

62. The Commission requests comment on the effects of an alternative that implements a ban on volume-based transaction pricing for all exchange order types.

63. How important are the various privileges afforded to registered market makers by the exchanges to their willingness to participate and ability to function effectively? What is the effect of registered market makers on exchange liquidity?

64. Do commenters believe that volume-based transaction pricing serves a unique role in the function of registered market makers? In particular, do such tiers improve the participation of registered market makers, or improve their performance on exchange as a market maker? Do such tiers create a barrier to entry for smaller registered market makers? What is the effect of volume-based tiering on competition among registered market makers to provide liquidity in a given security?

65. If the Commission prohibited the application of volume-based pricing for all order types with a carve-out for the application of volume-based pricing only for registered market makers, would requiring the monthly disclosure of the number of members which qualify for any tiers which fall within the carve-out provide meaningful information? Could knowledge of the distribution of tier qualification across registered market makers influence order-routing decisions?

66. How impactful would the proposed disclosure provisions, expanded to apply to all volume-based tiers, without any prohibition on the application of volume-based pricing, be on addressing competitive imbalances between broker-dealers? Do there exist data to support conclusions on such impacts? Would the proposed disclosure provisions influence order routing decisions by exchange members?

67. Would the information revealed through the monthly disclosure of the number of exchange members qualifying for each pricing tier, absent any prohibition of the application of volume-based pricing, meaningfully influence future exchange transaction price schedules? Would the disclosures promote exchange competition? Do there exist data to support conclusions on such influence?

68. The Commission requests comment on all aspects of the costs of

the proposal to require equities exchanges to provide the proposed tiers disclosures electronically on EDGAR in Inline XBRL. Are there costs that the Commission has over- or understated? Are there additional costs that the Commission has not mentioned? Please explain your answer.

69. Are the Commission's assessment of the costs of the requirements to provide the proposed disclosures in Inline XBRL correct? Please explain why or why not. Would the use of a different structured data language impact the cost of the structuring requirement? Please explain why or why not.

70. Is the Commission's assessment of the costs of the requirements to provide the disclosures to the public using EDGAR correct? Please explain why or why not. How would the costs change if the Commission required exchanges to post the disclosures on their individual websites rather than submit the disclosures using EDGAR?

71. Should the proposed fee tiers disclosures be provided in a structured data language other than Inline XBRL? For example, should exchanges structure the proposed fee tiers disclosures using a custom XML schema specific to those disclosures? Why or why not? Alternatively, should exchanges structure the proposed fee tiers disclosures using a pipe-delimited ASCII format rather than Inline XBRL? Why or why not? Should the Commission instead require the proposed fee tiers disclosures be provided in an unstructured format? Are there other alternatives related to structured data languages that would be appropriate? How would the use of a different language impact the usability and accessibility of the tables for data users? What time or expense is associated with the recommended structured data language? Would a particular structured data language require any filers or users to license commercial software they otherwise would not, and, if so, at what expense?

V. Regulatory Flexibility Act Certification

The Regulatory Flexibility Act (''RFA'') [287] requires Federal agencies, in promulgating rules, to consider the impact of those rules on small entities. Section 603(a) [288] of the Administrative Procedure Act,[289] as amended by the RFA, generally requires the Commission to undertake a regulatory flexibility analysis of all proposed rules, or proposed rule amendments, to determine the impact of such rulemaking on ''small entities.'' [290] Section 605(b) of the RFA states that this requirement shall not apply to any proposed rule or proposed rule amendment which, if adopted, would not have a significant economic impact on a substantial number of small entities.[291]

The proposed rule would apply only to national securities exchanges registered with the Commission that trade NMS stocks. Rule 0–10(e) states that the term ''small business,'' when referring to an exchange, means any exchange that has been exempted from the reporting requirements of 17 CFR 242.601 (Rule 601 of Regulation NMS), and is not affiliated with any person (other than a natural person) that is not a small business or small organization as defined in Rule 0–10.[292] The exchanges subject to this proposed rulemaking do not satisfy this standard. Therefore, none of the exchanges that would be subject to the proposed rule are ''small entities'' for purposes of the RFA.[293]

For the above reasons, the Commission certifies that proposed Rule 6b–1 would not have a significant economic impact on a substantial number of small entities for purposes of the RFA.

The Commission requests comment regarding this certification. In particular, the Commission solicits comment on the following:

72. Do commenters agree with the Commission's certification? If not, please describe the nature of any impact on small entities and provide empirical data to illustrate the extent of the impact.

VI. Consideration of Impact on the Economy

For purposes of the Small Business Regulatory Enforcement Fairness Act of 1996, or ''SBREFA,'' [294] the Commission must advise OMB whether a proposed regulation constitutes a ''major'' rule. Under SBREFA, a rule is considered ''major'' where, if adopted, it results in or is likely to result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers or individual industries; or (3) significant adverse effects on competition, investment, or innovation. The Commission requests comment on whether this proposal would be a ''major rule'' for purposes of the SBREFA. The Commission also requests comment on the potential effect of proposed Rule 6b–1 on the U.S. economy on an annual basis; any potential increase in costs or prices for consumers or individual industries; and any potential effect on competition, investment, or innovation. Commenters are requested to provide empirical data and other factual support for their views to the extent possible.

Statutory Authority

Pursuant to the Exchange Act (15 U.S.C. 78a *et seq.*), and particularly sections 2, 3(b), 5, 6, 11, 11A, 15, 15A, 17, 19, 23(a), 24, and 36 thereof, 15 U.S.C. 78b, 78c(b), 78e, 78f, 78k, 78k–1, 78*o,* 78*o*–1, 78q, 78s, 78w(a), 78x, and 78mm, the Commission is proposing to amend §§ 232.101 and 232.405 and is proposing new § 240.6b–1, as set forth below.

List of Subjects

17 CFR Part 232

Electronic filing, Reporting and recordkeeping requirements, Securities.

17 CFR Part 240

Fees, Reporting and recordkeeping requirements, Securities.

Text of the Proposed Rules

In accordance with the foregoing, the Securities and Exchange Commission proposes to amend title 17, chapter II of the Code of Federal Regulations as follows:

PART 232—REGULATION S–T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

■ 1.The general authority citation for part 232 continues to read as follows:

Authority: 15 U.S.C. 77c, 77f, 77g, 77h, 77j, 77s(a), 77z–3, 77sss(a), 78c(b), 78*l,* 78m, 78n, 78*o*(d), 78w(a), 78*ll,* 80a–6(c), 80a–8, 80a–29, 80a–30, 80a–37, 80b–4, 80b–6a, 80b–10, 80b–11, 7201 *et seq.;* and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

■ 2. Amend § 232.101:

[287] 5 U.S.C. 601 *et seq.*

[288] 5 U.S.C. 603(a).

[289] 5 U.S.C. 551 *et seq.*

[290] The Commission has adopted definitions for the term ''small entity'' for purposes of Commission rulemaking in accordance with the RFA. Those definitions, as relevant to this proposed rulemaking, are set forth in 17 CFR 240.0–10 (Rule 0–10). *See* Securities Exchange Act Release No. 18451 (Jan. 28, 1982), 47 FR 5215 (Feb. 4, 1982) (File No. AS–305).

[291] *See* 5 U.S.C. 605(b).

[292] *See* 17 CFR 240.0–10(e).

[293] *See also* Securities Exchange Act Release Nos. 82873 (Mar. 14, 2018), 83 FR 13008, 13074 (Mar. 26, 2018) (File No. S7–05–18) (Transaction Fee Pilot for NMS Stocks Proposing Release); 55341 (May 8, 2001), 72 FR 9412, 9419 (May 16, 2007) (File No. S7–06–07) (Proposed Rule Changes of Self-Regulatory Organizations proposing release); Access Fee Proposal, *supra* note 17, at 87 FR at 80357.

[294] Public Law 104–121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C., 15 U.S.C. and as a note to 5 U.S.C. 601).

■ a. In paragraph (a)(1)(xxx), by removing the word ''and'' from the end of the paragraph;
■ b. In paragraph (a)(1)(xxxi), by removing the period and adding it its place ''; and''; and
■ c. By adding paragraph (a)(1)(xxxii).

The addition reads as follows:

§ 232.101 Mandated electronic submissions and exceptions.

(a) * * *
(1) * * *
(i) * * *

(xxxii) Disclosures provided pursuant to § 240.6b–1(c) of this chapter.

* * * * *

■ 3. Amend § 232.405 by:
■ a. Revising the introductory text, and paragraphs (a)(2), (a)(3)(i) introductory text, (a)(3)(ii), (a)(4), and (b)(1) introductory text;
■ b. Adding paragraph (b)(6); and
■ c. Revising Note 1 to § 232.405.

The revisions and addition read as follows:

§ 232.405 Interactive Data File submissions.

This section applies to electronic filers that submit Interactive Data Files. Section 229.601(b)(101) of this chapter (Item 601(b)(101) of Regulation S–K), General Instruction F of Form 11–K (§ 249.311 of this chapter); paragraph (101) of Part II—Information Not Required to be Delivered to Offerees or Purchasers of Form F–10 (§ 239.40 of this chapter), § 240.13a–21 of this chapter (Rule 13a–21 under the Exchange Act), paragraph 101 of the Instructions as to Exhibits of Form 20–F (§ 249.220f of this chapter), paragraph B.(15) of the General Instructions to Form 40–F (§ 249.240f of this chapter), paragraph C.(6) of the General Instructions to Form 6–K (§ 249.306 of this chapter), § 240.17Ad–27(d) of this chapter (Rule 17Ad–27(d) under the Exchange Act), Note D.5 of § 240.14a–101 of this chapter (Rule 14a–101 under the Exchange Act), Item 1 of § 240.14c–101 of this chapter (Rule 14c–101 under the Exchange Act), General Instruction I of Form F–SR (§ 249.333 of this chapter), General Instruction C.3.(g) of Form N–1A (§§ 239.15A and 274.11A of this chapter), General Instruction I of Form N–2 (§§ 239.14 and 274.11a–1 of this chapter), General Instruction C.3.(h) of Form N–3 (§§ 239.17a and 274.11b of this chapter), General Instruction C.3.(h) of Form N–4 (§§ 239.17b and 274.11c of this chapter), General Instruction C.3.(h) of Form N–6 (§§ 239.17c and 274.11d of this chapter), General Instruction 2.(*l*) of § 274.12 of this chapter (Form N–8B–2), General Instruction 5 of § 239.16 of this chapter (Form S–6), General Instruction C.4 of Form N–CSR (§§ 249.331 and 274.128 of this chapter), and § 240.6b–1(c) of this chapter (Rule 6b–1(c) under the Exchange Act) specify when electronic filers are required or permitted to submit an Interactive Data File (§ 232.11), as further described in note 1 to this section. This section imposes content, format, and submission requirements for an Interactive Data File, but does not change the substantive content requirements for the financial and other disclosures in the Related Official Filing (§ 232.11).

(a) * * *

(2) Be submitted only by an electronic filer either required or permitted to submit an Interactive Data File as specified by Item 601(b)(101) of Regulation S–K, General Instruction F of Form 11–K (§ 249.311 of this chapter); paragraph (101) of Part II—Information Not Required to be Delivered to Offerees or Purchasers of Form F–10 (§ 239.40 of this chapter), § 240.13a–21 of this chapter (Rule 13a–21 under the Exchange Act), paragraph 101 of the Instructions as to Exhibits of Form 20–F (§ 249.220f of this chapter), paragraph B.(15) of the General Instructions to Form 40–F (§ 249.240f of this chapter), paragraph C.(6) of the General Instructions to Form 6–K (§ 249.306 of this chapter), Rule 17Ad–27(d) under the Exchange Act, Note D.5 of Rule 14a–101 under the Exchange Act, Item 1 of Rule 14c–101 under the Exchange Act, General Instruction I to Form F–SR (§ 249.333 of this chapter), General Instruction C.3.(g) of Form N–1A (§§ 239.15A and 274.11A of this chapter), General Instruction I of Form N–2 (§§ 239.14 and 274.11a–1 of this chapter), General Instruction C.3.(h) of Form N–3 (§§ 239.17a and 274.11b of this chapter), General Instruction C.3.(h) of Form N–4 (§§ 239.17b and 274.11c of this chapter), General Instruction C.3.(h) of Form N–6 (§§ 239.17c and 274.11d of this chapter), General Instruction 2.(*l*) of § 274.12 of this chapter (Form N–8B–2), General Instruction 5 of § 239.16 of this chapter (Form S–6), General Instruction C.4 of Form N–CSR (§§ 249.331 and 274.128 of this chapter), or Rule 6b–1(c) under the Exchange Act (§ 240.6b–1(c) of this chapter), as applicable;

(3) * * *

(i) If the electronic filer is not a management investment company registered under the Investment Company Act of 1940 (15 U.S.C. 80a *et seq.*), a separate account as defined in section 2(a)(14) of the Securities Act (15 U.S.C. 77b(a)(14)) registered under the Investment Company Act of 1940, a business development company as defined in section 2(a)(48) of the Investment Company Act of 1940 (15 U.S.C. 80a–2(a)(48)), a unit investment trust as defined in Section 4(2) of the Investment Company Act of 1940 (15 U.S.C. 80a–4), a national securities exchange as defined in 17 CFR 242.600(b)(53) (Rule 600(b)(53) of Regulation NMS), or a clearing agency that provides a central matching service, and is not within one of the categories specified in paragraph (f)(1)(i) of this section, as partly embedded into a filing with the remainder simultaneously submitted as an exhibit to:

* * * * *

(ii) If the electronic filer is a management investment company registered under the Investment Company Act of 1940 (15 U.S.C. 80a *et seq.*), a separate account (as defined in section 2(a)(14) of the Securities Act (15 U.S.C. 77b(a)(14)) registered under the Investment Company Act of 1940, a business development company as defined in section 2(a)(48) of the Investment Company Act of 1940 (15 U.S.C. 80a–2(a)(48)), a unit investment trust as defined in Section 4(2) of the Investment Company Act of 1940 (15 U.S.C. 80a–4), a national securities exchange as defined in 17 CFR 242.600(b)(53) (Rule 600(b)(53) of Regulation NMS), or a clearing agency that provides a central matching service, and is not within one of the categories specified in paragraph (f)(1)(ii) of this section, as partly embedded into a filing with the remainder simultaneously submitted as an exhibit to a filing that contains the disclosure this section requires to be tagged; and

(4) Be submitted in accordance with the EDGAR Filer Manual and, as applicable, Item 601(b)(101) of Regulation S–K, General Instruction F of Form 11–K (§ 249.311 of this chapter), paragraph (101) of Part II—Information Not Required to be Delivered to Offerees or Purchasers of Form F–10 (§ 239.40 of this chapter), Rule 13a–21 under the Exchange Act, paragraph 101 of the Instructions as to Exhibits of Form 20–F (§ 249.220f of this chapter), paragraph B.(15) of the General Instructions to Form 40–F (§ 249.240f of this chapter), paragraph C.(6) of the General Instructions to Form 6–K (§ 249.306 of this chapter), Rule 17Ad–27(d) under the Exchange Act, Note D.5 of Rule 14a–101 under the Exchange Act, Item 1 of Rule 14c–101 under the Exchange Act, General Instruction I to Form F–SR (§ 249.333 of this chapter), General Instruction C.3.(g) of Form N–1A (§§ 239.15A and 274.11A of this chapter), General Instruction I of Form N–2 (§§ 239.14 and 274.11a–1 of this chapter), General Instruction C.3.(h) of

Form N–3 (§§ 239.17a and 274.11b of this chapter), General Instruction C.3.(h) of Form N–4 (§§ 239.17b and 274.11c of this chapter), General Instruction C.3.(h) of Form N–6 (§§ 239.17c and 274.11d of this chapter); Instruction 2.(*l*) of § 274.12 of this chapter (Form N–8B–2); General Instruction 5 of § 239.16 of this chapter (Form S–6); General Instruction C.4 of Form N–CSR (§§ 249.331 and 274.128 of this chapter), or Rule 6b–1(c) under the Exchange Act (§ 240.6b–1(c) of this chapter).

(b) * * *

(1) If the electronic filer is not a management investment company registered under the Investment Company Act of 1940 (15 U.S.C. 80a *et seq.*), a separate account (as defined in section 2(a)(14) of the Securities Act (15 U.S.C. 77b(a)(14)) registered under the Investment Company Act of 1940, a business development company as defined in section 2(a)(48) of the Investment Company Act of 1940 (15 U.S.C. 80a–2(a)(48)), a unit investment trust as defined in Section 4(2) of the Investment Company Act of 1940 (15 U.S.C. 80a–4), a clearing agency that provides a central matching service, or a national securities exchange as defined in 17 CFR 242.600(b)(53) (Rule 600(b)(53) of Regulation NMS), an Interactive Data File must consist of only a complete set of information for all periods required to be presented in the corresponding data in the Related Official Filing, as applicable, no more and no less, from all of the following categories:

* * * * *

(6) If the electronic filer is a national securities exchange as defined in 17 CFR 242.600(b)(53) (Rule 600(b)(53) of Regulation NMS), an Interactive Data File must consist of the disclosure provided pursuant to § 240.6b–1(c) of this chapter (Rule 6b–1(c) under the Exchange Act).

* * * * *

Note 1 to § 232.405:

Item 601(b)(101) of Regulation S–K specifies the circumstances under which an Interactive Data File must be submitted and the circumstances under which it is permitted to be submitted, with respect to §§ 239.11 (Form S–1), 239.13 (Form S–3), 239.25 (Form S–4), 239.18 (Form S–11), 239.31 (Form F–1), 239.33 (Form F–3), 239.34 (Form F–4), 249.310 (Form 10–K), 249.308a (Form 10–Q), and 249.308 (Form 8–K) of this chapter. General Instruction F of Form 11–K (§ 249.311 of this chapter) specifies the circumstances under which an Interactive Data File must be submitted, and the circumstances under which it is permitted to be submitted, with respect to Form 11–K. Paragraph (101) of Part II—Information not Required to be Delivered to Offerees or Purchasers of Form F–10 (§ 239.40 of this chapter) specifies the circumstances under which an Interactive Data File must be submitted and the circumstances under which it is permitted to be submitted, with respect to Form F–10. Paragraph 101 of the Instructions as to Exhibits of Form 20–F (§ 249.220f of this chapter) specifies the circumstances under which an Interactive Data File must be submitted and the circumstances under which it is permitted to be submitted, with respect to Form 20–F. Paragraph B.(15) of the General Instructions to Form 40–F (§ 249.240f of this chapter) and Paragraph C.(6) of the General Instructions to Form 6–K (§ 249.306 of this chapter) specify the circumstances under which an Interactive Data File must be submitted and the circumstances under which it is permitted to be submitted, with respect to §§ 249.240f (Form 40–F) and 249.306 of this chapter (Form 6–K). Rule 17Ad–27(d) under the Exchange Act specifies the circumstances under which an Interactive Data File must be submitted with respect the reports required under Rule 17Ad–27. Note D.5 of § 240.14a–101 of this chapter (Schedule 14A) and Item 1 of § 240.14c–101 of this chapter (Schedule 14C) specify the circumstances under which an Interactive Data File must be submitted with respect to Schedules 14A and 14C. Rule 13a–21 under the Exchange Act and General Instruction I to Form F–SR (§ 249.333 of this chapter) specify the circumstances under which an Interactive Data File must be submitted, with respect to Form F–SR. Item 601(b)(101) of Regulation S–K, paragraph (101) of Part II—Information not Required to be Delivered to Offerees or Purchasers of Form F–10, paragraph 101 of the Instructions as to Exhibits of Form 20–F, paragraph B.(15) of the General Instructions to Form 40–F, and paragraph C.(6) of the General Instructions to Form 6–K all prohibit submission of an Interactive Data File by an issuer that prepares its financial statements in accordance with §§ 210.6–01 through 210.6–10 of this chapter (Article 6 of Regulation S–X). For an issuer that is a management investment company or separate account registered under the Investment Company Act of 1940 (15 U.S.C. 80a *et seq.*) or a business development company as defined in section 2(a)(48) of the Investment Company Act of 1940 (15 U.S.C. 80a–2(a)(48)), or a unit investment trust as defined in Section 4(2) of the Investment Company Act of 1940 (15 U.S.C. 80a–4), General Instruction C.3.(g) of Form N–1A (§§ 239.15A and 274.11A of this chapter), General Instruction I of Form N–2 (§§ 239.14 and 274.11a–1 of this chapter), General Instruction C.3.(h) of Form N–3 (§§ 239.17a and 274.11b of this chapter), General Instruction C.3.(h) of Form N–4 (§§ 239.17b and 274.11c of this chapter), General Instruction C.3.(h) of Form N–6 (§§ 239.17c and 274.11d of this chapter), General Instruction 2.(*l*) of Form N–8B–2 (§ 274.12 of this chapter), General Instruction 5 of Form S–6 (§ 239.16 of this chapter), and General Instruction C.4 of Form N–CSR (§§ 249.331 and 274.128 of this chapter), as applicable, specifies the circumstances under which an Interactive Data File must be submitted. For national securities exchanges as defined in 17 CFR 242.600(b)(53) (Rule 600(b)(53) of Regulation NMS), Rule 6b–1(c) under the Exchange Act (§ 240.6b–1(c) of this chapter) specifies the circumstances under which an Interactive Data File must be submitted.

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

■ 4. The general authority citation for part 240 continues to read as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78c–3, 78c–5, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78j–4, 78k, 78k–1, 78*l,* 78m, 78n, 78n–1, 78*o,* 78*o*–4, 78*o*–10, 78p, 78q, 78q–1, 78s, 78u–5, 78w, 78x, 78dd, 78*ll,* 78mm, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4, 80b–11, 7201 *et seq.,* and 8302; 7 U.S.C. 2(c)(2)(E); 12 U.S.C. 5221(e)(3); 18 U.S.C. 1350; and Pub. L. 111–203, 939A, 124 Stat. 1376 (2010); and Pub. L. 112–106, sec. 503 and 602, 126 Stat. 326 (2012), unless otherwise noted.

* * * * *

■ 5. Add § 240.6b–1 to read as follows:

§ 240.6b–1 Volume-Based Exchange Transaction Pricing for NMS Stocks.

(a) A national securities exchange shall not offer volume-based transaction fees, rebates, or other incentives in connection with the execution of agency or riskless principal orders in NMS stocks, as defined in 17 CFR 242.600(b)(55) (Rule 600(b)(55) of Regulation NMS). For purposes of this section, the term *riskless principal* means a transaction in which, after having received an order to buy from a customer, the broker or dealer purchased the security from another person to offset a contemporaneous sale to such customer or, after having received an order to sell from a customer, the broker or dealer sold the

security to another person to offset a contemporaneous purchase from such customer.

(b) A national securities exchange that offers volume-based transaction fees, rebates, or other incentives in connection with the execution of proprietary orders in NMS stocks for the account of a member shall:

(1) Have rules to require members to engage in practices that facilitate the exchange's ability to comply with the prohibition in paragraph (a) of this section; and

(2) Establish, maintain, and enforce written policies and procedures reasonably designed to detect and deter members from receiving volume-based transaction pricing in connection with the execution of agency or riskless principal orders in NMS stocks.

(c) A national securities exchange that offers volume-based transaction fees, rebates, or other incentives in connection with the execution of proprietary orders in NMS stocks for the account of a member shall submit electronically to the Commission the following information each calendar month within five calendar days after the end of the month, which will be made publicly available:

(1) The number of members that executed proprietary orders in NMS stocks for the member's account on the exchange during the month; and

(2) For each volume-based transaction fee, rebate, and other incentive, a summary table that includes the following information:

(i) A label to identify the base fee or rebate;

(ii) A label to identify each pricing tier that corresponds to the label used in the exchange's pricing schedule;

(iii) The amount of the fee, rebate, or other incentive identified;

(iv) An explanation of the tier requirements; and

(v) The total number of members that qualified for the base fee, base rebate, or each tier during the month.

(3) The disclosures required under this paragraph (c) shall be provided in an Interactive Data File in accordance with 17 CFR 232.405 (Rule 405 of Regulation S–T).

By the Commission.

Dated: October 18, 2023.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2023–23398 Filed 11–3–23; 8:45 am]

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 512

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 512

[CMS–1782–F]

RIN 0938–AV05

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule updates and revises the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year (CY) 2024. This rule also updates the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury (AKI). In addition, this final rule updates requirements for the ESRD Quality Incentive Program and the ESRD Treatment Choices Model.

DATES: These regulations are effective on January 1, 2024.

FOR FURTHER INFORMATION CONTACT:

ESRDPayment@cms.hhs.gov, for issues related to the ESRD PPS and coverage and payment for renal dialysis services furnished to individuals with AKI.

ESRDApplications@cms.hhs.gov, for issues related to applications for the Transitional Drug Add-on Payment Adjustment (TDAPA) or Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES).

ESRDQIP@cms.hhs.gov, for issues related to the ESRD Quality Incentive Program (QIP).

ETC–CMMI@cms.hhs.gov, for issues related to the ESRD Treatment Choices (ETC) Model.

SUPPLEMENTARY INFORMATION:

Current Procedural Terminology (CPT) Copyright Notice: Throughout this final rule, we use CPT® codes and descriptions to refer to a variety of services. We note that CPT® codes and descriptions are copyright 2020 American Medical Association (AMA). All Rights Reserved. CPT® is a registered trademark of the AMA. Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

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I. Executive Summary

A. Purpose

This rule finalizes changes related to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), payment for renal dialysis services furnished to individuals with acute kidney injury (AKI), the ESRD Quality Incentive Program (QIP), and the ESRD Treatment Choices (ETC) Model. Additionally, this rule finalizes policies that reflect our commitment to achieving equity in health care for our beneficiaries by supporting our ability to assess whether, and to what extent, our programs and policies perpetuate or exacerbate systemic barriers to opportunities and benefits for underserved communities. Our policy objectives include commitment to advancing health equity, which stands as the first pillar of the Centers for Medicare & Medicaid Services (CMS) Strategic Plan,[1] and reflect the goals of the Administration, as stated in the President's Executive Order 13985.[2] We define health equity as the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.'' [3] In the calendar year (CY) 2023 ESRD PPS final rule, we noted that, when compared with all Medicare fee-for-service (FFS) beneficiaries, Medicare FFS beneficiaries receiving dialysis are disproportionately young, male, African American, have disabilities and low income as measured by eligibility for both Medicare and Medicaid (dual eligible status), and reside in an urban setting (87 FR 67183). In this final rule, we continue to address health equity for beneficiaries with ESRD who are members of underserved communities, including but not limited to those living in rural communities, those who have disabilities, and racial and ethnic minorities. The term 'underserved communities' refers to populations sharing a particular characteristic, including geographic communities, that have been systematically denied a full

[1] Centers for Medicare & Medicaid Services (2022). Health Equity. Available at: *https://www.cms.gov/pillar/health-equity.*

[2] 86 FR 7009 (January 25, 2021). *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[3] Centers for Medicare & Medicaid Services (2022). Health Equity. Available at: *https://www.cms.gov/pillar/health-equity.*

opportunity to participate in aspects of economic, social, and civic life.[4] Specifically, in the CY 2024 ESRD PPS proposed rule (88 FR 42431), we requested information regarding a potential payment adjustment for geographically isolated and rural ESRD facilities, proposed additional payment for the subgroup of Pediatric ESRD Patients (as defined in 42 CFR 413.171), and proposed policies to further our efforts to determine if payment to ESRD facilities treating patients with co-morbidities such as sickle cell anemia is aligned with resource use by such ESRD facilities. As discussed in sections II.B.1.g and II.B.1.j of this final rule, we are now finalizing the proposed payment adjustment for Pediatric ESRD Patients and policies to improve the measurement of individual resource use. Additionally, we are adding three new measures to the ESRD QIP measure set that are aimed at promoting health equity for ESRD patients, including by enabling ESRD facilities to identify gaps experienced by their patient populations.

1. End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), established that beginning CY 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket percentage increase, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This final rule updates the ESRD PPS for CY 2024.

2. Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

On June 29, 2015, the President signed the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27). Section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a new subsection (r) that provides for payment for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate beginning January 1, 2017. This final rule updates the AKI payment rate for CY 2024.

3. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

The End-Stage Renal Disease Quality Incentive Program (ESRD QIP) is authorized by section 1881(h) of the Act. The Program establishes incentives for facilities to achieve high quality performance on measures with the goal of improving outcomes for ESRD beneficiaries. This final rule finalizes several updates for the ESRD QIP, including: (1) updates that will begin with Payment Year (PY) 2026, including one new quality measure, modifications to two current measures, and the removal of two measures; (2) the addition of two new measures beginning with PY 2027; (3) a revision to the regulatory definition of ''minimum total performance score'' that more accurately captures how we calculate the median of national ESRD facility performance on reporting measures; and (4) the codification of our previously finalized measure selection, retention, and removal policies.

4. End-Stage Renal Disease Treatment Choices (ETC) Model

The ETC Model is a mandatory Medicare payment model tested under section 1115A of the Act. The ETC Model is operated by the Center for Medicare and Medicaid Innovation (Innovation Center) and tests the use of payment adjustments to encourage greater utilization of home dialysis and kidney transplants, to preserve or enhance the quality of care furnished to Medicare beneficiaries while reducing Medicare expenditures.

The ETC Model was finalized as part of a final rule published in the **Federal Register** on September 29, 2020, titled ''Medicare Program: Specialty Care Models to Improve Quality of Care and Reduce Expenditures'' (85 FR 61114), referred to herein as the ''Specialty Care Models final rule.'' We revised and updated certain ETC Model policies in the CY 2022 ESRD PPS final rule (86 FR 61874), and the CY 2023 ESRD PPS final rule (87 FR 67136). In this final rule, we are finalizing a modification to our regulations at 42 CFR 512.390 to acknowledge the availability of administrative review of targeted review requests. This change will provide ETC Participants with information about the availability of administrative review if an ETC Participant wishes to seek additional review of its targeted review request.

B. Summary of the Major Provisions

1. ESRD PPS

- *Update to the ESRD PPS base rate for CY 2024:* The final CY 2024 ESRD PPS base rate is $271.02, an increase from the CY 2023 ESRD PPS base rate of $265.57. This amount reflects the application of the combined wage index and transitional pediatric ESRD add-on payment adjustment (TPEAPA) budget-neutrality adjustment factor (0.999534) and a productivity-adjusted market basket percentage increase of 2.1 percent as required by section 1881(b)(14)(F)(i)(I) of the Act, equaling $271.02 (($265.57 × 0.999534) × 1.021 = $271.02).

- *Annual update to the wage index:* We adjust wage indices on an annual basis using the most current hospital wage data and the latest core-based statistical area (CBSA) delineations to account for differing wage levels in areas in which ESRD facilities are located. For CY 2024, we are updating the wage index values based on the latest available data.

- *Annual update to the outlier policy:* We are updating the outlier policy based on the most current data. Accordingly, we are updating the Medicare allowable payment (MAP) amounts for adult and pediatric patients for CY 2024 using the latest available CY 2022 claims data. We are updating the ESRD outlier services fixed dollar loss (FDL) amount for pediatric patients using the latest available CY 2022 claims data and updating the FDL amount for adult patients using the latest available claims data from CY 2020, CY 2021, and CY 2022. For pediatric beneficiaries, the final FDL amount will decrease from $23.29 to $11.32, and the MAP amount will decrease from $25.59 to $23.36, as compared to CY 2023 values. For adult beneficiaries, the final FDL amount will decrease from $73.19 to $71.76, and the MAP amount will decrease from $39.62 to $36.28. The 1.0 percent target for outlier payments was not achieved in CY 2022. Outlier payments represented approximately 0.8 percent of total

[4] 86 FR 7009 (January 25, 2021). *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

Medicare payments rather than 1.0 percent.

• *Update to the offset amount for the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) for CY 2024:* The final CY 2024 average per treatment offset amount for the TPNIES for capital-related assets that are home dialysis machines is $10.00. This offset amount reflects the application of the ESRD Bundled (ESRDB) productivity-adjusted market basket update of 2.1 percent ($9.79 × 1.021 = $10.00). There are no capital-related assets set to receive the TPNIES in CY 2024 for which this offset will apply.

• *Clarifications to the TPNIES eligibility criteria:* We are finalizing certain clarifications regarding our evaluation of the TPNIES eligibility criteria under § 413.236(b).

• *TPNIES application received for CY 2024:* In this final rule, we announce our determination on the one TPNIES application under consideration for the TPNIES for CY 2024 payment.

• *Modifications to the administrative process for the low-volume payment adjustment (LVPA):* We are finalizing exceptions to the current LVPA attestation process for ESRD facilities that are affected by disasters and other emergencies. These exceptions will allow ESRD facilities to close and reopen in response to a disaster or other emergency and still receive the LVPA. Additionally, the exceptions will allow an ESRD facility to receive the LVPA even if it exceeds the LVPA treatment volume threshold if its treatment counts increase due to treating additional patients displaced by a disaster or emergency.

• *Policy to measure patient-level utilization:* We are finalizing a requirement for ESRD facilities to report the time on machine (that is, the amount of time that a beneficiary spends receiving an in-center hemodialysis treatment) on claims, effective January 1, 2025. This will serve to provide more data to better inform CMS's pursuit of equitable payment policies in the future.

• *Transitional Pediatric ESRD Add-on Payment Adjustment (TPEAPA):* We are finalizing the establishment of a new budget neutral add-on payment adjustment of 30 percent of the per treatment payment amount for renal dialysis services furnished to Pediatric ESRD Patients effective January 1, 2024, for CYs 2024, 2025, and 2026. This will serve to bring Medicare payments for renal dialysis services furnished to pediatric patients more in line with their estimated relative costs for the next 3 years until further collection and analysis of cost report data can be conducted.

• *Add-on payment adjustment following the end of the transitional drug add-on payment adjustment (TDAPA) period:* We are finalizing a new add-on payment adjustment for certain new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the end of the TDAPA period, which we call the post-TDAPA add-on payment adjustment. This payment adjustment will be case-mix adjusted and set at 65 percent of expenditure levels for the given renal dialysis drug or biological product. The post-TDAPA add-on payment adjustment will be applied to all ESRD PPS payments and paid for 3 years.

• *Reporting of discarded billing units of certain renal dialysis drugs and biological products paid for under the ESRD PPS:* We are finalizing a new policy to require the use of the JW or JZ modifier on claims to track discarded amounts of single-dose container and single-use package renal dialysis drugs and biological products paid for under the ESRD PPS, effective January 1, 2025.

2. Payment for Renal Dialysis Services Furnished to Individuals With AKI

We are updating the AKI payment rate for CY 2024. The final CY 2024 payment rate is $271.02, which is the same as the base rate finalized for the ESRD PPS for CY 2024.

3. ESRD QIP

We are finalizing several updates for the ESRD QIP. Beginning with PY 2026, we are adding the Facility Commitment to Health Equity reporting measure to the ESRD QIP measure set, modifying the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) reporting measure to align with updated measure specifications developed by the Centers for Disease Control and Prevention (CDC), removing the Ultrafiltration Rate reporting measure and the Standardized Fistula Rate clinical measure, and updating the Clinical Depression Screening and Follow-Up measure's scoring methodology and converting that measure to a clinical measure. Beginning with PY 2027, we are adding the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure to the ESRD QIP measure set. In addition, we are revising the codified definition of ''minimum total performance score'' and codifying our previously finalized measure selection, retention, and removal policies.

4. ETC Model

We are finalizing a modification to our regulations at § 512.390 to acknowledge the ability of the CMS Administrator to review the results of ETC Participants' targeted review requests.

C. Summary of Costs and Benefits

In section VII.D.5 of this final rule, we set forth a detailed analysis of the impacts that the finalized changes will have on affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Final ESRD PPS

The impact table in section VII.D.5.a of this final rule displays the estimated change in Medicare payments to ESRD facilities in CY 2024 compared to estimated Medicare payments in CY 2023. The overall impact of the CY 2024 changes is projected to be a 2.1 percent increase in Medicare payments. Hospital-based ESRD facilities have an estimated 3.1 percent increase in Medicare payments compared with freestanding ESRD facilities with an estimated 2.0 percent increase. We estimate that the aggregate ESRD PPS expenditures will increase by approximately $190 million in CY 2024 compared to CY 2023. This reflects an increase of approximately $180 million from the payment rate update and the final post-TDAPA add-on payment adjustment and approximately $10 million in estimated TDAPA payment amounts for Korsuva® and Jesduvroq (daprodustat), as further described in the following paragraphs. Because of the projected 2.1 percent overall payment increase, we estimate there will be an increase in beneficiary coinsurance payments of 2.1 percent in CY 2024, which translates to approximately $40 million.

Section 1881(b)(14)(D)(iv) of the Act provides that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate. Under this authority, CMS implemented § 413.234 to establish the TDAPA, a transitional drug add-on payment adjustment for certain new renal dialysis drugs and biological products and § 413.236 to establish the TPNIES, a transitional add-on payment adjustment for certain new and innovative equipment and supplies. The TDAPA and the TPNIES are not budget neutral.

As discussed in section II.D of this final rule, the TPNIES payment period for the Tablo® System ends on December 31, 2023. As discussed in section II.E of this final rule, the TDAPA

payment period for Korsuva® (difelikefalin) will continue through March 31, 2024, and for Jesduvroq, will continue throughout 2024. As described in section VII.D.5 of this final rule, we estimate that the overall TDAPA payment amounts in CY 2024 will be approximately $13.3 million, of which, approximately $2.7 million will be attributed to beneficiary coinsurance amounts. We note that these expenditures are estimated in addition to the overall $180 million increase described in the preceding paragraphs and are not fully represented in the detailed impact analysis shown in Table 24.

Lastly as discussed in section II.B.1.i of this final rule, we are finalizing a non-budget-neutral payment adjustment for certain new renal dialysis drugs and biological products after the TDAPA period ends, starting in CY 2024. The structure of the post-TDAPA add-on payment adjustment for a new renal dialysis drug or biological product will be based on the case-mix adjusted average per-treatment expenditure for such drug or biological product. We will apply a 65 percent risk-sharing adjustment to the calculated payment amount for the post-TDAPA add-on payment adjustment. We are finalizing a 3-year period following TDAPA during which the drug or biological product would be included in the post-TDAPA add-on payment adjustment. During this period, the renal dialysis drug or biological product would be considered for outlier payments, if it meets the definition of an ESRD outlier service. The first drug that will meet these criteria in CY 2024 will be Korsuva®, which fits into the existing ESRD PPS functional category for antipruritic drugs and biological products. The post-TDAPA add-on payment adjustment calculated for Korsuva® will be $0.2493.

2. Impacts of the Final Payment Rate for Renal Dialysis Services Furnished to Individuals With AKI

The impact table in section VII.D.5.c of this final rule displays the estimated change in Medicare payments to ESRD facilities for renal dialysis services furnished to individuals with AKI compared to estimated Medicare payments for such services in CY 2023. The overall impact of the CY 2024 changes is projected to be a 2.0 percent increase in Medicare payments for individuals with AKI. Hospital-based ESRD facilities have an estimated 2.1 percent increase in Medicare payments compared with freestanding ESRD facilities that have an estimated 2.0 percent increase. The overall impact reflects the effects of the final Medicare payment rate update and final CY 2024 ESRD PPS wage index. We estimate that the aggregate Medicare payments made to ESRD facilities for renal dialysis services furnished to individuals with AKI, at the final CY 2024 ESRD PPS base rate, will increase by $1 million in CY 2024 compared to CY 2023.

3. Impacts of the Final Changes to the ESRD QIP

We estimate that the overall economic impact of the PY 2026 ESRD QIP will be approximately $136.9 million. The $136.9 million estimate for PY 2026 includes $120.9 million in costs associated with the collection of information requirements and approximately $16 million in payment reductions across all facilities. We also estimate that the overall economic impact of the PY 2027 ESRD QIP will be approximately $144.3 million. The $144.3 million estimate for PY 2027 includes $130.5 million in costs associated with the collection of information requirements and approximately $13.8 million in payment reductions across all facilities.

4. Impacts of the Final Changes to the ETC Model

The impact estimate in section VII.D.5.d of this final rule describes the estimated change in anticipated Medicare program savings arising from the ETC Model over the duration of the ETC Model as a result of the changes in this final rule. We estimate that the ETC Model will result in $28 million in net savings over the 6.5-year duration of the ETC Model. We also estimate that the changes in this final rule will produce no change in net savings for the ETC Model. As the ETC Model targeted review process has already been finalized in the Specialty Care Models final rule and ETC Participants are not required to seek administrative review of targeted review determinations, we expect there will be minimal additional burden associated with the administrative review policy we are finalizing.

II. Calendar Year (CY) 2024 End Stage Renal Disease (ESRD) Prospective Payment System (PPS)

A. Background

1. Statutory Background

On January 1, 2011, CMS implemented the ESRD PPS, a case-mix adjusted bundled PPS for renal dialysis services furnished by ESRD facilities, as required by section 1881(b)(14) of the Act, as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148), established that beginning with CY 2012, and each subsequent year, the Secretary shall annually increase payment amounts by an ESRD market basket percentage increase reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 632 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240) included several provisions that apply to the ESRD PPS. Section 632(a) of ATRA added section 1881(b)(14)(I) to the Act, which required the Secretary, by comparing per patient utilization data from 2007 with such data from 2012, to reduce the single payment for renal dialysis services furnished on or after January 1, 2014, to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals (excluding oral-only ESRD-related drugs). Consistent with this requirement, in the CY 2014 ESRD PPS final rule, we finalized $29.93 as the total drug utilization reduction and finalized a policy to implement the amount over a 3- to 4-year transition period (78 FR 72161 through 72170).

Section 632(b) of ATRA prohibited the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS prior to January 1, 2016. Section 632(c) of ATRA required the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted. Section 217 of PAMA included several provisions that apply to the ESRD PPS. Specifically, sections 217(b)(1) and (2) of PAMA amended sections 1881(b)(14)(F) and (I) of the Act and replaced the drug utilization adjustment that was finalized in the CY 2014 ESRD PPS final rule (78 FR 72161 through 72170) with specific provisions that dictated the market basket update for CY 2015 (0.0 percent) and how the market basket percentage increase should be reduced in CY 2016 through CY 2018.

Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to provide that the Secretary may not pay for oral-only ESRD-related drugs under the ESRD PPS prior to January 1, 2024. Section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by

requiring that in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must use data from the most recent year available. Section 217(c) of PAMA provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment.

Section 204 of the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295) amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis drugs and biological products cannot be made under the ESRD PPS bundled payment prior to January 1, 2025.

2. System for Payment of Renal Dialysis Services

Under the ESRD PPS, a single per-treatment payment is made to an ESRD facility for all the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to individuals for the treatment of ESRD in the ESRD facility or in a patient's home. We have codified our definition of renal dialysis services at § 413.171, which is in 42 CFR part 413, subpart H, along with other ESRD PPS payment policies. The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients and accounts for patient case-mix variability. The adult case-mix adjusters include five categories of age, body surface area, low body mass index, onset of dialysis, and four comorbidity categories (that is, pericarditis, gastrointestinal tract bleeding, hereditary hemolytic or sickle cell anemia, myelodysplastic syndrome). A different set of case-mix adjusters are applied for the pediatric population. Pediatric patient-level adjusters include two age categories (under age 13, or age 13 to 17) and two dialysis modalities (that is, peritoneal or hemodialysis) (§ 413.235(a) and (b)).

The ESRD PPS provides for three facility-level adjustments. The first payment adjustment accounts for ESRD facilities furnishing a low volume of dialysis treatments (§ 413.232). The second payment adjustment reflects differences in area wage levels developed from core-based statistical areas (CBSAs) (§ 413.231). The third payment adjustment accounts for ESRD facilities furnishing renal dialysis services in a rural area (§ 413.233).

There are four additional payment adjustments under the ESRD PPS. The ESRD PPS provides adjustments, when applicable, for: (1) a training add-on for home and self-dialysis modalities (§ 413.235(c)); (2) an additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care (§ 413.237); (3) a TDAPA for certain new renal dialysis drugs and biological products (§ 413.234(c)); and (4) a TPNIES for certain new and innovative renal dialysis equipment and supplies (§ 413.236(d)).

3. Updates to the ESRD PPS

Policy changes to the ESRD PPS are proposed and finalized annually in the **Federal Register**. The CY 2011 ESRD PPS final rule was published on August 12, 2010, in the **Federal Register** (75 FR 49030 through 49214). That rule implemented the ESRD PPS beginning on January 1, 2011, in accordance with section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA, over a 4-year transition period. Since the implementation of the ESRD PPS, we have published annual rules to make routine updates, policy changes, and clarifications.

Most recently, we published a final rule, which appeared in the November 7, 2022, issue of the **Federal Register**, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model,'' referred to herein as the ''CY 2023 ESRD PPS final rule.'' In that rule, we updated the ESRD PPS base rate, wage index, and outlier policy for CY 2023. We also finalized changes that included rebasing and revising the ESRD Bundled (ESRDB) market basket to reflect a 2020 base year, refining the methodology for outlier calculations, implementing a wage index floor of 0.600, implementing a permanent 5 percent cap on year-over-year wage index decreases for ESRD facilities, and modifying the definition of ''oral-only drug.'' For further detailed information regarding these updates, see 87 FR 67136.

B. Provisions of the Proposed Rule, Public Comments, and Response to the Comments on the CY 2024 ESRD PPS

The proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model'' (88 FR 42430 through 42544), referred to herein as the ''CY 2024 ESRD PPS proposed rule,'' appeared in the **Federal Register** on June 30, 2023, with a comment period that ended on August 25, 2023. In that rule, we proposed to make a number of annual updates for CY 2024, including updates to the ESRD PPS base rate, wage index, outlier policy, and the offset amount for the TPNIES. We also proposed two new exceptions to the LVPA eligibility requirements for ESRD facilities impacted by a disaster or other emergency, a new add-on payment adjustment for pediatric ESRD patients, a new add-on payment adjustment for certain new drugs and biological products after the TDAPA period ends, a new reporting requirement for discarded billing units of certain renal dialysis drugs or biological products, and a new reporting requirement for time on machine data for in-center hemodialysis treatments. We proposed clarifications regarding our evaluation of the TPNIES eligibility criteria under § 413.236(b) and included a summary of the one CY 2024 TPNIES application that we received by the February 1, 2023 deadline with our preliminary analysis of the applicant's claims related to substantial clinical improvement and other eligibility criteria for the TPNIES. In addition, the proposed rule included a request for information regarding potential changes to the LVPA and a potential new payment adjustment for geographic isolation.

We received 344 public comments on our ESRD PPS proposals, including comments from kidney and dialysis organizations, such as large and small dialysis organizations; for-profit and non-profit ESRD facilities; ESRD networks; and a dialysis coalition. We also received comments from patients; healthcare providers for adult and pediatric ESRD beneficiaries; home renal dialysis services and advocacy organizations; provider and legal advocacy organizations; administrators and insurance groups; a non-profit dialysis association, a professional association, and alliances for kidney care and home dialysis stakeholders; drug and device manufacturers; health care systems; a health care consultant; and the Medicare Payment Advisory Commission (MedPAC).

We received comments related to issues that we either did not discuss in the CY 2024 ESRD PPS proposed rule or that we discussed for the purpose of background or context, but for which we did not propose changes in the rule. These include, for example, concerns regarding staff training, education for kidney disease patients, access to innovation for Medicare Advantage

beneficiaries, transportation for ESRD patients, nutrition for ESRD patients, and telehealth. We also received several comments on Medicare coverage for certain Humanitarian Use Devices. We are not providing detailed responses to those comments in this final rule because they are out of the scope of the CY 2024 ESRD PPS proposed rule. We thank the commenters for their input and will consider the recommendations in potential future rulemaking.

We received numerous comments on the potential inclusion of oral-only drugs into the ESRD PPS bundled payment beginning January 1, 2025. As noted in the CY 2023 ESRD PPS final rule (87 FR 67180), we expect that the only oral-only drugs and biological products that would be included in the ESRD bundled payment in CY 2025 are phosphate binders. Commenters expressed concerns on potential access and health equity issues, which could result from including oral-only drugs and biological products in the ESRD PPS bundled payment. Some commenters also expressed additional concerns associated with the potential inclusion of oral-only drugs and biological products in the ESRD PPS bundled payment, such as concerns about the following: the administrative burden of managing a patient's dosage and combination of phosphate lowering drugs; administration of the prescription insofar as patients think they must go to the ESRD facility to obtain the phosphate binders; confusion for patients, in that some patients think the phosphate lowering drugs would only be dispensed at the ESRD facility, and since the drugs must be taken with food, they would not be able to take the drugs because eating during dialysis is not allowed, or they must go to the ESRD facility to get the phosphate binders even when they do not have a dialysis treatment; innovation of new oral-only drugs and biological products, such as phosphate lowering therapies, would be unavailable because of the cost of the new drugs or biological products; and the definition of oral-only drugs and biological products for phosphate lowering agents until an intravenous or injectable equivalent of the drug is available. We thank the commenters for their insight regarding the potential inclusion of oral-only drugs and biological products in the ESRD PPS bundled payment beginning in CY 2025; however, we did not make any proposals related to the potential inclusion of oral-only drugs and biological products in the ESRD PPS bundled payment in CY 2025 in the CY 2024 ESRD PPS proposed rule. We will take commenters' insight, concerns, and recommendations into consideration for future rulemaking on this topic.

Additionally, we received some comments from commenters including ESRD patients and caregivers which contained details of quality-of-care concerns or adverse quality events for which the commenters had first-hand experience. We address these comments as they concern the proposals in the CY 2024 ESRD PPS proposed rule, but we wish to note that any serious adverse quality events can be reported to the CMS ombudsman. Information on beneficiary rights and how to report quality events can be found at *https://www.cms.gov/center/special-topic/ombudsman/medicare-beneficiary-ombudsman-home*.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the CY 2024 ESRD PPS.

1. CY 2024 ESRD PPS Update

a. CY 2024 ESRD Bundled (ESRDB) Market Basket Percentage Increase; Productivity Adjustment; and Labor-Related Share

(1) Background

In accordance with section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket percentage increase and reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The application of the productivity adjustment may result in the increase factor being less than 0.0 for a year and may result in payment rates for a year being less than the payment rates for the preceding year. Section 1881(b)(14)(F)(i) of the Act also provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services.

As required under section 1881(b)(14)(F)(i) of the Act, CMS developed an all-inclusive ESRD Bundled (ESRDB) input price index using CY 2008 as the base year (75 FR 49151 through 49162). We subsequently revised and rebased the ESRDB input price index to a base year of CY 2012 in the CY 2015 ESRD PPS final rule (79 FR 66129 through 66136). In the CY 2019 ESRD PPS final rule (83 FR 56951 through 56964), we finalized a rebased ESRDB input price index to reflect a CY 2016 base year. In the CY 2023 ESRD PPS final rule (87 FR 67141 through 67154), we finalized a revised and rebased ESRDB input price index to reflect a CY 2020 base year.

Although ''market basket'' technically describes the mix of goods and services used for ESRD treatment, this term is also commonly used to denote the input price index (that is, cost categories, their respective weights, and price proxies combined) derived from a market basket. Accordingly, the term ''ESRDB market basket,'' as used in this document, refers to the ESRDB input price index.

The ESRDB market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres-type price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time are not measured.

(2) CY 2024 ESRD Market Basket Update

We proposed to use the 2020-based ESRDB market basket as finalized in the CY 2023 ESRD PPS final rule (87 FR 67141 through 67154) to compute the proposed CY 2024 ESRDB market basket percentage increase based on the best available data. Consistent with historical practice, we proposed to estimate the ESRDB market basket percentage increase based on IHS Global Inc.'s (IGI) forecast using the most recently available data at the time of rulemaking. IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets. As discussed in the CY 2024 ESRD PPS proposed rule (88 FR 42435 through 42436), we proposed to calculate the market basket update for CY 2024 based on the proposed market basket percentage increase and the proposed productivity adjustment, following our longstanding methodology.

(a) CY 2024 Market Basket Percentage Increase

Based on IGI's first quarter 2023 forecast of the 2020-based ESRDB market basket, the proposed CY 2024 market basket percentage increase was 2.0 percent. We also proposed that if more recent data became available after the publication of the CY 2024 ESRD PPS proposed rule and before the publication of the final rule (for example, a more recent estimate of the market basket percentage increase), we would use such data, if appropriate, to determine the CY 2024 market basket percentage increase in this final rule.

(b) Productivity Adjustment

Under section 1881(b)(14)(F)(i) of the Act, as amended by section 3401(h) of the Affordable Care Act, for CY 2012 and each subsequent year, the ESRDB market basket percentage increase shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year (FY), year, cost reporting period, or other annual period) (the ''productivity adjustment'').

The Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the United States economy. As we noted in the CY 2023 ESRD PPS final rule (87 FR 67155), the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act previously was published by BLS as private nonfarm business MFP. Beginning with the November 18, 2021, release of productivity data, BLS replaced the term ''multifactor productivity'' with ''total factor productivity'' (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology.[5] As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as private nonfarm business TFP; however, as mentioned previously, the data and methods are unchanged. We referred readers to *https://www.bls.gov/productivity/* for the BLS historical published TFP data. A complete description of IGI's TFP projection methodology is available on CMS's website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch*. In addition, in the CY 2022 ESRD PPS final rule (86 FR 61879), we noted that effective for CY 2022 and future years, we will be changing the name of this adjustment to refer to it as the productivity adjustment rather than the MFP adjustment. We stated this was not a change in policy, as we will continue to use the same methodology for deriving the adjustment and rely on the same underlying data.

Based on IGI's first quarter 2023 forecast, the proposed productivity adjustment for CY 2024 (the 10-year moving average of TFP for the period ending CY 2024) was 0.3 percentage point. Furthermore, we proposed that if more recent data became available after the publication of the CY 2024 ESRD PPS proposed rule and before the publication of this final rule (for example, a more recent estimate of the productivity adjustment), we would use such data, if appropriate, to determine the CY 2024 productivity adjustment in this final rule.

(c) CY 2024 Market Basket Update

In accordance with section 1881(b)(14)(F)(i) of the Act, we proposed to base the CY 2024 market basket percentage increase on IGI's first quarter 2023 forecast of the 2020-based ESRDB market basket. We proposed to then reduce this percentage increase by the estimated productivity adjustment for CY 2024 based on IGI's first quarter 2023 forecast. Therefore, the proposed CY 2024 ESRDB market basket update was equal to 1.7 percent (2.0 percent market basket percentage increase reduced by a 0.3 percentage point productivity adjustment). Furthermore, as noted previously, we proposed that if more recent data became available after the publication of the CY 2024 ESRD PPS proposed rule and before the publication of the final rule (for example, a more recent estimate of the market basket and/or productivity adjustment), we would use such data, if appropriate, to determine the CY 2024 market basket percentage increase and productivity adjustment in the final rule.

We invited public comment on our proposals for the CY 2024 ESRDB market basket update and productivity adjustment. Approximately 150 commenters, including large dialysis organizations (LDOs); provider advocacy organizations; nonprofit dialysis associations; a coalition of dialysis organizations; a network of dialysis organizations; professional organizations and several ESRD facilities, commented on the proposed CY 2024 ESRDB market basket update. The following is a summary of the public comments received on these proposals and our responses.

Comment: Commenters generally supported increasing the ESRD PPS base rate and the utilization of the most recent data available (for example, a more recent estimate of the market basket and/or productivity adjustment) to determine the final CY 2024 ESRD PPS update. MedPAC recommended that the ESRD PPS base rate increase for CY 2024 should be updated by the amount determined under current law, and commented that analysis reported in the March 2023 Report to the Congress: Medicare Payment Policy [6] concluded that this increase is warranted based on its analysis of payment adequacy (which includes an assessment of beneficiary access, supply and capacity of facilities, facilities' access to capital, quality, and financial indicators for the sector). Many commenters expressed concern that the CY 2024 payment update does not adequately factor in the effects of many challenges faced by ESRD facilities, such as the impact of the COVID–19 public health emergency (PHE), inflationary pressure, higher patient acuity, Federal budget sequestration, increasing labor costs due to labor shortages, and other increased costs, such as personal protective equipment (PPE), drugs, and supplies. Several commenters also asserted that during the last two ESRD PPS rulemaking cycles the ESRDB market basket updates have not kept pace with the market basket increases for other Medicare providers, such as hospitals and Skilled Nursing Facilities (SNFs). Commenters additionally noted that the proposed CY 2024 ESRDB market basket increase was lower than certain other estimates of overall inflation and healthcare-specific inflation. One commenter stated that since the ESRD PPS' inception, the annual updates in several years have fallen far below other measures, such as general inflation or health care inflation as measured by the Consumer Price Index (CPI).

Response: We are required to update ESRD PPS payments annually by the market basket update adjusted for productivity, as directed by section 1881(b)(14)(F)(i) of the Act. Specifically, section 1881(b)(14)(F)(i)(I) of the Act states that the increase factor shall be based on an ESRD market basket percentage increase for a bundled payment system for renal dialysis services that reflects changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services. We believe the increase in the 2020-based ESRDB market basket adequately reflects the average change in the price of goods and services ESRD facilities purchase to provide ESRD medical services and is technically appropriate to use as the ESRD payment update factor. The ESRDB market basket is a fixed-weight, Laspeyres-type index that measures price changes over time and would not reflect increases in costs associated with changes in the volume or intensity of

[5] Total Factor Productivity in Major Industries—2020. Available at: *https://www.bls.gov/news.release/prod5.nr0.htm.*

[6] *https://www.medpac.gov/wp-content/uploads/2023/03/Mar23_MedPAC_Report_To_Congress_v2_SEC.pdf.*

input goods and services. As such, the ESRDB market basket update would reflect the prospective price pressures described by the commenters (such as wage growth or higher energy prices) but would not inherently reflect other factors that might increase the level of costs, such as the quantity of labor used or any shifts between contract workers and staffed employees. We note that cost changes (that is, the product of price and quantities) would only be reflected when a market basket is rebased, and the base year weights are updated to a more recent time period. We finalized the 2020-based ESRDB market basket in the CY 2023 ESRD PPS final rule (87 FR 67141), and therefore, any change in the cost structure for ESRD facilities that occurred between 2016 and 2020 is now reflected in the cost weights for the 2020-based ESRDB market basket, which was the most recent fully complete cost data available at the time of rulemaking. We will continue to monitor the cost share weights and, if technically appropriate, consider rebasing the ESRDB market basket more frequently than usual should the cost weights change significantly. Any proposal to rebase the ESRDB market basket would occur through notice-and-comment rulemaking. The final CY 2024 ESRDB market basket update reflects the most recent available data regarding prices of labor used to provide renal dialysis services. As set forth later in section II.B.1.a.(2)(c) of this final rule, the final productivity-adjusted CY 2024 ESRDB market basket update is 2.1 percent, representing a ESRDB market basket increase of 2.4 percent reduced by a productivity adjustment of 0.3 percent. We note that the final CY 2024 ESRDB market basket update is 0.4 percentage points higher than the proposed CY 2024 ESRDB market basket update. We recognize that this 2.1 percent productivity-adjusted ESRDB market basket update may still be lower than some commenters believe is appropriate; however, it reflects the most recent available data regarding expected price inflation for inputs required to provide renal dialysis services based on CMS's longstanding methodology.

We acknowledge commenters' claims that the CY 2024 ESRD PPS proposed market basket increase is less than increases for other Medicare payment systems, including the Inpatient Prospective Payment System (IPPS) and the Hospital Outpatient Prospective Payment System (OPPS). In response to these concerns, we note that one cause of these differences is that the mix of inputs used to provide renal dialysis services is different from those used for other services captured by other CMS market baskets. For example, the ESRDB market basket labor cost weights (reflecting those cost weights that use an Employment Cost Index (ECI) as price proxy) are generally lower than the labor cost weights in other CMS PPS market baskets, and the pharmaceuticals and medical supply cost weights in the ESRDB market basket (which is based on the ESRD Medicare cost report (Form CMS–265–11)) are higher than the pharmaceuticals and medical supply cost weights in other CMS PPS market baskets.[7] The weighting together of these different mixes of inputs can appropriately result in differential rates of increase for various market baskets. Additionally, we acknowledge that many measures of inflation are higher than both the proposed 1.7 percent and the final 2.1 percent productivity-adjusted ESRDB market basket update for CY 2024. We note that some of the measures of inflation that commenters referenced in their comments are either measures of past inflation or measures of current inflation. The ESRDB market basket update is based on a forecast for the changes in input prices as measured by the ESRDB market basket for CY 2024, and not a measure of inflation during CY 2023. Under section 1881(b)(14)(F)(i) of the Act, the annual market basket update reflects the changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services. We believe that this is a more accurate estimate of the changes in input prices faced by ESRD facilities than less specific measures such as overall inflation or inflation across the entire healthcare sector. Additionally, concerns raised by commenters that the ESRDB market basket updates have been lower than general inflation or healthcare inflation measures are not relevant comparisons, because the law requires that the increase be based on an index that measures input price pressures for providing renal dialysis services. We acknowledge that many patients, ESRD facilities, and other health care providers believe that rising prices are a major concern in providing high quality care; however, we project that growth in input prices for renal dialysis services will slow in CY 2024 relative to CY 2023, which is reflected in the productivity-adjusted ESRDB market basket update of 2.1 percent.

Comment: Several commenters indicated a belief that the ESRDB market basket update would have an impact on quality of care provided by ESRD facilities. Other commenters indicated that they believe the current quality of care that ESRD PPS beneficiaries receive is too low, and used this belief as justification for either supporting or opposing the ESRDB market basket update.

Response: We appreciate commenters' insight into the quality of care which Medicare beneficiaries receive at ESRD facilities. Medicare beneficiaries have a right to safe, appropriate, and quality health services. For ESRD facilities, the Federal health and safety requirements are codified at 42 CFR part 494. To determine if a facility meets ESRD conditions for coverage, the State survey agency (SA), or a CMS-approved national accrediting organization (AO), performs an on-site survey of the facility. After the initial approval, dialysis facilities have routine onsite surveys to monitor compliance with the Federal requirements. If a dialysis facility is found to be deficient in one or more of the standards in the conditions for coverage, it may participate in, or be covered under, the Medicare program only if the dialysis facility has submitted an acceptable plan of correction for achieving compliance within a reasonable period of time acceptable to CMS. In the case of an immediate jeopardy situation (that is, a situation in which the facility's non-compliance with one or more Medicare conditions for coverage has caused, or is likely to cause, serious injury, harm, impairment, or death to a patient), we may require a shorter time period for achieving compliance.

When poor quality or unsafe health care is furnished by any type of Medicare-certified provider or supplier, a complaint may be filed by anyone, including patients, family members, or staff. Dialysis facility complaints relating to improper care, unsafe conditions, and quality of care may be filed with the State Health Department or the ESRD Network.[8]

CMS has an established complaint process to protect all patients from abuse, neglect, exploitation, and inadequate care and supervision. The goal of the complaints process is to establish a system that will assist in promoting and protecting the health and safety of all patients receiving health services in a Medicare-certified facility. The procedures for handling complaints

[7] Public data can be found at *https://www.bls.gov/eci/home.htm* and *https://www.cms.gov/data-research/statistics-trends-and-reports/cost-reports.*

[8] *https://www.cms.gov/training-education/open-door-forums/end-stage-renal-disease-clinical-laboratories-esrd/network.*

are outlined in Chapter 5 of the State Operations Manual,[9] and they are followed when complaints and reported incidents, including referrals from the public or other Federal entities, involve Medicare-certified providers/suppliers. The evaluation, investigation, and resolution of complaints are critical certification activities. CMS and the SAs, or AOs, are responsible for ensuring that participating providers/suppliers of healthcare services continually meet Federal requirements. This requires that the SA, or AO, promptly reviews complaints/incidents, conducts unannounced onsite investigations of reports alleged noncompliance, and informs the CMS locations any time a facility is found to be out of compliance with the applicable certification requirements. We believe the resources provided by the ESRD PPS are appropriate to enable ESRD facilities to comply with the requirements and procedures described above.

Comment: One ESRD patient stated that ESRD facilities were already being paid too much and that the quality of care provided by ESRD facilities was insufficient given the payment amount.

Response: We appreciate the comments on Medicare payment amounts to ESRD facilities. As stated previously, we are required to update ESRD PPS bundled payments by the market basket update adjusted for productivity under section 1881(b)(14)(F)(i) of the Act, which states that the Secretary shall annually increase payment amounts by an ESRD market basket percentage increase that reflects changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services. As such, we believe that the final CY 2024 ESRDB market basket update is appropriate. We note that MedPAC states that payment rates are adequate for the ESRD facilities. In addition, regarding the commenter's belief that ESRD facilities are being paid too much, and the concerns the commenter noted citing specific quality of care issues for ESRD patients, we note that, as described earlier in this section, CMS is actively engaged in efforts to ensure Medicare ESRD beneficiaries receive quality care. Additionally, the ESRD QIP actively monitors and adjusts payments to facilities under the ESRD PPS based on their performance on several quality measures.

Comment: Several commenters, including a coalition of dialysis organizations, stated that ESRD facilities face relatively small profit margins when caring for Medicare beneficiaries and indicated that they believe the ESRDB market basket increase amount would lead to lower standards of care in CY 2024 and that to prevent this, CMS should consider increasing payments by a larger amount. One ESRD patient characterized the proposed CY 2024 ESRDB market basket update as being insufficient for the extent of the financial impact of recent inflationary events. Numerous commenters stated that a larger payment rate increase would allow ESRD facilities to hire more staff and increase the quality of care. Some commenters suggested that CMS reevaluate the proposed market basket update and instead increase ESRD PPS payments by a larger amount.

Response: We understand that commenters are concerned about the profit margins for ESRD facilities. As stated previously, we believe that the final CY 2024 ESRDB market basket update reflects the most recent available data regarding the input prices required to provide renal dialysis services. We did not propose any additional increases to the ESRD PPS base rate to improve ESRD facility margins or otherwise account for factors that commenters believe are not adequately represented in the market basket update methodology, and we are not finalizing any such increases. We will continue to monitor the adequacy of the ESRD PPS payment amount and will consider these comments in potential future rulemaking. In addition, as described earlier in this section, CMS is actively engaged in efforts to ensure Medicare ESRD beneficiaries receive quality care.

Comment: Several commenters, including a provider advocacy organization, noted that the ESRD PPS payment rate update would have implications for Medicare Advantage payment rates. Many of these commenters expressed that the proposed ESRDB market basket update of 1.7 percent would lead to lower payments from Medicare Advantage.

Response: We understand that some commenters are concerned about the impact that the proposed CY 2024 ESRDB market basket update would have on rates for other payors, including Medicare Advantage. However, we are required to update the ESRD PPS bundled payment by the market basket update adjusted for productivity under section 1881(b)(14)(F)(i) of the Act, which states that the Secretary shall annually increase payment amounts by an ESRD market basket percentage increase that reflects changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services. This update is not intended to account for or direct the business practices of other payors. We note that the final productivity-adjusted CY 2024 ESRDB market basket update is 2.1 percent, which represents an increase to the proposed productivity-adjusted CY 2024 ESRDB market basket update of 1.7 percent, and we anticipate that the increase alleviates some of the commenters' concerns. We did not propose to make any additional methodological changes to the market basket update or ESRD PPS base rate to account for other payors and are not finalizing any additional methodological changes on this topic.

Comment: We received numerous other comments on potential implications of the proposed CY 2024 ESRDB market basket update. Several commenters claimed the proposed CY 2024 ESRD PPS base rate update would have a negative impact on other factors including, but not limited to, wait times for dialysis appointments, access to innovative treatments for ESRD patients, ESRD treatments for nursing home patients, ESRD treatments for the elderly, Medicare Part A payments, and hospitalizations for ESRD PPS patients.

Response: We recognize that commenters are concerned about the impact that the magnitude of the CY 2024 ESRDB market basket update has on ESRD facilities' ability to provide quality renal dialysis services. As stated previously, the final CY 2024 ESRDB market basket update reflects the most recent available data regarding prices for inputs used to provide renal dialysis services. We recognize that payment policy within the ESRD PPS can affect the quality and accessibility of renal dialysis services; however, the CY 2024 ESRDB market basket update adequately reflects the average change in the price of goods and services ESRD facilities purchase to provide renal dialysis services, so we do not agree with commenters' claims that the ESRDB market basket update would have a negative impact on these other factors. We did not propose any changes to the existing ESRDB market basket update methodology in the CY 2024 ESRD PPS proposed rule and are not finalizing any such methodological changes in this rule. We appreciate the insight of commenters into the implications of the ESRDB market basket update and will keep these implications in mind in future rulemaking.

Comment: Several commenters questioned CMS's longstanding market basket methodology. Commenters expressed concern over the accuracy of the forecast underlying the proposed

[9] *https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/downloads/som107c05pdf.pdf.*

market basket update for CY 2024, including that CMS's use of the IGI forecast for determining the market basket update does not capture the specialized nature of ESRD facility costs. A few commenters requested that CMS reexamine the forecasting approach or consider other methods and data sources to calculate the final rule market basket update that better reflect the rapidly increasing input prices and costs facing ESRD facilities. Other commenters indicated that they believed that it is inappropriate to continue to use the same mix of goods and services that were used at the inception of the ESRD PPS in the CY 2011 ESRD PPS final rule. One ESRD facility suggested that, because there has been significant variation between the forecasted and actual ESRDB market basket price growth, CMS should evaluate whether the market basket methodology is inherently flawed. Several commenters believed that a retrospective adjustment to the base rate to account for past differences between the ESRDB market basket update for a given year and what the ESRDB market basket update would have been for that year based on the actual changes in prices, known as a forecast error adjustment, could alleviate some of the perceived flaws in the market basket update methodology.

Response: We thank commenters for providing these comments on the ESRDB market basket update methodology. In response to the commenters' request that we reexamine the current forecasting approach for determining the ESRDB market basket update, we provide the following information. IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the price proxies used in the market baskets. At the time of the CY 2024 ESRD PPS proposed rule, based on the IGI first quarter 2023 forecast with historical data through the fourth quarter of 2022, the 2020-based ESRDB market basket update was forecasted to be 2.0 percent for CY 2024, reflecting forecasted compensation price growth of 3.7 percent (by comparison, compensation price growth in the ESRDB market basket averaged 2.6 percent from 2013 to 2022). In the CY 2024 ESRD PPS proposed rule, we proposed that if more recent data became available, we would use such data, if appropriate, to derive the final CY 2024 ESRDB market basket update for the final rule. For this final rule, we now have an updated forecast of the price proxies underlying the market basket that incorporates more recent historical data and reflects a revised outlook regarding the U.S. economy and expected price inflation for CY 2024. Based on IGI's third quarter 2023 forecast with historical data through the second quarter of 2023, we are projecting a CY 2024 ESRDB market basket update of 2.4 percent (reflecting forecasted compensation price growth of 4.1 percent) and a productivity adjustment of 0.3 percentage point. Therefore, for CY 2024 a final ESRDB productivity-adjusted market basket update of 2.1 percent (2.4 percent less 0.3 percentage point) will be applicable, compared to the 1.7 percent productivity-adjusted market basket update that was proposed. We note that section 1881(b)(14)(F)(i) of the Act states that the Secretary shall annually increase payment amounts by an ESRD market basket percentage increase that reflects changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services. We believe that the current market basket update methodology as finalized in the CY 2011 ESRD PPS final rule (75 FR 49151 through 49162), and most recently updated in the CY 2023 ESRD PPS final rule (87 FR 67141 through 67157) to reflect a 2020 base year, fulfills this statutory requirement. We support the continued use of the current mix of goods and services to provide continuity to the financial impacts of the ESRD PPS payment policy, and we note that the weighting for this mix of goods and services is updated periodically through rebasing. However, we will consider the commenter's suggestion regarding the use of different methods or other data sources for the ESRDB market basket for future rulemaking. We discuss the commenters' request for a forecast error adjustment below. We did not propose any methodological changes to the ESRDB market basket update methodology for CY 2024, and we are finalizing the continued use of the ESRDB market basket methodology as finalized in the CY 2023 ESRD PPS final rule (87 FR 67141 through 67157). We do not believe that the ESRDB market basket update is inherently flawed because the forecast errors for CYs 2021 and 2022 were higher-than-normal due to the high inflation during the COVID–19 PHE, which we discuss further in section II.B.1.a.(2)(d) of this final rule. We will continue to monitor the performance of the ESRDB market basket update, and we will keep these comments on the market basket methodology in mind for future rulemaking. We note that CMS engages with the public, including the dialysis industry and associations, routinely throughout the year in our continuing efforts to align payment with resource utilization. We welcome continuing dialogue on the topic of improving the market basket update methodology, and other topics pertinent to the ESRD PPS, toward the common goal of improving care for ESRD patients.

Comment: Some commenters provided information on additional rising costs faced by ESRD facilities that the commenters believed were not adequately captured in the proposed CY 2024 ESRDB market basket update. These additional costs included the following: costs associated with compliance with additional regulations regarding infection control; costs related to supply chain problems; rising costs for certain supplies; and cost related to changes in labor, such as additional pay for traveling nurses or contract nurses.

Response: We appreciate the insight into changing costs that ESRD facilities face. As stated previously, the final CY 2024 ESRDB market basket update reflects the most recent available data regarding prices for inputs used to provide renal dialysis services. These costs which commenters listed are included in the ESRDB and so the change in their prices would be included in the CY 2024 ESRDB market basket update. If the rising costs the commenters' mentioned are due to an increase in quantity of the good purchased, rather than an increase in price, we note that such cost changes would only be reflected when a market basket is rebased, and the base year weights are updated to a more recent time period. We finalized the 2020-based ESRDB market basket in the CY 2023 ESRD PPS final rule (87 FR 67141); therefore, any change in the cost structure for ESRD facilities that occurred between 2016 and 2020 is now reflected in the cost weights for the 2020-based ESRDB market basket, which was the most recent fully complete cost data available at the time of rulemaking. We believe that it is technically appropriate to use the 2020-based ESRDB market basket for the CY 2024 ESRDB market basket update.

Comment: One commenter asserted that experience over the past few years has indicated that the ESRD PPS methodology is unable to reflect short-term and long-term impacts of an economic shock, such as the COVID–19 PHE. The commenter noted that although CMS offers detailed explanations of the market basket's construction and issues data through its website, the dialysis provider community still has little insight into the factors contributing to annual

payment updates that the commenter believes consistently fail to reflect increases in the cost of care delivery. The commenter urged CMS to engage in a formal dialogue with the kidney care community outside of the annual rulemaking process to better identify the methodology's limitations and inform development of improvements. The commenter also requested that IGI have representation and participation in this dialogue.

Response: We appreciate the commenter's concerns regarding the market basket methodology. Our longstanding ESRDB market basket update methodology sets rates prospectively on an annual basis. We acknowledge that over the course of a year, short term changes in economic conditions can lead to uncertainty, which may be exacerbated by economic shocks. Because the ESRD PPS base rate is updated annually, the purpose of the ESRDB market basket update is to account for the change in price of the ESRDB from year to year, not necessarily to capture the effect of shorter term fluctuations of prices. That short term fluctuations are not addressed by the ESRDB market basket update is a consequence of the annual nature of the update as required by section 1881(b)(14)(F) of the Act. We believe the ESRDB market basket update appropriately captures the change in the price of goods and services over time in the long term. Some commenters have suggested a forecast error adjustment as a way to mitigate the impact of these short-term uncertainties, which we discuss in further detail in section II.B.1.a.(2)(d) of this final rule. CMS will continue to engage with the public regarding ways to ensure the Medicare ESRD PPS payments are appropriate and that the market basket price proxies and base year weights are accurate.

Comment: We received several comments, including from a patient organization, stating that the proposed ESRDB market basket update would not sufficiently support innovation.

Response: We note that ESRD PPS policies to encourage the adaptation of new innovations, such as the TDAPA and TPNIES, are add-on payment adjustments to the base rate, and although there is only one ESRD PPS bundled payment, these adjustments are not a part of the ESRDB and therefore, are not included in the ESRD PPS base rate or the ESRDB market basket update. This is similarly true for the post-TDAPA add-on payment adjustment that we are finalizing in this rule, which is described in further detail in section II.B.1.i of this final rule. These add-on payment adjustments are actively supporting the adoption of certain new and innovative drugs, biological products, equipment and supplies by ESRD facilities, by providing additional payment to offset the additional cost of those drugs, biological products, equipment and supplies. We did not propose any changes to the ESRDB market basket update methodology to account for innovation within the ESRD PPS and are not finalizing any such changes in this final rule. We will consider these comments on supporting innovation and access to innovative products in potential future rulemaking.

Comment: We received approximately 90 comments related to the nature of labor costs at ESRD facilities, including comments from large dialysis organizations, advocacy organizations, ESRD facilities, providers, and a coalition of dialysis organizations. Commenters generally stated that labor costs at ESRD facilities are increasing, which is driving overall cost increases at ESRD facilities, and that the proposed ESRDB market basket update was insufficient to cover these increased labor costs. Many of the commenters cited that the growth in their labor costs has outpaced the ESRDB market basket updates or the growth of the market basket compensation cost category in the ESRDB market basket. Additionally, some commenters noted that labor costs were rising across the healthcare sector, which the commenters asserted was not appropriately reflected in the ESRDB market basket update. Commenters described other barriers to hiring and maintaining staff including, but not limited to, burnout, lack of resources, inability to match competitive pay, and long travel times for staff. A coalition of dialysis organizations commented that it was increasingly difficult for ESRD facilities to hire new staff while competing with other health care providers with more resources and non-healthcare employers. They stated that this was leading to some ESRD facilities having to turn away patients or being unable to continue operations. One LDO noted that staffing concerns are leading to ESRD facilities using a higher percentage of more-expensive contract labor and that contract labor wages and benefits make up 1.9 percent and 0.5 percent of the 2020-based ESRDB, respectively. Some commenters highlighted the COVID–19 PHE as a significant factor in the workforce shortage that ESRD facilities face; however, some commenters indicated that they believe this workforce shortage has been in progress for a long time.

Some ESRD facilities and LDOs included various additional information or data on the extent to which their labor costs have increased over the past few years. Several commenters, including an LDO and a non-profit dialysis organization, referenced an analysis that showed labor costs grew at a compound average growth rate of 6.96 percent from 2018 to 2022, whereas the proxy for labor used in the ESRDB market basket update methodology grew at a compound average growth rate of 3.15 percent from 2018 to Q1 2022. One provider advocacy organization commented that its analysis found that direct patient care labor costs per dialysis treatment increased by 18.9 percent from 2017 to 2022.

Commenters also stated that the increasing labor costs were resulting in staffing concerns at ESRD facilities. Some of these comments highlighted access issues arising from fewer available dialysis sessions. Some comments referenced quality issues related to the burden placed on workers at ESRD facilities by low staffing and the limited training of staff at ESRD facilities due to high turnover. Many of these comments came from ESRD patients, caretakers and patient advocates and included the commenters' personal experience on the issues related to receiving care at ESRD facilities (for example, difficulty finding appointments, having to travel significant distances to get care, and how low staffing at ESRD facilities has impacted their care). Other commenters conveyed their concern about inadequate staffing and related many incidents of significant adverse events and sub-standard quality care, which they attributed to low staffing. A kidney disease patient organization included multiple testimonials from ESRD patients regarding their issues in trying to locate dialysis treatments.

Some commenters highlighted the impact that staffing shortages had on home dialysis. Several patients expressed a willingness and desire for self-dialysis training, but stated they were unable to receive self-dialysis dialysis training due to staff shortages at their clinics.

Response: We thank commenters for their insight into labor supply and labor costs at ESRD facilities, and we recognize that labor costs are a driving factor in cost increases at ESRD facilities. We acknowledge that CY 2022 price growth for the 2016-based ESRDB market basket was higher (5.1 percent) than was forecasted at the time of the CY 2022 ESRD PPS final rule (2.4 percent). We note that the lower projected CY 2024 ESRDB market basket percent increase (2.4 percent) relative to the observed CY 2022 historical increase, as well as the forecasted CY

2023 ESRDB market basket increase of 3.1 percent, reflect the expectation that wage and price pressures will lessen in CY 2024 compared to recent years. As described previously, the ESRDB market basket measures price changes (including changes in the prices for wages and salaries and benefits) over time and would not reflect increases in costs associated with changes in the volume or intensity of input goods and services until the market basket is rebased. An ESRD-specific compensation price index is unavailable; therefore, we use a composite wage and benefit index of various Employment Cost Indices (ECIs) reflecting the occupational mix of full-time equivalents (FTE) data from ESRD Medicare Cost reports and ECIs from BLS (87 FR 67147). Health-related occupations account for 79 percent of the 2020-based ESRDB compensation cost weight and are proxied by the ECI for All Civilian Workers in Hospitals, reflecting similar medical occupations used in ESRD facilities (particularly nurses) and their associated price growth. As discussed in the CY 2023 ESRD PPS final rule, we believe the composite weighted index for wages and salaries and benefits to be a reasonable proxy for the compensation component of the ESRDB market basket. We note that section 1881(b)(14)(F)(i) of the Act states that the Secretary shall annually increase payment amounts by an ESRD market basket percentage increase that reflects changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services. While labor is included in the mix of goods and services in the ESRD PPS bundled payment, the annual market basket increase accounts for more than the price change for labor. As such, it is possible for the market basket increase to be less than the increase in the price of labor if the other goods and services included in the ESRDB do not experience as large of a price increase. Our analysis of the data used to determine the ESRDB market basket forecast indicates that this dynamic is reflected in the market basket increases for the past few years. For example, in 2021 the overall market basket forecast was an increase of 1.9 percent, but the labor portion of the ESRDB market basket was forecasted to increase by 2.5 percent. We recognize commenters' view that the proposed ESRDB market basket increase for CY 2024 was less than ESRD facilities' reported labor increases. However, if, as commenters have stated, labor is the driving factor for the increase in costs for ESRD facilities, it would be expected that the labor percentage increase would be greater than the overall ESRDB market basket percentage increase. This is because the ESRDB market basket increase is a weighted average of the changes in prices for the ESRDB market basket. Labor is only one part of the ESRDB market basket, and commenters have indicated that other components of the ESRDB market basket have not experienced the same growth in price as labor. We believe the 2020-based ESRDB market basket increase adequately reflects the average change in the price of goods and services ESRD facilities purchase to provide renal dialysis services, including labor, and is technically appropriate to use as the ESRD PPS payment update factor. The ESRDB market basket update will reflect the expected prospective price pressures described by the commenters as increasing during a high inflation period (such as faster wage growth or higher energy prices) but inherently will not reflect other factors that might increase the level of costs, such as the quantity of labor used. Therefore, the final CY 2024 ESRDB market basket update reflects the most recent available data regarding both prices and the items and services used to provide renal dialysis services.

We thank commenters for including detailed information and data on the changes to labor costs that ESRD facilities face. We agree that during the COVID–19 PHE, labor costs increased more than normal. According to our analysis, the ESRDB market basket compensation price growth was forecasted to increase a cumulative 18.9 percent from CY 2017 to CY 2022. This is the same as the figure which one commenter described as being the change in direct labor costs over that time. We recognize that some comments indicated that ESRD facilities experienced larger or smaller changes in labor costs than this over that time. We note that the ESRDB market basket does not measure each individual ESRD facility's own experience, but instead the ESRDB market basket cost weights reflect the experience of the average ESRD facility. Therefore, if one area of the country experienced an increase in labor costs at a higher rate than other areas of the country, that would not be wholly captured in the annual update. Instead, the relative difference in labor cost growth should be captured in changes to the wage index for that ESRD facility. However, we recognize that our wage index methodology uses historical data instead of a forecast and as such takes longer to update in response to periods of large change.

We appreciate comments from ESRD patients which highlighted their experiences at ESRD facilities. We are concerned by the comments which indicate access and quality concerns at ESRD facilities related to staffing issues. We note that § 494.180(b) requires that an ESRD facility have an adequate number of qualified and trained staff; however, the governing body of the facility has a measure of discretion when determining staffing. The ESRD PPS provides a bundled payment that encompasses all renal dialysis services, including labor. We recognize that staffing shortages can pose a difficulty to ESRD patients who desire training for self-dialysis. We note that the ESRD PPS includes an add-on payment adjustment for self-dialysis training (42 CFR 413.235(c); 81 FR 77851 to 77856). We appreciate the comments regarding these staffing issues and will consider them for potential future rulemaking.

Comment: One commenter encouraged CMS to explore other changes to the composition of the market basket to better capture evolving dynamics in the labor force. The commenter provided as an example that the ECI may no longer accurately capture the changing composition and cost structure of the hospital labor market given the large increases in short-term contract labor use and its growing costs.

Several commenters expressed concern that not all the ESRDB market basket price proxies, particularly the labor-related price proxies, accurately reflect ESRD facilities' faster than expected cost growth. One commenter noted that for healthcare providers across all sectors, the impact of the tight labor market (both in the healthcare sector and general economy overall) has forced ESRD facilities to rely more heavily on contracted labor. The commenter further pointed out that under the 2020-based ESRDB market basket, contract labor wages and benefits have 1.9 percent and 0.5 percent weights, respectively; however, the commenter expressed concern that these weights were derived by assuming that ESRD facilities use the same labor amount and mix as they did more than a decade ago, which does not reflect the current environment in which dialysis providers deliver care. They stated that use of the U.S. Census Bureau's Services Annual Survey (SAS) data may not reflect staffing ratio or minimum wage requirements adopted by State and municipal governments since 2012, the recent years' shift in labor mix, unanticipated increase in compensation

expenses, or the COVID–19 PHE's overall impact on the healthcare labor force.

A few commenters stated that certain market basket components rely, to some extent, on severely lagged data, which during times of unusual circumstances, could limit a forecast model's ability to capture economic shocks and the subsequent impact on health care providers' costs. The commenters stated, for example, the BLS's ECI price proxies generally hold the employment mix constant for several years. They stated that the ECI's weights reflected the 2012 occupational mix until recently (the December 2022 BLS release updated the data to reflect 2021 employment weights). The commenters noted that since ECI employment weights are held constant for a period this would introduce inaccuracies into the market basket updates. They stated that since the ECI 2012 weights were used for the price proxies in the ESRDB market basket through the CY 2022 rulemaking cycles it could have resulted in errors in the ESRDB market basket update.

Response: We appreciate the commenters' concerns about the composition of the ESRDB market basket and whether the price proxies used in the market basket are accurately capturing the price pressures experienced by ESRD facilities.

The commenters are correct that the ECI data are based on fixed occupational weights; however, we believe these indexes continue to be technically appropriate measures of pure compensation inflation to be used in the ESRDB market basket. Because the market baskets are intended to measure price changes over time, and not changes in costs that also reflect quantity and intensity changes, the fixed occupational distribution of the ECI is appropriate. BLS periodically updates these distributions (in the January 2023 release of December 2022 ECI data they introduced updated 2021 fixed employment weights, replacing the 2012 weights used through September 2022). Additionally, the observed ECI for Wages and Salaries for All Civilian workers in Hospitals (which accounts for 29 percent of the 2020-based ESRDB market basket) data has reflected recent wage ''price'' pressures as growth in 2021 and 2022 accelerated relative to 2020. The projection of the ECI also considers anticipated wage pressures due to various economic and industry-specific factors; the hospital ECI is projected to grow faster in 2023 compared to the historical average growth in the series, particularly prior to 2021. We note that when developing its forecast for the ECI for All Civilian Workers in Hospitals, IGI considers overall labor market conditions (including rise in contract labor employment due to tight labor market conditions) as well as trends in contract labor wages, which both have an impact on wage pressures for workers employed directly by the hospital. We also acknowledge the commenters' concerns that the ECI only reflects employed labor costs; however, we note that the alternative publicly available average hourly earnings series also does not include contract labor costs. Additionally, we analyzed the FTE data reported on the Medicare cost reports and found that the share of contract labor FTEs is about 2 percent of all FTEs and has remained relatively constant in 2021 and 2022. We will continue to monitor the cost report data as it is received to ensure that the ECI series used to proxy ESRD labor categories continues to offer the most appropriate price proxies for measuring compensation price growth in ESRD facilities.

Lastly, we acknowledge commenters' concern that the contract labor cost weight in the ESRDB market basket relies on 2012 SAS data published by the United States Census Bureau inflated to 2020-dollar values as the basis for the contract labor cost weight. We proposed and finalized the methodology for deriving the compensation cost share weights in the CY 2023 ESRD PPS rulemaking cycle (87 FR 67141 through 67157). Because the Medicare cost report data does not capture the specific costs for contract labor, we therefore must rely on other data sources to estimate the share of contract labor costs that are reported within Administrative and General costs on the cost reports. We have not identified any other data source that provides specific contract labor costs for ESRD facilities.

Final Rule Action: After consideration of the comments received, we are finalizing a CY 2024 ESRDB productivity-adjusted market basket increase of 2.1 percent based on the most recent data available. As noted previously, based on the more recent data available for this CY 2024 ESRD PPS final rule (that is, IGI's third quarter 2023 forecast of the 2020-based ESRDB market basket with historical data through the second quarter of 2023), the CY 2024 ESRDB market basket update is 2.4 percent. Based on the more recent data available from IGI's third quarter 2023 forecast, the current estimate of the productivity adjustment for CY 2024 is 0.3 percentage point. Therefore, the current estimate of the CY 2024 ESRD productivity-adjusted market basket increase factor is equal to 2.1 percent (that is, the 2.4 percent market basket update reduced by the 0.3 percentage point productivity adjustment).

(d) Requests for a Forecast Error Payment Adjustment

In the CY 2024 ESRD PPS proposed rule (88 FR 42435), we discussed that in the CY 2023 ESRD PPS final rule (87 FR 67157), many commenters requested that CMS apply a forecast error payment adjustment to the ESRD PPS base rate to support ESRD facilities during the inflationary period occurring at that time, particularly accounting for what commenters stated was an error in the forecasted payment updates for CYs 2021 and 2022. In response to those comments, we reminded readers that ESRDB market basket updates are set prospectively, meaning the update relies on a mix of both historical data for part of the period for which the update is calculated and forecasted data for the remainder. We explained that while there is no precedent to adjust for market basket forecast error in the annual ESRD PPS update, the forecast error for a market basket update is calculated as the actual market basket increase for a given year less the forecasted market basket increase.[10] We also explained that due to the uncertainty regarding future price trends, forecast errors can be both positive and negative. For example, the CY 2017 ESRDB forecast error was −0.8 percentage point, while the CY 2021 ESRDB forecast error was +1.2 percentage points. At the time of the CY 2023 ESRD PPS final rule, CY 2022 historical data was not yet available to calculate a forecast error for CY 2022; however, based on the latest available historical data for CY 2022, we now calculate that the CY 2022 ESRDB forecast error was +2.7 percentage points.

We further noted that, in the CY 2023 ESRD PPS final rule (87 FR 67156), we recognized that recent higher inflationary trends impacted the outlook for price growth over the next several quarters. For that CY 2023 ESRD PPS final rule, we used an updated forecast of the price proxies underlying the market basket that incorporated more recent historical data and reflected a revised outlook regarding the U.S. economy and expected price inflation for CY 2023 for ESRD facilities. We explained that predictability in

[10] FAQ—Market Basket Definitions and General Information. Available at: *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/medicareprogramratesstats/downloads/info.pdf.*

Medicare payments is important to enable ESRD facilities to budget and plan their operations, and that forecast errors are unpredictable (87 FR 67517). Prior to the COVID–19 PHE period, the positive differences between the actual and forecasted market basket increase in prior years have offset negative differences over time. Therefore, we stated in the CY 2024 ESRD PPS proposed rule that, in accordance with our longstanding ESRDB market basket update methodology, we would not propose to apply a forecast error adjustment to the ESRDB market basket update for CY 2024.

Comment: We received approximately 30 comments related to CMS's decision not to propose a forecast error adjustment for CY 2024. These commenters, including a coalition of dialysis providers, several LDOs, and numerous provider and patient advocacy organizations, requested that CMS reevaluate and implement a payment adjustment to account for past forecast errors. Many commenters requested that CMS apply a forecast error adjustment to the ESRD PPS payment update for CY 2024. Some specific suggestions for payment adjustments included: a CY 2024 adjustment of 10 to 20 percent per discharge; an adjustment for the ''underpayment'' of ESRD facilities since 2020; and/or the adoption a forecast error adjustment like the one used in the SNF PPS. Several commenters stated that absent a forecast error adjustment they may be forced to close some of their ESRD facilities, particularly those facilities located in areas with vulnerable populations.

The commenters stated that the forecast error was driven mainly by unforeseen increased costs for labor (including a higher reliance on contract labor staff), equipment, and medical supplies (including PPE and pharmaceuticals), which resulted in increased costs to provide care to ESRD beneficiaries that were never properly reimbursed under the Medicare ESRD PPS payments. Commenters stated that while the growth in these costs has begun to stabilize somewhat in 2023, they continue to be substantially higher than pre-pandemic levels. Commenters also pointed out that while high wage inflation and labor shortages affect all health care providers, dialysis providers are particularly vulnerable because there is not variation in types of services performed or billed and due to the less variable payer mix that relies more on Medicare and Medicaid payment than other health care provider types.

One commenter noted that while other health care providers have experienced similar forecast errors in CY 2022 and CY 2023, the current cumulative underpayment error for the ESRD PPS exceeds the errors in other payment systems such as IPPS, home health, and long-term care hospitals.

Some commenters acknowledged that since the market basket updates are set prospectively, they are inherently imperfect, and forecast errors from year to year may occur in either a positive or negative direction. However, several commenters noted that in the case of the ESRDB market basket these differences have not offset one another over time. The commenters stated a belief that the magnitude of the errors in 2021 and 2022, which they state resulted from a flawed methodology that failed to accurately forecast higher than normal inflation, are highly unlikely to even out over time unless there is a similar, fast moving deflationary event resulting in the same magnitude in the forecast.

Many commenters requested CMS establish a payment adjustment modeled after the forecast error adjustment for payments to SNFs that was established in 2004 (68 FR 46057). These commenters responded to CMS's view that historical negative forecast errors are offset by positive errors by noting that over the past few years the forecast errors have been predominantly positive, at 1.2 percent and 2.7 percent in CYs 2021 and 2022 respectively. As such, the ESRD PPS base rate is lower than it would have been if the forecasts had been accurate. Many of these commenters supported a forecast error adjustment methodology that would, like the SNF adjustment of 2004, only be applied if the error is larger than a certain threshold. Multiple commenters supported a threshold of 0.5 percentage point for this adjustment. Many commenters compared the state of SNF payment in 2004 and of the ESRD PPS today, emphasizing the similarities in the amount by which the recent market basket updates had been incorrect, the source of the error mainly attributable to unexpectedly large increases in the costs of labor, and certain similar statutory language describing the SNF PPS and the ESRD PPS. A coalition of dialysis organizations suggested that for the CY 2024 ESRD PPS final rule CMS should adjust the ESRD PPS base rate by the cumulative forecast error since 2019 but added that they would also approve of adjusting the ESRD PPS base rate by the cumulative forecast error since the inception of the ESRD PPS in 2011. Some commenters, including an LDO, suggested in lieu of a permanent forecast error adjustment policy for ESRDs, CMS could apply a one-time positive adjustment to the ESRD PPS base rate to account for the forecast error in recent years, with commenters suggesting it be applied to the ESRD PPS base rate in a non-budget neutral manner. Some commenters, including an LDO, recognized that CMS's view that the market basket errors could balance out over time could be true for small variations; however, the commenters stated that it would not hold true for periods of significant missed forecasts due to periods of rapid change, for example during the COVID–19 PHE. Generally, commenters stated that they agreed with CMS on the importance of predictability for payments but stated that payment accuracy was more important, so a forecast error payment adjustment would be useful as it would improve payment accuracy.

Some comments included additional information on what commenters stated could happen with or without a forecast error adjustment. One LDO commented that their analysis indicated that the under-forecast would lead to a total of $1.8 billion in underpayments between CY 2021 to 2027. One patient-led dialysis organization recommended an ''Essential Worker Safety Catch'' to revise past updates to ensure labor is adequately compensated. A provider advocacy organization questioned CMS's use of 2020-cost reports in determining payment for CY 2024, saying it was outdated and inaccurate. One ESRD facility commented that given the size of recent errors, they believed it was likely that errors would continue to increase and potentially become larger in the future.

Response: While the projected ESRDB market basket updates for CY 2021 and CY 2022 were under-forecast (that is, actual increases were greater than forecasted), as is the preliminary CY 2023 forecast error, this was largely due to unanticipated inflationary and labor market pressures as the economy emerged from the COVID–19 PHE. An analysis of the forecast error of the ESRDB market basket over a longer period shows the forecast error has been both positive and negative. We recognize that the COVID–19 PHE and high inflationary environment have had an adverse impact on costs for ESRD facilities. Due to ESRD payments being set prospectively, we rely on a projection of the ESRDB market basket that reflects both historical and forecasted trends. Due to the uncertainty regarding future price trends, the difference between the projected and actual market basket increases can be both positive and negative. We note that from CY 2012 to CY 2020, the only year in which the forecast error of the ESRDB

market basket update exceeded the 0.5 percentage point threshold in absolute terms (which is applicable for the SNF PPS forecast error adjustment) was CY 2017. The forecasted CY 2017 ESRDB market basket update was 0.8 percentage point higher than the actual CY 2017 percentage increase of the 2012-based ESRDB market basket based on historical data. We also acknowledge that the ESRDB market basket forecast errors for CY 2021 (1.2 percentage points) and CY 2022 (2.7 percentage points) exceeded the 0.5 percentage point threshold where the forecasted ESRDB market basket updates were lower than the actual percentage increases based on historical data. These recent forecast errors were largely a function of uncertainty in the overall economy and the health sector specifically due to the nature of the COVID–19 PHE and the unforeseen rapidly accelerating inflationary environment. Rapid increase in costs during the COVID–19 PHE has led to a positive forecast error for every Medicare PPS.

The data on which the final CY 2024 ESRDB market basket update is based is the most recent available data. We note that the 2020 cost report data was used for rebasing the market basket as finalized in the CY 2023 ESRD PPS final rule (87 FR 67141 through 67154), and at the time of CY 2023 rulemaking the 2020 cost report data was the most recent year of complete cost report data available to develop the ESRDB market basket cost weights. The ESRDB market basket cost weights do not change from year to year since it is a fixed-weight Laspeyres index; therefore, for CY 2024, we use the most recent available forecast of the price proxies to estimate the growth in the input prices of this mix of goods and services for providing renal dialysis services for the coming year. The most recent forecast of the price proxies in the ESRDB market basket for this final rule is the IGI third quarter 2023 forecast with historical data through the second quarter of 2023. This is the established methodology as finalized in the CY 2011 ESRD PPS final rule (75 FR 49151 through 49162). Therefore, while the weighting of the various goods and services that make up the ESRDB market basket did utilize 2020 data for rebasing, it is inaccurate to characterize the CY 2024 market basket increase as being based on 2020 data generally. We do not agree with the commenter that stated a belief that because forecast errors have been greater in recent years it is likely that forecast errors will be larger in the future. As we have indicated, the larger-than-normal forecast errors in CY 2021 and CY 2022 were largely due to unanticipated inflationary and labor market pressures as the economy emerged from the COVID–19 PHE, which we do not anticipate will continue in CY 2024. Our preliminary estimates of the CY 2023 ESRD PPS forecast error indicate that it was smaller than the forecast errors in CY 2022 and CY 2021.

For these reasons, after evaluating the historical performance of the ESRDB market basket and the financial environment unique to ESRD facilities, we do not believe it is appropriate to include adjustments to the ESRDB market basket update for future years based on the difference between the actual and forecasted ESRDB market basket increase in prior years. However, we will continue to monitor the overall performance of the ESRDB market basket update, including analyzing the change in the price of labor inputs for ESRD facilities over time. We will take commenters' concerns into consideration for potential future rulemaking.

Comment: One LDO commented that they believe that CMS has a statutory obligation to implement a forecast error adjustment under section 1881(b)(14)(F)(i) of the Act, which states that the Secretary shall annually increase payment amounts by an ESRD market basket percentage increase for a bundled payment system for renal dialysis services that reflects changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services. The commenter acknowledged that forecasting prices is inherent in a PPS but indicated that they believe that the current methodology fails to annually capture the changes over time in the price of providing renal dialysis services. The commenter stated that correcting for prior and future forecast errors is a step CMS can easily implement to ensure the ESRD PPS payment, and future market basket update factors, reflect the prices of delivering renal dialysis services. The commenter noted that in 2004 when CMS implemented a forecast error adjustment in the payment system for SNFs it was based on very similar statutory language and was implemented under what the commenter stated were ''virtually identical'' circumstances to the ESRD PPS today.

Response: We thank the commenter for sharing their view on this issue; however, we do not agree that CMS's position regarding an ESRD PPS forecast error payment adjustment conflicts with any statutory requirements for the ESRD PPS. We appreciate the commenter's interpretation of the circumstances involved in the implementation of the forecast error adjustment for SNF payment; however, we disagree with the claim that the circumstance was virtually identical to the ESRD PPS today. While the cumulative under-forecast of the SNF market basket increases in 2004 was based on a rapid increase in the price of labor, it was not due to a PHE as occurred with the ESRD PPS's under-forecast in recent years. Additionally, it was an issue which only SNFs were experiencing, unlike the current ESRD PPS environment where multiple Medicare payment systems have faced similar forecast errors. We note that when CMS finalized a forecast error adjustment for the SNF payment system, we concluded that a forecast error adjustment was appropriate for payment accuracy for SNFs; not that it was required under the statute (68 FR 46057). For these reasons, we do not agree with the commenter's stated belief that a forecast error adjustment would be required to fulfill the ESRD PPS statutory requirements, and, at this time, for the reasons discussed previously, we do not believe that a forecast error payment adjustment would be appropriate for the ESRD PPS.

Final Rule Action: After consideration of the comments we received, we are finalizing a CY 2024 ESRDB productivity-adjusted market basket increase of 2.1 percent based on the most recent data available. As noted previously, based on the more recent data available for this CY 2024 ESRD PPS final rule (that is, IGI's third quarter 2023 forecast of the 2020-based ESRDB market basket with historical data through the second quarter of 2023), the CY 2024 ESRDB market basket update is 2.4 percent. Based on the more recent data available from IGI's third quarter 2023 forecast, the current estimate of the productivity adjustment for CY 2024 is 0.3 percentage point. Therefore, the current estimate of the CY 2024 ESRD productivity-adjusted market basket increase factor is equal to 2.1 percent (2.4 percent market basket update reduced by 0.3 percentage point productivity adjustment). We are finalizing our proposal to determine the CY 2024 ESRDB market basket update for the final rule without an adjustment to account for past forecast errors. Additionally, we did not propose and are not finalizing any methodology for a forecast error payment adjustment. We will continue to monitor the performance of the ESRDB market basket forecasts and will consider the information provided by commenters for potential future rulemaking.

(e) Labor-Related Share

We define the labor-related share as those expenses that are labor-intensive and vary with, or are influenced by, the local labor market. The labor-related share of a market basket is determined by identifying the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market. For the CY 2024 ESRD PPS payment update, we proposed to continue using a labor-related share of 55.2 percent, which was finalized in the CY 2023 ESRD PPS final rule (87 FR 67153 through 67154).

Comment: We received three comments which acknowledged our proposal to use the labor-related share of 55.2 percent as finalized in the CY 2023 ESRD PPS final rule. Additionally, one LDO commented on the weights attributed to contract labor and benefits in the 2020-based ESRDB market basket, indicating that they thought that these areas were under-represented in the 2020-based ESRDB market basket. This LDO recognized that CMS did not propose any changes to the labor-related share from CY 2023. One provider advocacy organization suggested CMS utilize a different labor-related share for ESRD facilities with low wage index values, noting that for facilities with low wage index values, labor likely relates to a smaller share of total costs.

Response: We thank commenters for reviewing the proposed labor-related share. We appreciate the comment on the weights of contract labor in the 2020-based ESRDB market basket. As stated in section II.B.1.a.(2)(c) of this final rule, changes in both the cost and quantity of an input are reflected when the ESRDB market basket is rebased, and the base year weights are updated to a more recent time period. We finalized the 2020-based ESRDB market basket in the CY 2023 ESRD PPS final rule (87 FR 67141), and, therefore, any change in the cost structure for ESRD facilities that occurred between 2016 and 2020 is now reflected in the cost weights for the 2020-based ESRDB market basket, which was the most recent fully complete cost data available at the time of rulemaking. Our monitoring indicates that the 2020-based ESRDB market basket is still appropriate for determining the cost weights for inputs for providing renal dialysis services. Therefore, following the methodology finalized in the CY 2011 ESRD PPS final rule (75 FR 49116), we consider the labor related components of the ESRDB market basket to be an appropriate basis for the labor-related share for the CY 2024 ESRD PPS payments. We will continue to monitor the cost share weights and, if technically appropriate, consider rebasing the ESRDB market basket more frequently than usual should the cost weights change significantly. We appreciate the suggestion to use a different labor-related share for low wage index ESRD facilities. We did not propose any methodological changes to the application of the labor-related share, such as using a different labor-related share for different ESRD facilities, but we will consider this comment in potential future rulemaking.

Comment: One commenter expressed appreciation that the labor-related share of the ESRD PPS increased from 52.3 percent to 55.2 percent in CY 2023 and stated that they believe this is a consistent trend with the ESRD PPS, for which CMS has increased the labor-related share of the market basket over the lifetime of the PPS. The commenter opined that increasing the labor-related share of the market basket, while positive, does not fully address the steep rising costs of labor needed to deliver care to Medicare beneficiaries with ESRD, since it only alters the percentage of ESRD PPS payments allocated to labor as compared with other inputs required for renal dialysis services but does not deliver more resources through the ESRD PPS to cover the rising costs of care associated with the increases in the cost of labor.

Response: The purpose of the labor-related share is to reflect the proportion of the national ESRD PPS base payment rate that is adjusted by the wage index. CMS adjusts the labor-related portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index, which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. Therefore, we include a cost category in the labor-related share if the costs are labor intensive and vary with the local labor market. We note that the historical increase to the labor-related share is based on the increase to the labor-related cost-weights in the ESRDB market basket.

As acknowledged by the commenter, the purpose of the labor-related share is to allocate ESRD payment between labor-related costs and non-labor costs. The labor-related share is not meant to increase payments overall for the rising cost of labor.

Final Rule Action: We are finalizing our proposal to use the labor-related share of 55.2 percent, as finalized in the CY 2023 ESRD PPS final rule, for CY 2024 ESRD PPS payments.

b. CY 2024 ESRD PPS Wage Indices

(1) Background

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. In the CY 2011 ESRD PPS final rule (75 FR 49200), we finalized an adjustment for wages at § 413.231. Specifically, CMS adjusts the labor-related portion of the ESRD PPS base rate to account for geographic differences in the area wage levels using an appropriate wage index, which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. We use the Office of Management and Budget's (OMB's) CBSA-based geographic area designations to define urban and rural areas and their corresponding wage index values (75 FR 49117). OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. The bulletins are available online at *https://www.whitehouse.gov/omb/information-for-agencies/bulletins/*.

We have also adopted methodologies for calculating wage index values for ESRD facilities that are in urban and rural areas where there is no hospital data. For a full discussion, see the CY 2011 and CY 2012 ESRD PPS final rules at 75 FR 49116 through 49117 and 76 FR 70239 through 70241, respectively. For urban areas with no hospital data, we compute the average wage index value of all urban areas within the State to serve as a reasonable proxy for the wage index of that urban CBSA, that is, we use that value as the wage index. For rural areas with no hospital data, we compute the wage index using the average wage index values from all contiguous CBSAs to represent a reasonable proxy for that rural area. We applied the statewide urban average based on the average of all urban areas within the State to Hinesville-Fort Stewart, Georgia (78 FR 72173), and we applied the wage index for Guam to American Samoa and the Northern Mariana Islands (78 FR 72172).

Under § 413.231(d), a wage index floor value of 0.6000 is applied under the ESRD PPS as a substitute wage index for areas with very low wage index values, as finalized in the CY 2023 ESRD PPS final rule (87 FR 67161). Currently, all areas with wage index values that fall below the floor are in Puerto Rico and the U.S. Virgin Islands. However, the wage index floor value is applicable for any area that may fall

below the floor. A further description of the history of the wage index floor under the ESRD PPS can be found in the CY 2019 ESRD PPS final rule (83 FR 56964 through 56967) and the CY 2023 ESRD PPS final rule (87 FR 67161).

An ESRD facility's wage index is applied to the labor-related share of the ESRD PPS base rate. In the CY 2023 ESRD PPS final rule (87 FR 67153), we finalized a labor-related share of 55.2 percent. In the CY 2021 ESRD PPS final rule (85 FR 71436), we updated the OMB delineations as described in the September 14, 2018, OMB Bulletin No. 18–04, beginning with the CY 2021 ESRD PPS wage index. In that same rule, we finalized the application of a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior CY. We finalized that the transition would be phased in over 2 years, such that the reduction in an ESRD facility's wage index would be capped at 5 percent in CY 2021, and no cap would be applied to the reduction in the wage index for the second year, CY 2022. In the CY 2023 ESRD PPS final rule (87 FR 67161), we finalized a permanent policy under § 413.231(c) to apply a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior CY. For CY 2024, as discussed in section II.B.1.a.(2)(e) of this final rule, the labor-related share to which the wage index will be applied is 55.2 percent.

(2) CY 2024 ESRD PPS Wage Index

For CY 2024, we proposed to update the wage indices to account for updated wage levels in areas in which ESRD facilities are located using our existing methodology. We proposed to use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient PPS. The ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix. For CY 2024, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2019, and before October 1, 2020 (FY 2020 cost report data).

For CY 2024, we proposed to update the ESRD PPS wage index to use the most recent hospital wage data. We proposed that if more recent data become available after the publication of the proposed rule and before the publication of the final rule (for example, a more recent estimate of the wage index), we would use such data, if appropriate, to determine the CY 2024 ESRD PPS wage index in the final rule.

We received several comments on our proposal to update the ESRD PPS wage index. The comments and our responses are set forth below.

Comment: We received several comments on CMS's proposal to use the most recent wage index data in the CY 2024 ESRD PPS final rule. Commenters were generally supportive of the use of more recent data. Additionally, several commenters reiterated support for the 5 percent cap on wage index decreases that we finalized in the CY 2023 ESRD PPS final rule (87 FR 67161).

Response: We thank the commenters for their support on the use of more recent data and for the policy to cap wage index decreases.

Comment: One ESRD facility expressed concerns that the ESRD PPS wage index does not reflect the realities that it faces and, specifically, does not accurately reflect the increase in its cost of labor over the past few years.

Response: We appreciate the concerns that the commenter raised; however, we did not propose to change the wage index methodology for CY 2024 and are not finalizing any changes to that methodology in this final rule. The wage data used to construct the ESRD PPS wage index are updated annually, based on the most current data available, and are based on OMB's CBSA delineations when applying the rural definitions and corresponding wage index values. As discussed in CY 2011 ESRD PPS final rule (75 FR 49200), the wage index reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. Because the wage index is scaled relative to the national average, it does not reflect changes over time to the cost of labor. Rather, the market basket increase accounts for national trends, including inflation. As discussed in the CY 2024 ESRD PPS proposed rule (88 FR 42435), we proposed to increase the ESRD PPS base rate for CY 2024 by the market basket increase factor in accordance with section 1881(b)(14)(F)(i) of the Act, which provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services that reflect the costs of furnishing renal dialysis services. As discussed in section II.B.1.a.(2).(c) of this final rule, the final productivity-adjusted market basket update for CY 2024 is 2.1 percent based on the latest available data. We note that this final update is 0.4 percentage point higher than the proposed update and reflects a revised outlook regarding the U.S. economy and expected price inflation for CY 2024 for ESRD facilities. We believe the final productivity-adjusted market basket update will address some of the commenter's concerns regarding rising wages due to inflation.

Comment: Several commenters, including MedPAC, a coalition of dialysis organizations and an LDO, suggested that CMS reevaluate the wage index methodology for the ESRD PPS. MedPAC recommended we establish an ESRD PPS wage index for all ESRD facilities using wage data that represents all employers and industry-specific occupational weights, rather than the hospital wage data currently used. Two ESRD facilities and a provider advocacy organization requested CMS use the floors and reclassifications that IPPS uses for their wage index. Some of these commenters additionally indicated a belief that this change would help ESRD facilities compete with hospitals for labor.

Response: We appreciate the suggestions from commenters on how to improve the ESRD PPS wage index methodology. The use of hospital wage data for the ESRD PPS wage index is set forth in §§ 413.196(d)(2) and 413.231(a). As we previously discussed in the CY 2011 ESRD PPS proposed rule (74 FR 49968), the ESRD PPS wage index uses the same wage index values used in the basic case-mix adjusted composite payment system, which are calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix. The application of the pre-floor, pre-reclassification hospital wage index for the ESRD case-mix adjusted composite payment system is further discussed in the CY 2009 Physician Fee Schedule (PFS) final rule (73 FR 69726, 69758) and the CY 2007 PFS final rule (71 FR 69624, 69685). We did not propose changes to the ESRD PPS wage index methodology for CY 2024, and we are not finalizing any changes to that methodology in this final rule.

As discussed in the CY 2023 ESRD PPS final rule (87 FR 67160), the wage index is intended to be a relative measure of the value of labor in prescribed labor market areas. There is a variety of reasons why our longstanding ESRD PPS wage index policy has not applied the same floors or reclassifications as applied under the IPPS, which we note, are not applied to the ESRD PPS wage index by statute (sections 1881(b)(12)(D) & (b)(14)(D)(iv)(II) of the Act). For example, applying reclassifications to the ESRD PPS wage index would

significantly increase administrative burden, both for ESRD facilities and for CMS, that would be associated with ESRD facilities reclassifying from one CBSA to another, and it would significantly increase the complexity of the methodology.

Furthermore, because floors and reclassifications would be applied budget-neutrally under the wage index, these policies would increase the wage index for some ESRD facilities while reducing ESRD PPS payments for all other ESRD facilities, which would upset the long-settled expectations with which ESRD facilities across the country have been operating. For example, under the IPPS rural floor policy, section 4410(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33) provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. Applying the IPPS rural floor to the ESRD PPS wage index would result in increasing the wage index for any ESRD facilities located in an urban area whose wage index is less than the rural wage index for that State. As we discussed in the CY 2023 ESRD PPS final rule (87 FR 67164 through 67165) with respect to the increase to the ESRD PPS wage index floor in that year, a higher wage index floor will slightly decrease the ESRD PPS base rate for all ESRD facilities due to the application of the budget neutrality factor. Given that increasing the wage index floor results in a proportional decrease in the base rate for all ESRD facilities, we established a wage index floor value that strikes a balance between providing increased payment to areas for which labor costs are higher than the current wage index for the relevant CBSAs indicates, while maintaining the accuracy of payments under the ESRD PPS and minimizing the overall impact to all ESRD facilities.

For these reasons, we believe that the ESRD PPS wage index is the most appropriate data to use for estimating the variation in wage levels across the country. However, we will take these comments into consideration to potentially inform future rulemaking.

Comment: A non-profit health insurance organization commented that they believed a wage index floor of 0.7000 was justified and suggested CMS reevaluate the current wage index floor of 0.6000. The commenter indicated that CMS would find it appropriate to raise the wage index floor to 0.7000.

Response: We appreciate the suggestion and will consider it for potential future rulemaking. We did not propose any change to the current wage index floor of 0.6000 specified in § 413.231(d) and are not finalizing any changes to that floor in this final rule.

Final Rule Action: We are finalizing our proposal to update the ESRD PPS wage index for CY 2024 to use the most recent hospital wage data, as proposed. The final CY 2024 ESRD PPS wage index is set forth in Addendum A and is available on CMS's website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices*. Addendum A provides a crosswalk between the CY 2023 wage index and the CY 2024 wage index. Addendum B provides an ESRD facility level impact analysis. Addendum B is available on CMS's website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices*.

c. CY 2024 Update to the Outlier Policy

(1) Background

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high-cost outliers due to unusual variations in the type or amount of medically necessary care, including variability in the amount of erythropoiesis stimulating agents (ESAs) necessary for anemia management. Some examples of the patient conditions that may be reflective of higher facility costs when furnishing dialysis care are frailty and obesity. A patient's specific medical condition, such as secondary hyperparathyroidism, may result in higher per treatment costs. The ESRD PPS recognizes that some patients require high-cost care, and we have codified the outlier policy and our methodology for calculating outlier payments at § 413.237.

Section 413.237(a)(1) enumerates the following items and services that are eligible for outlier payments as ESRD outlier services: (i) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (ii) renal dialysis laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (iii) renal dialysis medical/surgical supplies, including syringes, used to administer renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (iv) renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including renal dialysis oral-only drugs effective January 1, 2025; and (v) renal dialysis equipment and supplies, except for capital-related assets that are home dialysis machines (as defined in § 413.236(a)(2)), that receive the transitional add-on payment adjustment as specified in § 413.236 after the payment period has ended.[11]

In the CY 2011 ESRD PPS final rule (75 FR 49142), CMS stated that for purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the ESRD facility to identify the actual ESRD outlier services furnished to the patient by line item (that is, date of service) on the monthly claim. Renal dialysis drugs, laboratory tests, and medical/surgical supplies that are recognized as ESRD outlier services were specified in Transmittal 2134, dated January 14, 2011.[12] We use administrative issuances and guidance to continually update the renal dialysis service items available for outlier payment via our quarterly update CMS Change Requests, when applicable. For example, we use these issuances to identify renal dialysis oral drugs that were or would have been covered under Medicare Part D prior to 2011 to provide unit prices for determining the imputed MAP amounts. In addition, we use these issuances to update the list of ESRD outlier services by adding or removing items and services that we determined, based our monitoring efforts, are either incorrectly included or missing from the list.

Under § 413.237, an ESRD facility is eligible for an outlier payment if its imputed (that is, calculated) MAP amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average estimated expenditure per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted MAP amount per treatment plus the FDL amount. As described in the following paragraphs, the ESRD

[11] Under § 413.237(a)(1)(vi), as of January 1, 2012, the laboratory tests that comprise the Automated Multi-Channel Chemistry panel are excluded from the definition of outlier services.

[12] Transmittal 2033 issued August 20, 2010, was rescinded, and replaced by Transmittal 2094, dated November 17, 2010. Transmittal 2094 identified additional drugs and laboratory tests that may also be eligible for ESRD outlier payment. Transmittal 2094 was rescinded and replaced by Transmittal 2134, dated January 14, 2011, which included one technical correction. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2134CP.pdf*.

facility's predicted MAP amount is the national adjusted average ESRD outlier services MAP amount per treatment, further adjusted for case-mix and facility characteristics applicable to the claim. We use the term ''national adjusted average'' in this section of this final rule for clarity, to distinguish the calculation of the average ESRD outlier services MAP amount per treatment from the calculation of the predicted MAP amount for a claim. The average ESRD outlier services MAP amount per treatment is based on utilization from all ESRD facilities, whereas the calculation of the predicted MAP amount for a claim is based on the individual ESRD facility and patient characteristics of the monthly claim. In accordance with § 413.237(c), ESRD facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold. ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

In the CY 2011 ESRD PPS final rule and codified in § 413.220(b)(4), using 2007 data, we established the outlier percentage, which is used to reduce the per treatment ESRD PPS base rate to account for the proportion of the estimated total Medicare payments under the ESRD PPS that are outlier payments, at 1.0 percent of total payments (75 FR 49142 through 49143). We also established the FDL amounts that are added to the predicted outlier services MAP amounts. The outlier services MAP amounts and FDL amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140). As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49139), the predicted outlier services MAP amounts for a patient are determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis used to compute the payment adjustments. In the CY 2023 ESRD PPS final rule, we finalized an update to the outlier methodology to better target 1.0 percent of total Medicare payments (87 FR 67170 through 67177). We finalized that we would continue to follow our established methodology for the calculation of the adult and pediatric MAP amounts, but we would prospectively calculate the adult FDL amounts based on the historical trend in FDL amounts that would have achieved the 1.0 percent outlier target in the 3 most recent available data years.

(2) CY 2024 Update to the Outlier Services MAP Amounts and FDL Amounts

For CY 2024, we proposed to update the MAP amounts for adult and pediatric patients using the latest available CY 2022 claims data. We proposed to update the ESRD outlier services FDL amount for pediatric patients using the latest available CY 2022 claims data, and to update the ESRD outlier services FDL amount for adult patients using the latest available claims data from CY 2020, CY 2021, and CY 2022, in accordance with the methodology finalized in the CY 2023 ESRD PPS final rule (87 FR 67170 through 67174). CY 2022 claims data showed outlier payments represented approximately 0.8 percent of total Medicare payments (88 FR 42432 and 42438).

The impact of this final update is shown in Table 1, which compares the outlier services MAP amounts and FDL amounts used for the outlier policy in CY 2023 with the updated estimates for this final rule. The estimates for the CY 2024 MAP amounts, which are included in Column II of Table 1, were inflation adjusted to reflect projected 2024 prices for ESRD outlier services.

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TABLE 1: Outlier Policy: Impact of Using Updated Data for the Outlier Policy

	Column I Final outlier policy for CY 2023 (based on 2021 data, price inflated to 2023) *		Column II Final outlier policy for CY 2024 (based on 2022 data, price inflated to 2024) **	
	Age < 18	Age >= 18	Age < 18	Age >= 18
Average outlier services MAP amount per treatment	$24.13	$41.36	$22.30	$37.92
Adjustments			.	.
Standardization for outlier services	1.0819	0.9774	1.0691	0.9763
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$25.59	$39.62	$23.36	$36.28
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	$23.29	$73.19	$11.32	$71.76
Patient-month-facilities qualifying for outlier payment	12.90%	5.90%	20.86%	4.87%

*Column I was obtained from Column II of Table 11 from the CY 2023 ESRD PPS final rule (87 FR 67176).
**The FDL amount for adults incorporates retrospective adult FDL amounts calculated using data from CYs 2020, 2021, and 2022.

As demonstrated in Table 1, the estimated FDL per treatment that determines the CY 2024 outlier threshold amount for adults (Column II; $71.76) is lower than that used for the CY 2023 outlier policy (Column I; $73.19). The lower threshold is accompanied by a decrease in the adjusted average MAP for outlier services from $39.62 to $36.28. For pediatric patients, there is a decrease in the FDL amount from $23.29 to $11.32. There is a corresponding decrease in the adjusted average MAP for outlier services among pediatric patients, from $25.59 to $23.36.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2024 would be 4.87 percent for adult patients and 20.86 percent for pediatric patients, based on the 2022 claims data and methodology finalized in the CY 2023 ESRD PPS final rule. The outlier MAP and FDL amounts continue to be lower for pediatric patients than adults due to the continued lower use of outlier services (primarily reflecting lower use of ESAs and other injectable drugs).

(3) Outlier Percentage

In the CY 2011 ESRD PPS final rule (75 FR 49081) and under § 413.220(b)(4), we reduced the per treatment base rate by 1 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments as described in § 413.237. In the 2023 ESRD PPS final rule, we finalized a change to the outlier methodology to better achieve this 1 percent target (87 FR 67170 through 67174). We stated in the CY 2024 ESRD PPS proposed rule that, based on the CY 2022 claims, outlier payments represented approximately 0.9 percent of total payments. Based on more complete CY 2022 claims data, this figure has been updated to 0.8 percent for this final rule, which is below the 1 percent target due to declines in the use of outlier services. However, this is significantly closer to the 1 percent target than the outlier payments based on CY 2021 claims, which represented approximately 0.5 percent of total payments. In the CY 2024 ESRD PPS proposed rule, we noted that we believe the update to the outlier MAP and FDL amounts for CY 2024 would increase payments for ESRD beneficiaries requiring higher resource utilization. This would move us even closer to meeting our 1 percent outlier policy goal, because we would be using more current data for computing the MAP and FDL amounts, which is more reflective of current outlier services utilization rates. We also noted that the proposed recalibration of the FDL amounts would result in no change in payments to ESRD facilities for beneficiaries with renal dialysis items and services that are not eligible for outlier payments.

The comments and our responses to the comments on our proposed updates to the outlier policy are set forth below.

Comment: We received several comments on CMS's proposals to update the FDL and MAP amounts for CY 2024. Commenters were generally supportive of the use of more recent data to determine the CY 2024 ESRD PPS final MAP and FDL amounts. Several commenters stated that they appreciated that the methodological changes CMS made to the outlier policy in the CY 2023 ESRD PPS final rule resulted in the total percentage of payments for outliers being closer to the 1 percent target than ever before. However, some commenters noted that the ESRD PPS base rate is reduced on the assumption that 1 percent of total payments will be attributable to outlier payments, and if the actual percentage is less than 1 percent it means that total payments to ESRD facilities are less than they should be. Commenters suggested that CMS should implement a policy to recompense ESRD facilities for

underpayment when total outlier payments are less than 1 percent of total ESRD PPS payments. One commenter recommended CMS reduce the outlier target to 0.5 percent of total payments.

Response: We appreciate the support for the proposed use of more recent data to update the MAP and FDL amounts for the outlier policy and the thoughtful suggestions provided by commenters. We acknowledge that, even with annually adjusting the MAP and FDL amounts to reflect the most recent utilization and costs of ESRD PPS eligible outlier services according to the updated outlier methodology finalized in the CY 2023 ESRD PPS final rule, total outlier payments have not yet reached the 1 percent target. However, the performance of the outlier payments has improved significantly due to the modification to the outlier methodology finalized in CY 2023 ESRD PPS final rule, as outlier payments represented 0.8 percent of the total payments in CY 2022. We appreciate the comments suggesting solutions for refining the outlier policy methodology, for example, reducing the outlier percentage, as defined at § 413.220(b)(4), to less than 1 percent or establishing a mechanism that pays back ESRD facilities those allocated outlier amounts that were not paid out in the projected year. We did not propose any modifications to the ESRD PPS outlier policy for CY 2024 codified at § 413.220, and we are not finalizing any changes to the methodology in this final rule. We will consider the commenters' suggestions regarding changes in methodology in potential future rulemaking.

Final Rule Action: After considering the public comments, we are finalizing the updated outlier thresholds for CY 2024 displayed in Column II of Table 1 of this final rule based on the most current data.

d. Impacts to the CY 2024 ESRD PPS Base Rate

(1) ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), CMS established the methodology for calculating the ESRD PPS per-treatment base rate, that is, the ESRD PPS base rate, and calculating the per-treatment payment amount, which are codified at §§ 413.220 and 413.230. The CY 2011 ESRD PPS final rule also provides a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate for projected outlier payments and budget neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. Specifically, the ESRD PPS base rate was developed from CY 2007 claims (that is, the lowest per patient utilization year as required by section 1881(b)(14)(A)(ii) of the Act), updated to CY 2011, and represented the average per treatment MAP for composite rate and separately billable services. In accordance with section 1881(b)(14)(D) of the Act and our regulation at § 413.230, the per-treatment payment amount is the sum of the ESRD PPS base rate, adjusted for the patient specific case-mix adjustments, applicable facility adjustments, geographic differences in area wage levels using an area wage index, and any applicable outlier payment, training adjustment add-on, TDAPA, and TPNIES.

(2) Annual Payment Rate Update for CY 2024

In the CY 2024 ESRD PPS proposed rule, we proposed an ESRD PPS base rate for CY 2024 of $269.99 (88 FR 42432). We are finalizing an ESRD PPS base rate for CY 2024 of $271.02. This update reflects several factors, described in more detail as follows:

Wage Index Budget-Neutrality Adjustment Factor: We compute a wage index budget-neutrality adjustment factor that is applied to the ESRD PPS base rate. For CY 2024, we did not propose and are not finalizing any changes to the methodology used to calculate this factor, which is described in detail in the CY 2014 ESRD PPS final rule (78 FR 72174). We computed the final CY 2024 wage index budget-neutrality adjustment factor using treatment counts from the 2022 claims and facility-specific CY 2023 payment rates to estimate the total dollar amount that each ESRD facility would have received in CY 2023. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2024. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the final CY 2024 ESRD PPS wage index and final labor-related share for CY 2024. As discussed in section II.B.1.b of this final rule, the ESRD PPS wage index for CY 2024 includes an update to the most recent hospital wage data and continued use of the 2018 OMB delineations. The total of these payments becomes the new CY 2024 amount of wage-adjusted expenditures for all ESRD facilities. The wage index budget-neutrality factor is calculated as the target amount divided by the new CY 2024 amount. When we multiplied the wage index budget neutrality factor by the applicable CY 2024 estimated payments, aggregate Medicare payments to ESRD facilities would remain budget neutral when compared to the target amount of expenditures. That is, the wage index budget neutrality adjustment factor ensures that wage index adjustments do not increase or decrease aggregate Medicare payments with respect to changes in wage index updates. The final CY 2024 wage index budget-neutrality adjustment factor is 1.000031. This CY 2024 wage index budget-neutrality adjustment factor reflects the impact of all wage index policy changes, including the final CY 2024 ESRD PPS wage index and labor-related share.

TPEAPA Budget-Neutrality Adjustment Factor: As explained in section II.B.1.g.(7) of this final rule, we are finalizing a new, budget-neutral transitional add-on payment adjustment for pediatric ESRD renal dialysis services, which we call the TPEAPA. The final CY 2024 budget-neutrality adjustment factor for the TPEAPA is 0.999503. The budget-neutrality adjustment factor for the TPEAPA is discussed in section II.B.1.g of this final rule.

Combined Wage Index and TPEAPA Budget-Neutrality Adjustment Factor: For purposes of calculating the ESRD PPS base rate for CY 2024, we are using one combined budget-neutrality adjustment factor includes both the wage index budget-neutrality adjustment factor and the TPEAPA budget-neutrality adjustment factor. The CY 2024 combined wage index and TPEAPA budget neutrality factor is 0.999534 (1.000031×0.999503). This application would yield a CY 2024 ESRD PPS base rate of $265.48 prior to the application of the CY 2024 market basket update percentage ($\$265.57 \times 0.999534 = \$265.45$).

Market Basket Update: Section 1881(b)(14)(F)(i)(I) of the Act provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket percentage increase. As discussed previously in section II.B.1.a.(2)(a) of this final rule, the latest CY 2024 projection of the ESRDB market basket percentage increase is 2.4 percent. In CY 2024, this amount must be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, as required by section 1881(b)(14)(F)(i)(II) of the Act. As discussed previously in section II.B.1.a.(2)(b) of this final rule, the latest CY 2024 projection of the productivity adjustment is 0.3 percentage point, thus yielding a CY 2024 productivity-adjusted ESRDB market basket update of 2.1 percent for

CY 2024. Therefore, the final CY 2024 ESRD PPS base rate is $271.02 (($265.57 × 0.999534) × 1.021 = $271.02).

The comments and our responses to the comments on our proposed updates to the ESRD PPS base rate are set forth below.

Comment: We received several comments which characterized the proposed CY 2024 ESRD PPS base rate as too low. Some of these commenters requested that CMS increase the base rate. The reasoning for this requested increase varied by commenter. Some commenters wanted an increase to account for recent under-forecasts, whereas other commenters wanted an increase to allow facilities to provide an increased quality of care.

Response: The CY 2024 ESRD PPS base rate is derived from the CY 2023 ESRD PPS base rate, the CY 2024 ESRDB market basket update, and the CY 2024 combined wage index-TPEAPA budget neutrality factor. In accordance with section 1881(b)(14)(F) of the Act, the primary factor in determining the ESRD PPS base rate increase from one year to the next is the ESRDB market basket update. We believe the final CY 2024 ESRDB market basket update reflects the most recent available data regarding the forecasted prices of labor used to provide renal dialysis services. We discuss the CY 2024 ESRDB market basket update in more detail in section II.B.1.a of this final rule, with detailed responses to comments on the magnitude of the productivity-adjusted ESRDB market basket increase in section II.B.1.a.(2)(c) of this final rule and detailed responses to comments on previous forecast errors for the ESRDB market basket update in section II.B.1.a.(2)(d) of this final rule. We appreciate the concerns of the commenters, but we did not propose any new payment adjustments to the base rate based on those concerns. We will continue to monitor the adequacy of the ESRD PPS payment and will consider these commenters' insights for future rulemaking.

Final Rule Action: We are finalizing a CY 2024 ESRD PPS base rate of $271.02. This amount reflects the combined CY 2024 wage index-TPEAPA budget-neutrality adjustment factor of 0.999534, and the CY 2024 ESRD PPS productivity-adjusted market basket update of 2.1 percent.

e. Update to the Average per Treatment Offset Amount for Home Dialysis Machines

In the CY 2021 ESRD PPS final rule (85 FR 71427), we expanded eligibility for the TPNIES under § 413.236 to include certain capital-related assets that are home dialysis machines when used in the home for a single patient. To establish the TPNIES basis of payment for these items, we finalized the additional steps that the Medicare Administrative Contractors (MACs) must follow to calculate a pre-adjusted per treatment amount, using the prices they establish under § 413.236(e) for a capital-related asset that is a home dialysis machine, as well as the methodology that CMS uses to calculate the average per treatment offset amount for home dialysis machines that is used in the MACs' calculation, to account for the cost of the home dialysis machine that is already in the ESRD PPS base rate. For purposes of this final rule, we refer to this as the ''TPNIES offset amount.''

The methodology for calculating the TPNIES offset amount is set forth in § 413.236(f)(3). Section 413.236(f)(3)(v) states that effective January 1, 2022, CMS annually updates the amount determined in § 413.236(f)(3)(iv) by the ESRD bundled market basket percentage increase factor minus the productivity adjustment factor. The TPNIES for capital-related assets that are home dialysis machines is based on 65 percent of the MAC-determined pre-adjusted per treatment amount, reduced by the TPNIES offset amount, and is paid for 2 CYs.

As we discussed in the CY 2024 ESRD PPS proposed rule (88 FR 42432), there are currently no capital-related assets that are home dialysis machines set to receive TPNIES for CY2024, as the TPNIES payment period for the Tablo® System ends on December 31, 2023, and the only TPNIES application for CY 2024 is not for a home dialysis machine. However, as required by § 413.236(f)(3)(v), we proposed to update the TPNIES offset amount annually according to the methodology described previously.

We proposed a CY 2024 TPNIES offset amount for capital-related assets that are home dialysis machines of $9.96, based on the proposed CY 2024 ESRDB productivity-adjusted market basket update of 1.7 percent (2.0 percent market basket percentage increase reduced by 0.3 percentage point productivity adjustment). We explained in the CY 2024 ESRD PPS proposed rule that applying the proposed update factor of 1.017 to the CY 2023 offset amount resulted in the proposed CY 2024 offset amount of $9.96 ($9.79 × 1.017 = $9.96). We proposed to update this calculation to use the most recent data available in the CY 2024 ESRD PPS final rule.

We received three comments on this proposal to update the TPNIES offset amount for capital related assets that are home dialysis machines, including comments from an LDO and a device manufacturer. The comments and our responses to the comments on the proposed update to the TPNIES offset amount are set forth below.

Comment: A device manufacturer requested that CMS remove the TPNIES offset for capital-related assets that are home dialysis machines. The commenter and two others indicated that they believe that the TPNIES offset, combined with the 65 percent reduction for risk sharing, are leading to capital-related assets that are home dialysis machines being undervalued. An LDO agreed that the TPNIES for capital-related assets that are home dialysis machines should be offset by an amount currently in the base rate.

Response: We appreciate the commenters' insight into the impacts of the TPNIES offset for capital-related assets that are home dialysis machines. We did not propose any methodological changes for this TPNIES offset amount set forth at § 413.236(f), and we are not finalizing any changes. We will consider the commenters' concerns for potential future rulemaking.

Final Rule Action: We are finalizing our proposal to calculate the CY 2024 TPNIES offset amount using the most recent data available. The CY 2023 TPNIES offset amount for capital-related equipment that are home dialysis machines used in the home is $9.79. As discussed previously in section II.B.1.a.(2)(c) of this final rule, the final CY 2024 ESRDB productivity-adjusted market basket update is 2.1 percent (2.4 percent market basket percentage increase reduced by 0.3 percent productivity adjustment). Applying the update factor of 1.021 to the CY 2023 TPNIES offset amount results in a final CY 2024 TPNIES offset amount of $10.00 ($9.79 × 1.021).

f. Refinement of the Low-Volume Payment Adjustment (LVPA)

(1) Background

Section 1881(b)(14)(D)(iii) of the Act provides that the ESRD PPS shall include a payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services, and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment shall not be less than 10 percent. Therefore, the ESRD PPS provides a facility-level payment adjustment to ESRD facilities

that meet the definition of a low-volume facility. In this section of the final rule, we discuss the low volume-payment adjustment (LVPA) under the ESRD PPS.

The current amount of the LVPA is 23.9 percent. In the CY 2011 ESRD PPS final rule (75 FR 49118 through 49125), we finalized the methodology used to target the appropriate population of ESRD facilities that were low-volume and to determine the treatment threshold for those ESRD facilities identified. After consideration of public comments, we established an 18.9 percent adjustment for ESRD facilities that furnish less than 4,000 treatments annually and indicated that this increase to the ESRD PPS base rate would encourage small ESRD facilities to continue providing access to care.

In the CY 2016 ESRD PPS proposed rule (80 FR 37819), we analyzed ESRD facilities that met the definition of a low-volume facility under § 413.232(b) as part of the updated regression analysis and found that these ESRD facilities still had higher costs compared to other ESRD facilities. A regression analysis of CYs 2012 and 2013 low-volume facility claims and cost report data indicated a multiplier of 1.239 percent; therefore, we proposed an updated LVPA adjustment factor of 23.9 percent in the CY 2016 ESRD PPS proposed rule (80 FR 37819) and finalized this policy in the CY 2016 ESRD PPS final rule (80 FR 69001). In CY 2021, 366 ESRD facilities received the LVPA. Using the most recent available data for CY 2022, the number of ESRD facilities receiving the LVPA was 353.

(a) Current LVPA Methodology

Under § 413.232(b), a low-volume facility is an ESRD facility that, based on the submitted documentation: (1) furnished less than 4,000 treatments in each of the 3 cost-reporting years (based on as-filed or final settled 12-consecutive month costs reports, whichever is most recent, except as specified in paragraph (g)(4)) preceding the payment year; and (2) has not opened, closed, or received a new provider number due to a change in ownership (except where the change in ownership results in a change in facility type) in the 3 cost-reporting years (based on as-filed or final settled 12-consectuive month cost reports, whichever is most recent) preceding the payment year.

In addition, under § 413.232(c), for purposes of determining the number of treatments furnished by the ESRD facility, the number of treatments considered furnished by the ESRD facility equals the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both under common ownership with and 5 road miles or less from the ESRD facility in question. To receive the LVPA, an ESRD facility must submit a written attestation statement to its Medicare Administrative Contractor (MAC) confirming that it meets all the requirements specified in § 413.232 and qualifies as a low-volume ESRD facility. For purposes of determining eligibility for the LVPA, ''treatments'' mean total hemodialysis equivalent treatments (Medicare and non-Medicare). For peritoneal dialysis patients, one week is considered equivalent to three hemodialysis treatments (80 FR 68994). Section 413.232(e) generally imposes a yearly November 1st deadline for attestation submissions unless extraordinary circumstances justify an exception and specifies exceptions for certain years where the deadline is in December or January. The November 1st attestation timeframe provides 60 days for a MAC to verify that an ESRD facility meets the LVPA eligibility criteria (76 FR 70236). The ESRD facility would then receive the LVPA payment for all the Medicare-eligible treatments in the payment year. Once an ESRD facility is determined to be eligible for the LVPA, a 23.9 percent increase is applied to the ESRD PPS base rate for all treatments furnished by the ESRD facility (80 FR 69001).

In the CY 2021 ESRD PPS final rule (85 FR 71443), we finalized a policy to allow ESRD facilities flexibility for LVPA eligibility due to the COVID–19 PHE. Under § 413.232(g)(4), for purposes of determining ESRD facilities' eligibility for payment years 2021, 2022, and 2023, we will only consider total dialysis treatments for any 6 months of their cost-reporting period ending in 2020. ESRD facilities that would not otherwise meet the number of treatments criterion because of the COVID–19 PHE may attest that their total dialysis treatments for those 6 months of their cost reporting period ending in 2020 are less than 2,000. The attestation must further include that although the total number of treatments furnished in the entire year otherwise exceeded the LVPA threshold, the excess treatments furnished were due to temporary patient shifting resulting from the COVID–19 PHE. MACs will annualize the total dialysis treatments for the total treatments reported in those 6 months by multiplying by 2.

(b) Current Issues and Concerns From Interested Parties

Interested parties, including MedPAC and the Government Accountability Office (GAO),[13] have recommended that we make refinements to the LVPA to better target ESRD facilities that are critical to beneficiary access to dialysis care in remote or isolated areas.[14] These groups and other interested parties have also have expressed concern that the strict treatment count introduces a ''cliff-effect'' that may incentivize ESRD facilities to restrict their patient caseload to remain below 4,000 treatments per year to meet the LVPA threshold.[15]

(2) Requests for Information on Modification of LVPA Methodology and Development of a New Payment Adjustment Based on Geographic Isolation

In the CY 2024 ESRD PPS proposed rule (88 FR 42440 through 42441), we explained that we recognize the importance of revising the ESRD PPS LVPA adjustment methodology to ensure that payments accurately reflect differences in cost and adequately target low-volume facilities, and to strive for healthcare equity for ESRD beneficiaries. The LVPA and rural adjusters currently result in increased payments to some geographically isolated ESRD facilities, but these adjusters do not specifically target geographically isolated ESRD facilities. We noted several points of concern that interested parties have raised in the past, as well as certain statutory limitations that could apply to some of the methodological approaches suggested in the past. We solicited information from the public about potential approaches to refine the ESRD PPS methodology, which we would take into consideration for any potential changes to the LVPA in the future.

This section addresses several RFIs regarding the LVPA and a potential new adjustment for geographically isolated ESRD facilities.

(a) Comment Solicitation for Modifications to LVPA Methodology

In the CY 2024 ESRD PPS proposed rule, we solicited comments on

[13] *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun20_ch7_reporttocongress_sec.pdf.*

[14] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf.*

[15] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf.*

potential changes to the LVPA methodology (88 FR 42441 through 42444), including maintaining a single threshold, establishing LVPA tiers, and/or utilizing a continuous function. Any potential refinements to the LVPA methodology that may result from our consideration of these comments would be proposed through notice-and-comment rulemaking in the future. We requested that commenters keep in mind that section 1881(b)(14)(D)(iii) of the Act requires the LVPA to reflect the extent to which costs incurred by low-volume facilities in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services.

(i) Maintain a Single LVPA Threshold

As discussions about modifying the existing treatment threshold or payment adjustment percentage have been ongoing since the beginning of the multi-year LVPA reform efforts, we solicited comments on maintaining a single threshold for the LVPA. ESRD facilities that fall below the treatment threshold would continue to receive payment, and payments would not be adjusted for those ESRD facilities above the threshold. We stated that we were engaged in continuing monitoring efforts to align resource use with payment. As noted in the CY 2024 ESRD PPS proposed rule (88 FR 42442), if we were to re-compute the LVPA percentage amount using the latest available claims and cost report data and the methodology established in the CY 2011 and CY 2016 ESRD PPS final rules (75 FR 49118 through 49125 and 80 FR 69001), the current treatment threshold of 4,000 treatments per year would correspond to a 17.6 percent payment adjustment. The 4,000-treatment threshold could be maintained, or the treatment threshold could be recalibrated to maintain the 23.9 percent payment adjustment. Maintaining a single threshold would not address concerns regarding the potential for gaming or remove what commenters call the payment cliff. Potential approaches for a single LVPA threshold are outlined in Table 2.

TABLE 2: Potential Approaches for a Single LVPA Threshold

Option	Description
Status quo	4,000-treatment threshold with 23.9 percent payment adjuster
Maintain Treatment Threshold	4,000-treatment threshold with 17.6 percent payment adjuster
Maintain Payment Adjuster	Reduce treatment threshold to 3,750 treatments to maintain 23.9 percent payment adjuster

(ii) Establishment of Multiple LVPA Tiers

We solicited comments on creating a tiered payment adjustment that would include multiple thresholds, with separate payment adjustments calibrated so that ESRD facilities in tiers with the lowest treatment volume would receive the highest payment adjustment, and vice versa. MedPAC has previously recommended setting LVPA treatment thresholds at fewer than 4,000 treatments, between 4,000 and 4,999 treatments, and between 5,000 and 6,000 treatments, with payment adjustments calibrated so that ESRD facilities in tiers with the lowest volume would receive the highest payment adjustment, and vice versa.[16] Establishing multiple thresholds, with a separate payment adjustment for ESRD facilities under each threshold level, would reduce the potential for gaming through reduction of the magnitude of the payment cliff. Additionally, LVPA eligibility would be expanded to more ESRD facilities. We solicited comments regarding the establishment of multiple thresholds, including up to an eight-tiered structure for the LVPA. Tables 3 through 6 outline various methodological options. Tables 3 and 4 would establish larger adjustment factors on average than the current methodology but would require reductions to the ESRD PPS base rate to maintain budget neutrality. Tables 5 and 6 show adjustment factors which are scaled to maintain budget neutrality within the LVPA, keeping the LVPA's budget at the same amount that would occur under the current methodology without requiring reductions to the ESRD PPS base rate. As illustrated below, scaling the adjusters while maintaining budget neutrality within the LVPA results in lower LVPA adjusters. For example, Tier 1 (less than 5,000 treatments) in the Four-Tiered Model varies based on the approach to maintaining budget neutrality, as the LVPA adjuster is 13.7 percent where budget neutrality is maintained within the ESRD PPS (Table 3) and 5.8 percent where budget neutrality is maintained within the LVPA (Table 5). For comparison, the Eight-Tiered Model shows that for Tier 1 (less than 1,000 treatments), ESRD facilities would receive a 123 percent LVPA adjuster where budget neutrality is maintained within the ESRD PPS (Table 4) and 40.5 percent LVPA adjuster where budget neutrality is maintained within the LVPA (Table 6).

[16] *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun20_ch7_reporttocongress_sec.pdf.*

TABLE 3: LVPA Adjustment with Four Tiers ($1.20 reduction to the ESRD PPS Base Rate to Maintain Budget Neutrality)

Tier (by treatment count)	**LVPA Adjusters**
Tier 1 (less than 5,000)	13.7%
Tier 2 (5,000 – 5,999)	8.4%
Tier 3 (6,000 – 6,999)	4.7%
Tier 4 (7,000 – 7,999)	1.9%

TABLE 4: LVPA Adjustment with Eight Tiers ($1.80 reduction to the ESRD PPS Base Rate to Maintain Budget Neutrality)

Tier (by treatment count)	**LVPA Adjusters**
Tier 1 (less than 1,000)	123.0%
Tier 2 (1,000- 1,999)	57.6%
Tier 3 (2,000-2,999)	33.9%
Tier 4 (3,000-3,999)	21.4%
Tier 5 (4,000 – 4,999)	13.7%
Tier 6 (5,000 – 5,999)	8.4%
Tier 7 (6,000 – 6,999)	4.7%
Tier 8 (7,000 – 7,999)	1.9%

TABLE 5: LVPA Adjustment with Four Tiers (Adjusters scaled to maintain total LVPA payments at current levels)

Tier (by treatment count)	**LVPA Adjuster**	**Est. Facilities Receiving Adjustment**
Tier 1 (less than 5,000)	5.8%	767
Tier 2 (5,000 – 5,999)	3.6%	331
Tier 3 (6,000 – 6,999)	2.0%	332
Tier 4 (7,000 – 7,999)	0.8%	318

TABLE 6: LVPA Adjustment with Eight Tiers (Adjusters scaled to maintain total LVPA payments at current levels)

Tier (by treatment count)	LVPA Adjuster	Est. Facilities Receiving Adjustment
Tier 1 (less than 1,000)	40.5%	22
Tier 2 (1,000- 1,999)	19.0%	69
Tier 3 (2,000-2,999)	11.2%	137
Tier 4 (3,000-3,999)	7.1%	250
Tier 5 (4,000 – 4,999)	4.5%	290
Tier 6 (5,000 – 5,999)	2.8%	331
Tier 7 (6,000 – 6,999)	1.5%	332
Tier 8 (7,000 – 7,999)	0.6%	318

(iii) Continuous Function

We also solicited comments on potentially establishing a continuous function to adjust LVPA payments. Under this approach, ESRD facilities with the lowest treatment volume would receive the highest payment adjustment, and the payment adjustment would decrease continuously as volume increases. This could include calibration of the point at which the payment adjustment becomes zero to correspond with the existing 4,000 treatment upper bound, or establishment of a new upper bound based on a regression analysis. Establishment of a continuous function has the potential to significantly reduce the potential for gaming by eliminating payment cliffs entirely. Additionally, this would increase payment for ESRD facilities with the lowest volume, therefore better aligning payment with resource use. Furthermore, a continuous function would potentially expand LVPA eligibility to the most ESRD facilities.

In the CY 2024 ESRD PPS proposed rule, we noted that we are considering several approaches to modifying the LVPA to address concerns about its incentive structure, treatment threshold, and administrative burden, as expressed by interested parties (including the GAO, MedPAC, and industry representatives). We issued this RFI to seek feedback on the suggested changes to the LVPA, as described previously, and to solicit further input from interested parties to inform future modifications to the methodology used to determine the LVPA.

CMS welcomed input and responses to the following considerations, requests, and questions:

- Regarding concerns about a payment cliff in the existing LVPA, we are considering implementing payment tiers or a continuous adjustment, based on treatment volume, in place of the current single tiered adjustment.

++ Comment on which payment structure would be more appropriate: single threshold as currently employed, tiered structure, or continuous function, and provide the reasoning behind your recommendation.

++ Comment on which option would be most effective in removing gaming incentives and which option would bring greater congruency between cost of providing renal dialysis services and payment.

- Using the alternative methodology described previously, under a tiered or continuous payment adjustment, the treatment threshold for eligibility would be determined based on the median treatment count among all ESRD facilities (approximately eight thousand treatments per year). The resulting tiers and incremental payment adjustments between tiers could follow several different configurations.

++ What factors should be evaluated to best determine the treatment count threshold, as well as the tiering structure? Specifically, comment on the treatment volume beneath which per-treatment costs begin to increase.

++ Enumerate any concerns you might have should the implementation of a tiered or continuous adjustment result in an expanded set of eligible ESRD facilities, and payment redistribution.

- Interested parties have voiced concern regarding the administrative burden involved in the current LVPA attestation process. As such, we are considering potentially decreasing the number of years of attestation data needed to determine LVPA eligibility.

++ Comment on the extent to which this change would alleviate burden, and if there are other administrative changes that could be made to simplify this process.

++ Describe any anticipated effects of decreasing the amount of treatment volume data used to determine LVPA eligibility.

++ Describe the ways that simplifying the attestation process could help ESRD facilities with fewer resources to promote health equity by improving their ability to serve vulnerable and underserved communities.

(b) Comment Solicitation on the Development of a New Payment Adjustment Based on Geographic Isolation

CMS is striving to promote health equity by ensuring that ESRD facilities, including both rural and low-volume facilities, are being paid equitably for serving populations that are currently underserved. Therefore, in the CY 2024 ESRD PPS proposed rule (88 FR 42444 through 42445), we solicited comments on potentially assisting geographically isolated ESRD facilities and promoting access in these areas, including labor force hiring and retention. We stated that we considered establishing a new payment adjustment that accounts for isolation, rurality, and other geographical factors. We also requested information on geographic isolation to determine if ESRD facilities that are

currently considered rural would benefit from a geographic isolation adjustment. The new geographically based payment adjustment may consider local dialysis need (LDN), as explained later in this section, instead of basing payment strictly upon a rural designation, as set forth in § 413.233 and 413.231(b)(2). We considered changes to the eligibility criteria to address the concerns that GAO and MedPAC raised about targeting LVPA payments to ESRD facilities that are not located near other ESRD facilities that are necessary to protect access to care. As noted previously, under section 1881(b)(14)(D)(iii) of the Act, the LVPA must reflect the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services. We explained that our preliminary analysis found that, in general, low-volume facilities that are rural, isolated, or located in low-demand areas *did not* have higher costs than low-volume ESRD facilities overall. Therefore, certain changes that interested parties have suggested would not comport with the statutory requirements and limitations for the LVPA. We solicited comments on potential methodologies for creating a separate payment adjustment that could potentially address GAO and MedPAC's concerns, relying upon the authority under section 1881(b)(14)(D)(iv) of the Act, which states that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate.

We solicited responses to the following questions.

++ What factors should be considered in formulating a payment adjustment for ESRD facilities in isolated geographical areas or areas for which there is a low need for renal dialysis services?

++ What are the best ways to incentivize renal dialysis service provision in isolated geographic areas?

++ Our analysis of the LDN methodology has shown that low LDN census tracts intersect with areas designated as Health Professional Shortage Areas. What impact would a payment adjustment based on geographic isolation have on the ability of ESRD facilities in isolated areas to recruit and retain health care professionals?

++ Comment on the appropriateness of maintaining the rural facility adjustment under § 413.233 if we were to establish an LDN payment adjustment in conjunction with a modified LVPA.

++ Comment on the relationship between geographic isolation and cost. Please provide any data that could further inform CMS's understanding of the relationship between geographic isolation and cost for low volume facilities.

++ Comment on the appropriateness of utilizing driving time between current beneficiary address and treatment location as the appropriate metric for travel time.

++ Are there ways in which the suggested methodology for this potential payment adjustment could fail in targeting isolated ESRD facilities, or ESRD facilities in areas with low LDN?

++ Are there ways in which the determination of LDN might be subject to gaming?

++ Would a payment adjustment for ESRD facilities in areas with low LDN improve health equity? Are there specific recommendations to change the LDN methodology described above to promote quality access to care for all ESRD beneficiaries?

++ Comment on the favorability of CMS's implementation of a new payment adjustment for ESRD facilities in areas with low LDN as described above.

++ Are there any other considerations we should keep in mind when considering proposing a new payment adjustment based on an LDN methodology?

(c) Summary of Request for Information on Potential Modification to LVPA Methodology and Information Received From Commenters

As discussed above, in the CY 2024 ESRD PPS proposed rule (88 FR 42430), we sought comment on several approaches to modifying the LVPA to address concerns about its incentive structure, treatment threshold, and administrative burden. We issued an RFI to seek feedback from the public on potential changes to the LVPA methodology, including maintaining a single threshold, establishing LVPA tiers, and/or utilizing a continuous function to ensure that payments accurately reflect differences in cost and adequately target low-volume facilities. We also solicited comments on the establishment of an add-on payment adjustment for geographic isolation of ESRD facilities. We asked commenters whether a payment adjustment for geographic isolation of ESRD facilities in areas with low local dialysis need would improve health equity.

We received 23 public comments in response to our RFI, including from large, small, and non-profit dialysis organizations; an advocacy organization; a coalition of dialysis organizations; a large non-profit health system; and MedPAC. A high-level description of these comments is included in the following subsections of this CY 2024 ESRD PPS final rule.

We thank the commenters for their detailed and thoughtful comments. While we will not respond to these comments in this CY 2024 ESRD PPS final rule, we intend to take them into consideration for future rulemaking and future policy development. We will provide more detailed information about the commenters' recommendations in a future posting on CMS's website located at the following link: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources*.

(i) Responses on Criteria for Receiving LVPA Status

We received a wide range of responses to the RFI. Many commenters supported MedPAC's proposal of implementing a two-tier low-volume and isolated (LVI) adjustment in place of the LVPA so that facilities can expand services to meet patient needs without substantial payment decreases while limiting administrative burden. Some commenters supported maintaining a single threshold with varying recommendations for adjusted treatment counts. Other commenters supported establishing varying numbers of tiers at varying treatment counts. Some commenters also supported establishing a continuous function as described in the CY 2024 ESRD PPS proposed rule. Many comments included general concerns regarding the administrative burden and transparency of the various methodologies described. While we are not providing a detailed response to these comments in this final rule, we thank the commenters for their input and will consider the recommendations in potential future rulemaking.

(ii) Responses on the Local Dialysis Need (LDN) Methodology

Commenters generally believed that the LDN methodology was overly complicated and lacked transparency. Several commenters expressed renewed support for incorporating geographic isolation directly into the LVPA formula, using a methodology such as the LVI adjustment that MedPAC suggested. While we are not providing a detailed response to these comments in this final rule, we thank the commenters for their input and will consider the recommendations in potential future rulemaking.

(3) Exception to the Current LVPA Attestation Process for Disasters and Other Emergencies

Under our current regulations at § 413.232(b), a low-volume facility is an ESRD facility that, based on the submitted documentation (1) furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent, except as specified in § 413.232(g)(4)) preceding the payment year; and (2) has not opened, closed, or received a new provider number due to a change in ownership (except where the change in ownership results in a change in facility type) in the 3 cost reporting years (based on as-filed or final settled 12 consecutive month cost reports, whichever is most recent) preceding the payment year. When we first established these requirements in the CY 2011 ESRD PPS final rule, we explained that looking across data for three years provided us with sufficient information to view consistency in business operations (79 FR 49123). In the CY 2019 ESRD PPS final rule (83 FR 56949) and the CY 2021 ESRD PPS proposed rule (85 FR 42165), we acknowledged commenters' concerns that the eligibility criteria in the LVPA regulations are very explicit and leave little room for flexibility during disasters or other emergency situations like the COVID–19 PHE. Commenters have emphasized that low-volume facilities rely on the LVPA, and that loss of the payment adjustment could result in beneficiary access issues.

As discussed in the CY 2021 ESRD PPS proposed rule (85 FR 42165), the COVID–19 PHE caused ESRD facilities to have to shift patients among ESRD facilities to provide uninterrupted care to their Medicare ESRD population. In some cases, this patient shifting increased dialysis treatments at some low-volume ESRD facilities, putting the ESRD facility temporarily over the LVPA treatment threshold. This increase in dialysis treatments, resulting from the COVID–19 PHE, disqualified some ESRD facilities that would have otherwise received the LVPA of 23.9 percent per treatment. In the CY 2021 ESRD PPS final rule (85 FR 71485), we established a policy that ESRD facilities would be held harmless from increases in treatment counts due to temporary patient shifting because of the COVID–19 PHE. To be held harmless, ESRD facilities must follow the attestation process for the exception set forth in § 413.232(g)(4) and are expected to provide supporting documentation to the MACs upon request. Interested parties have expressed support for CMS's swift response to the COVID–19 PHE's impact on ESRD facilities, with an association of dialysis providers stating that holding harmless LVPA status for these ESRD facilities will better ensure that ESRD patients can continue to access the life-sustaining dialysis treatment they need, particularly in rural and underserved areas where low-volume facilities heavily depend on the LVPA to remain open and provide treatment for patients.

In the CY 2024 ESRD PPS proposed rule, we stated that we recognize there could be future circumstances, potentially like the circumstances of the COVID–19 PHE, in which it would be appropriate to provide flexibilities with respect to certain LVPA requirements (88 FR 42446). Commenters have previously expressed concerns about the strict attestation requirements for ESRD facilities to remain eligible for the LVPA, particularly when faced with a disaster or other emergency, such as a local or national emergency, natural disaster, catastrophic event, or public health emergency. We noted that during disasters or other emergencies, low-volume facilities could be forced to close, or could experience increases in their treatment counts if they treat patients who are displaced from a nearby ESRD facility that is impacted by such an event. For example, in August of 2021, an ESRD facility in Louisiana sustained significant damage because of Hurricane Ida, which required the ESRD facility to close for repairs and temporarily stop furnishing renal dialysis services. The ESRD facility served a rural community and for over 10 years received the LVPA due to the low number of dialysis treatments it furnished each year. This ESRD facility sought recourse to maintain its eligibility for the LVPA when it resumed operations following the required repairs to the ESRD facility, however, recourse was unavailable due to the limitations set forth in § 413.232(b). We explained that when we established the LVPA in the CY 2011 ESRD PPS final rule, we stated that we believed the LVPA should encourage small ESRD facilities to continue to provide access to care to an ESRD patient population where providing that care would otherwise be problematic (75 FR 49118). Given that these requirements for low-volume facilities were created to protect access to care for the vulnerable patient population that these ESRD facilities serve, we noted, adding certain flexibilities during disasters or other emergencies would promote our commitment to ensuring access to care for ESRD patients.

(a) Changes to the LVPA

We proposed to make two changes to the LVPA regulation at § 413.232 to allow for more administrative flexibilities during disasters or other emergencies. First, we proposed to create a new exception to the attestation process for disasters and other emergencies. Second, we proposed to establish a process that would allow low-volume facilities to close and reopen in response to a disaster or other emergency and still receive the LVPA. CMS would assess whether a particular situation is a disaster or other emergency based on the totality of the circumstances that could result in disruption of or inability to furnish renal dialysis services at one or more ESRD facilities, thus affecting the ESRD facility or facilities' ability to qualify for the LVPA. For purposes of the proposal, disasters or other emergencies would include, but not be limited to, the below examples:

- A public health emergency declared by the Secretary due to a significant outbreak of infectious disease or bioterrorist attacks.
- Natural disasters including winter storms, floods, tornados, hurricanes, wildfires, earthquakes, or any combination thereof.[17]
- Catastrophic events outside of an ESRD facility's control that disrupt operations and result in an ESRD facility's closure, for example, loss of operations or patient shifting due to a local emergency such as fire, floods, earthquakes, or tornadoes.
- Other disasters or emergency conditions under which a waiver could be granted pursuant to section 1135 of the Act.

We stated that these policy changes could help displaced ESRD patients maintain access to renal dialysis services by preventing ESRD facilities from permanently closing due to the loss of their LVPA. It is important that ESRD facilities that are receiving the LVPA can maintain LVPA eligibility despite the impacts caused by a disaster or other emergency. This policy could potentially protect other ESRD facilities that need to maintain the LVPA to remain open from potentially losing their LVPA by exceeding the treatment threshold because they accepted displaced patients. We noted that we do not want the fear of losing the LVPA due to increased treatments exceeding the threshold to disincentivize ESRD facilities from accepting patients from

[17] *https://www.dhs.gov/natural-disasters.*

other ESRD facilities experiencing a disaster or other emergency. It is also important that ESRD facilities that are forced to close due to a disaster or other emergency can maintain their LVPA eligibility upon reopening to ensure continued access in areas that otherwise may lack sufficient ESRD facilities. This policy could also help those ESRD facilities affected by the disaster or other emergency potentially resume operations and avoid permanent closure if they would be allowed to receive the LVPA upon reopening despite the closure or disruption of operations.

(i) Exception to the LVPA Treatment Threshold for ESRD Facilities That Accept Patients From an ESRD Facility Affected by a Disaster or Other Emergency

We proposed in the CY 2024 ESRD PPS proposed rule to create an exception to the LVPA treatment threshold requirements set forth in § 413.232(b)(1) under a new provision in § 413.232(g)(5), which would allow an ESRD facility to receive the LVPA even if it exceeds the LVPA threshold if its treatment counts increase due to treating additional patients displaced by a disaster or other emergency. Qualification for the exception would require an ESRD facility to absorb those displaced patients from an outside or adjacent ESRD facility that experienced a temporary closure or operational disruption (such as a water shut off). If an ESRD facility accepts the patients of the ESRD facility affected by the disaster or other emergency, causing that ESRD facility to meet or exceed the 4,000-treatment count for all dialysis patients, it would attest to its MAC that it furnished treatments equal to or in excess of 4,000 in the cost reporting year due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility due to a disaster or other emergency. We proposed to define temporary patient-shifting in the context of the LVPA in the ESRD PPS as providing renal dialysis services to one or more patient(s) at any time through the end of the CY following the 12-month period beginning when an ESRD facility first begins providing renal dialysis services to the displaced patient(s). The ESRD facility would be required to request this exception from CMS by writing to the ESRD Payment Mailbox (*ESRDPAYMENT@cms.hhs.gov*) no later than the annual attestation deadline of November 1st. CMS would review the exception request within 30 days to determine if the ESRD facility qualifies for the exception. If approved by CMS, the ESRD facility would be paid the LVPA for Medicare beneficiaries for up to the first 4,000 dialysis treatments in the payment year in which the temporary patient-shifting occurred. Under this exception, the ESRD facility would be held harmless for meeting or exceeding the 4,000-treatment threshold during one or more cost reporting years within the 3-year lookback for LVPA eligibility as long as their 4,000-treatment threshold was exceeded as a result of temporary patient-shifting from the ESRD facility that experienced the disaster or other emergency. If CMS does not approve the request, CMS would notify the ESRD facility and the MAC, and the ESRD facility would be disqualified from receiving the LVPA until it meets all the LVPA criteria (including the 3-year lookback). The ESRD facility receiving this exception must maintain documentation of the number of displaced patients treated and information about the ESRD facility or facilities that previously treated those patients and closed or experienced an operational disruption due to a disaster or other emergency and must provide such documentation to CMS and the MAC upon request. The ESRD facility requesting this exception would have to repeat the process for requesting an exception for each cost reporting year in which its treatment volume meets or exceeds 4,000 due to temporary patient-shifting from the ESRD facility that experienced the disaster or other emergency. Additionally, the ESRD facility requesting this exception would have to follow the attestation process as described at § 413.232(e) for the two payment years following the last cost reporting year in which its treatment volume meets or exceeds 4,000 due to treating displaced patients from the ESRD facility that experienced the disaster or other emergency and attest that the ESRD facility meets the criteria established at § 413.232.

We provided the following example: if a disaster occurs on June 1, 2024, which results in ESRD facility X's closure or operational disruption resulting in ESRD facility Y (an existing low-volume facility) treating additional patients from ESRD facility X that puts ESRD facility Y's total renal dialysis treatments for cost reporting year 2024 over the 4,000 treatment threshold, ESRD facility Y would be required to request an exception to § 413.232(b)(1) from CMS by November 1, 2024 to continue receiving the LVPA. Since ESRD facility Y began treating the displaced patients in CY 2024, the window for temporary patient shifting would extend until December 31, 2025. To be approved for the exception under the proposed provision in § 413.232(g)(5), CMS would determine that ESRD facility Y furnished treatments equal to or more than 4,000 in the cost reporting year due to temporary patient-shifting because of the closure or operational disruption of ESRD facility X resulting from a disaster or other emergency. Should the exception be approved by CMS, ESRD facility Y would receive the LVPA for up to the first 4,000 treatments it furnished in 2024. Additionally, ESRD facility Y would not be disqualified from receiving the LVPA for payment years (PYs) 2025 and 2026 due to exceeding the treatment volume threshold in cost reporting year 2024, assuming the temporary patient-shifting from ESRD facility X occurred only in cost reporting year 2024. For PY 2025 and PY 2026, ESRD facility Y would have to attest that it meets all the criteria for the LVPA because it furnished treatments equal to or more than 4,000 in the cost reporting year due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility resulting from a disaster or other emergency and received an exception for cost reporting year 2024. This would be the same attestation process as if ESRD facility Y did not furnish any excess treatments and was attesting that it continued to meet the criteria for the LVPA for those payment years. If the closure or operational disruption of ESRD facility X causes the treatment volume for ESRD facility Y to meet or exceed the 4,000-dialysis treatment threshold in cost reporting year 2025, ESRD facility Y would have to submit another request for an exception by November 1, 2025. Should this exception be approved, ESRD facility Y would receive the LVPA for up to the first 4,000 treatments it furnished in cost reporting year 2025 and would not be disqualified from receiving the LVPA for PYs 2026 and 2027 due to exceeding the treatment volume threshold in cost reporting year 2024 and cost reporting year 2025. If ESRD facility Y continued to treat displaced patients from ESRD facility X in cost reporting year CY 2026, it would only be considered temporary patient-shifting if ESRD facility Y treated those patients before January 1, 2026, and if patients treated after January 1, 2026 cause ESRD facility Y to exceed the 4,000-treatment volume threshold in cost reporting year 2026 then the ESRD facility would be disqualified from receiving the LVPA under § 413.232(b)(1). Under this example, ESRD facility Y would still have to meet the other eligibility requirements to

receive the LVPA in any PY in which the ESRD facility would receive the LVPA.

(ii) Exception to the LVPA Closure Provision for ESRD Facilities Affected by a Disaster or Other Emergency

In addition to the proposed exception to the treatment threshold requirement under § 413.232(b)(1) and (g)(5), we proposed an exception under § 413.232(g)(6) that would allow an ESRD facility to still receive the LVPA if it temporarily closes. That is, if an ESRD facility temporarily ceases to operate and the patients must go to another ESRD facility to receive renal dialysis services due to a disaster or other emergency, and the ESRD facility subsequently reopens, we proposed to create an exception to the requirement in § 413.232(b)(2) that an ESRD facility ''has not opened, closed, or received a new provider number'' in the 3 cost reporting years preceding the payment year. If an ESRD facility is affected by a disaster or other emergency and the ESRD facility is forced to close and re-open later, the ESRD facility would need to request an exception from CMS in writing at the ESRD Payment Mailbox at *ESRDPAYMENT@cms.hhs.gov* within 60 days of the closure and inform the MAC of the request. CMS would review the request within 30 days of receipt and either approve the request based on a determination that the ESRD facility closed due to a disaster or other emergency, or deny the request, and would inform both the ESRD facility and the MAC of its decision.

Under the proposal, upon reopening and providing renal dialysis services, the ESRD facility would be required notify CMS and the MAC in writing within 30 days of its reopening. CMS would acknowledge receipt of the written notification within 30 days. If the exception is approved and CMS is duly informed of the ESRD facility's reopening, the ESRD facility would remain eligible for the LVPA and the MAC would process payment accordingly. To continue receiving the LVPA the ESRD facility would still have to meet all the other eligibility requirements for the LVPA. The exception to § 413.232(b)(2) would be applicable for a period of 2 cost reporting years following the date of closure of the ESRD facility. After a period of 2-cost reporting years the ESRD facility would follow the normal attestation process for the LVPA specified in paragraphs (e) and (g) of § 413.232. The ESRD facility would be required to maintain documentation regarding its closure, and to provide such supporting documentation to CMS and/or the MAC upon request.

We provided the following example: If a disaster occurs on June 1, 2024, which results in an ESRD facility experiencing a closure, the ESRD facility would request an exception to § 413.232(b)(2) from CMS within 60 days of June 1, 2024 (that is, on or before July 31, 2024). CMS would review the request and notify the ESRD facility and the MAC within 30 days if the exception is approved or denied. If the ESRD facility then reopens on September 1, 2024, the ESRD facility would notify CMS and the MAC in writing within 30 days of reopening (that is, on or before October 1, 2024). CMS would notify the ESRD facility and the MAC of its receipt of the reopening notification within 30 days. If the exception was approved by CMS, the ESRD facility would remain eligible for the LVPA for the rest of payment year 2024 and for the entirety of payment year 2025 and payment year 2026, provided the ESRD facility continues to meet the other eligibility requirements for the LVPA.

We received 10 public comments on our proposals to modify the LVPA regulation at § 413.232 to allow for more administrative flexibilities during disasters or other emergencies. These comments came from three LDOs, a non-profit dialysis organization, a coalition of dialysis organizations, a non-profit advocacy organization, and a non-profit kidney organization. The comments on our proposals and our responses are set forth below.

Comment: All of the comments supported CMS's proposal to establish exceptions to the LVPA requirements for ESRD facilities impacted by a disaster or other emergency.

Response: We appreciate the support for our proposed exceptions to the LVPA requirements for ESRD facilities that are impacted by a disaster or other emergency.

Comment: One LDO requested that CMS reevaluate the attestation deadline for ESRD facilities that exceed the LVPA treatment volume threshold due to accepting displaced patients from an ESRD facility that closes or experiences an operational disruption due to a disaster or other emergency. This LDO noted that if the disaster were to occur late in the year, it might be difficult for an ESRD facility to meet the November 1st attestation deadline.

Response: We thank the commenter for the thoughtful suggestion on how to improve the proposed exception for ESRD facilities that exceed the 4,000-treatment volume threshold due to treating patients displaced by a disaster or other emergency. We note that § 413.232(e) currently states that ''to receive the low-volume adjustment an ESRD facility must provide an attestation statement, by November 1st of each year preceding the payment year, to its Medicare Administrative Contractor (MAC) that the facility meets all the criteria established in this section,'' except as otherwise specified. We did not propose to change the attestation deadline for ESRD facilities impacted by a disaster or other emergency. In the CY 2012 ESRD PPS final rule (76 FR 70236), we finalized a yearly November 1st deadline for attestation submission, and noted that this timeframe provides 60 days for a MAC to verify that an ESRD facility meets the LVPA eligibility criteria. It is important that all ESRD facilities have the same attestation deadline for the LVPA to allow adequate verification time for the MACs and so that those ESRD facilities eligible for LVPA are able to receive it timely. In the past when we have extended the LVPA attestation deadline, we have done so for all ESRD facilities (85 FR 71442). However, we believe that a November 1st deadline is necessary so that the LVPA attestations can be properly processed, and payments can begin on January 1st of the next CY. In response to the concern for ESRD facilities which are impacted by a disaster late in the year, we are modifying the proposed regulation language at § 413.232(g)(5) to allow an ESRD facility to request the exception to the 4,000-treatment volume threshold requirement up to 30 days after the end of the cost reporting year for which they are attesting. Although the ESRD facility would still have to submit an attestation by the November 1st deadline, this will allow additional flexibility for ESRD facilities that experience temporary patient shifting late in the year if their cost-reporting year ends within 30 days of the attestation deadline. We clarify that under this exception, an ESRD facility would have to submit the exception request by either the attestation deadline or 30 days after the end of the ESRD facility's cost reporting year, whichever is later, but would not be required to have received the exception by the attestation deadline. Then, in the event that the ESRD facility does not receive approval for the exception from CMS, the MAC would follow the current process. Specifically, as noted in § 413.232(h)(2), if the MAC determines an ESRD facility does not meet the definition of a low-volume facility, the MAC reprocesses claims and recoups

low-volume adjustments paid during the payment year.

Comment: A coalition of dialysis organizations requested that the exception to the attestation process for ESRD facilities that treat displaced patients be extended to ESRD facilities that treat displaced patients from ESRD facilities that closed for reasons not related to a disaster or other emergency. This commenter noted that between 2020 and 2023, 383 ESRD facilities closed, which impacted an estimated 21,000 patients.

Response: At this time, we do not agree that it is appropriate to allow ESRD facilities to exceed the LVPA treatment volume threshold due to treating displaced patients from ESRD facilities that close for reasons unrelated to disasters or other emergencies. If an ESRD facility closes due to a disaster or other emergency, the ESRD facility could re-open or another ESRD facility could open in its place, which would lead to the accepting ESRD facility returning to a lower treatment volume. However, if an ESRD facility closes for reasons unrelated to a disaster or other emergency, such as lack of demand or profitability, it is less likely that the ESRD facility would re-open or that a new ESRD facility would replace it. Additionally, implementing this commenter's suggestion could lead to perverse incentives. For example, an ESRD facility that does not receive the LVPA and closes temporarily has its patients receive treatment at another affiliated ESRD facility, which usually receives the LVPA (and therefore, a higher payment rate). If the commenter's suggestion were to be implemented, with the influx of new patients, the ''accepting'' ESRD facility could strategically surpass the 4,000-treatment level and still receive the LVPA.

Final Rule Action: We are finalizing our proposals to establish an exception process to allow a facility to close and reopen in response to a disaster or emergency and still receive the LVPA, and to allow a facility to receive the LVPA even if it exceeds the LVPA threshold if its treatment counts increase due to treating additional patients displaced by a closure or operational disruption caused by a disaster or other emergency, as proposed, with two modifications. First, as noted above, we are finalizing one modification to § 413.232(g)(5)(ii) to change the deadline by which the ESRD facility must request the exception to § 413.232(b)(1) to be the later of the attestation deadline or 30 days after the end of the cost reporting year for which the ESRD facility is attesting. Specifically, we are finalizing § 413.232(g)(5) which states that if an ESRD facility exceeds the 4,000-treatment volume threshold due to temporary patient shifting from an ESRD facility that experiences a closure or operational disruption due to a disaster or other emergency, the accepting ESRD facility would be able to apply for an exception to the requirement at 413.232(b)(1) and, if the exception is approved, the ESRD facility would not be disqualified from receiving the LVPA on the basis of 413.232(b)(1) due to exceeding the 4,000-treatment volume threshold in that cost reporting year. The deadline for requesting this exception would be either the attestation deadline or 30 days after the end of the cost reporting year for which the ESRD facility is attesting, whichever is later. We are finalizing a definition of temporary patient shifting in the context of the ESRD PPS LVPA as providing renal dialysis services to one or more patient(s) at any time through the end of the CY following the 12-month period beginning when an ESRD facility first begins providing renal dialysis services to the displaced patient(s). We are finalizing a second modification of the proposed regulation text at § 413.232(g)(5)(iv) to indicate that we will not limit the LVPA payment to 4,000 treatments for the payment year in which the temporary patient-shifting occurred due to a disaster or other emergency. We proposed that if an exception is approved under § 413.232(g)(5), the ESRD facility would be paid the low-volume adjustment on claims for Medicare beneficiaries for up to the first 4,000 dialysis treatments during the payment year in which the temporary patient-shifting occurred, so long as all other requirements for the low-volume adjustment are met. The intent of this proposed limit was to support stability of payments for ESRD facilities experiencing temporary patient-shifting due to an emergency at a level commensurate with their historical treatment volumes, while protecting the Medicare program against the risk of paying the LVPA for a large number of treatments. After further consideration of the operational and payment implications of this policy, we are making this change to be consistent with our historical practice of not limiting payment of the LVPA in the year in which the LVPA threshold is exceeded. We are concerned that limiting LVPA payment to 4,000 treatments for facilities would create operational confusion for facilities and could limit the ability of these ESRD facilities to take on patients who are displaced by a disaster or emergency. Furthermore, we considered that low-volume ESRD facilities generally receive the LVPA on fewer than 4,000 treatments per year, since the 4,000 treatment threshold includes all treatments that the facility provides. We therefore do not believe it is necessary to apply the proposed limit, since ESRD facilities operating under an exception would be unlikely to exceed 4,000 treatments paid under the ESRD PPS. We intend to monitor the use of these new exceptions to ensure that they are being applied appropriately and do not create opportunities for gaming.

Additionally, we are finalizing § 413.232(g)(6), which states that if an ESRD facility has closed and reopened in response to a disaster or other emergency, it would be able to apply for an exception to the requirement at 413.232(b)(2) and, if the exception is approved, the ESRD facility would not be disqualified from receiving the LVPA on the basis of 413.232(b)(2) due to closing in that year. The deadline for requesting this exception is 60 days after ESRD facility's closure.

(4) Technical Correction to § 413.232(g)

We proposed a technical correction at § 413.232(g) to replace ''their'' with ''its,'' to clarify the regulation language.

Final Rule Action: We did not receive comments regarding the technical correction to the regulations text for the LVPA, and we are finalizing this revision as proposed.

g. Transitional Pediatric ESRD Add-On Payment Adjustment for Pediatric Patients With ESRD Receiving Renal Dialysis Services

(1) Background

Section 1881(b)(14)(D)(iv)(I) of the Act provides that the ESRD PPS may include such payment adjustments as the Secretary determines appropriate, including a payment adjustment for pediatric providers of services and renal dialysis facilities. Determining such a payment adjustment has been historically difficult due to the consistent lack of data. The Medicare pediatric ESRD patient population receiving dialysis is small compared to the adult ESRD population, representing approximately 0.14 percent of the total ESRD patient population in 2022. In the past, CMS has considered various payment adjustments for pediatric patients with ESRD, including different Medicare payments by sex or comorbidities (74 FR 49984 through 49986). However, many of these considered adjustments were not used as we were unable to get acceptable

precision due to the small sample size of pediatric patients with ESRD.

Prior to the establishment of the ESRD PPS, payment for pediatric ESRD renal dialysis services was generally the same rate as adult ESRD renal dialysis services, unless the ESRD facility qualified for an exception to the composite rate. Section 1881(b)(7) of the Act stated that, subject to section 422(a)(2) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554) (BIPA), the Secretary shall provide for exceptions as may be warranted by unusual circumstances (including the special circumstances of sole facilities located in isolated, rural areas and of pediatric facilities). During this time, CMS received many comments and concerns regarding the payment rate for renal dialysis services furnished to pediatric patients with ESRD. Section 623(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) later amended section 422(a)(2) of BIPA to provide that any pediatric ESRD facility would be eligible for an exception to the composite rate, effective October 1, 2002. This statute defined pediatric ESRD facilities as facilities with at least 50 percent patients under the age of 18. This enabled pediatric ESRD facilities to obtain payments that specifically recognized the higher cost associated with treating these patients (69 FR 47530).

We finalized a basic case-mix adjustment to the composite payment rate in the CY 2005 Physician Fee Schedule (PFS) final rule published on November 15, 2004 (69 FR 66327). This included a 62 percent pediatric payment increase (that is, an adjustment factor of 1.62) applied to the composite payment rate per treatment for any facility when furnishing outpatient renal dialysis services to pediatric patients with ESRD. This factor was derived from the average exception amounts for 20 ESRD facilities that had received exceptions for pediatric patients. This was intended to be a temporary measure, which would be eliminated once we developed the case-mix methodology that would apply for the ESRD PPS bundled payment. The use of this methodology allowed CMS to provide additional payment for the pediatric ESRD population under the composite rate in a data-driven manner to account for the higher costs pediatric patients faced (69 FR 66327).

Section 153(b) of MIPPA added section 1881(b)(14) of the Act, which required CMS to implement an ESRD bundled PPS beginning January 1, 2011, under which a single payment for renal dialysis services is made in lieu of any other payment. Renal dialysis services generally include items and services included in the composite rate for renal dialysis services as of December 31, 2010, and services furnished to individuals for treatment of ESRD, which were formerly separately billable, including drugs and biological products and laboratory tests. In the CY 2011 ESRD PPS proposed rule, we proposed a single composite rate modifier of 1.199 for all Pediatric ESRD Patients receiving dialysis (74 FR 49982 through 49983). A ''Pediatric ESRD Patient'' is defined as an individual less than 18 years of age who is receiving renal dialysis services (§ 413.171). We also proposed an eight-group system for separately billable renal dialysis services furnished to Pediatric ESRD Patients with two subdivisions for each of the following factors: age (under 13, 13 to 17), modality (hemodialysis, peritoneal dialysis) and number of comorbidities (none, one or more) (74 FR 49983 through 49987). The CY 2011 ESRD PPS proposed rule then calculated an ''expanded bundle'' modifier, which combined the composite rate and separately billable modifiers for each of the eight groups (74 FR 44987). These expanded bundle modifiers were the proposed pediatric patient-specific case-mix adjustment factors that would be applied to the base rate under the ESRD PPS. These modifiers were based on a regression of costs for all renal dialysis services furnished to Pediatric ESRD Patients. Comments on this proposed rule indicated that many interested parties believe the expanded bundle modifier was insufficient (75 FR 49128). In the CY 2011 ESRD PPS final rule, we responded to those comments by implementing the first iteration of the current four-group system for both the expanded bundle and the separately billable services. This methodology was data driven, but unlike the simple regression for composite rate costs, allowed for different Medicare payment amounts based on two sets of two characteristics: age of the patient (under 13 or 13 to 17) and modality of the treatment (hemodialysis or peritoneal dialysis). Additionally, this methodology used the same groups for the expanded bundle and separately billable modifiers (75 FR 49134).

We codified the Pediatric ESRD Patient payment adjustment in § 413.235(b), which states that CMS adjusts the per treatment base rate for pediatric patients in accordance with section 1881(b)(14)(D)(iv)(I) of the Act, to account for patient age and treatment modality. These multipliers were updated in the CY 2016 ESRD PPS final rule using the same methodology (80 FR 69001 through 69002). The current expanded bundle case mix adjusters are presented in Table 7.

TABLE 7: Current Pediatric ESRDB Payment Modifiers

Current Pediatric ESRD Expanded Bundled Payment Modifiers by Age and Modality (Effective 1/1/2016)		
Age	**<13**	**13-17**
Hemodialysis	1.306	1.327
Peritoneal Dialysis	1.063	1.102

As we discussed in the CY 2024 ESRD PPS proposed rule (88 FR 42449), despite these changes intended to improve payment accuracy for renal dialysis services furnished to Pediatric ESRD Patients, we continue to receive comments and concerns from interested parties that the payment amounts for renal dialysis services furnished to Pediatric ESRD Patients are too low. In addition to comments received through the annual ESRD PPS rulemaking, we have also solicited comments from interested parties on several occasions. During the December 2020 TEP, we queried a panel of experts on how to improve payment for pediatric dialysis care under the ESRD PPS. Panelists [18] generally preferred creating more refined case-mix adjusters over creating

[18] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf.*

an entirely new pediatric ESRD PPS, citing the costs of creating an entirely new system both on CMS and the ESRD facilities and the need for new legislation to be able to increase payment through a separate pediatric ESRD PPS. Panelists also pointed to labor costs as a major reason for higher costs among pediatric dialysis clinics because these patients need more nursing attention and specialized pediatric nutritionists.

We noted that, in the CY 2023 ESRD PPS proposed rule (87 FR 38529), we issued a request for information regarding health equity for pediatric patients with ESRD. Many commenters asserted that Medicare payments for Pediatric ESRD Patients are too low and that the ESRD PPS bundled payment does not target the unique issues facing ESRD facilities furnishing renal dialysis services to Pediatric ESRD Patients.

As we explained in the CY 2024 ESRD PPS proposed rule, we are committed to improving health equity for Pediatric ESRD Patients receiving renal dialysis services by improving payment equity through more efficient Medicare payments. Ensuring Medicare payments are appropriate and reflect costs for renal dialysis services furnished to Pediatric ESRD Patients would allow more ESRD facilities to provide quality care to this vulnerable population. The main barrier to payment equity is the lack of sufficient data to determine the relative costs associated with furnishing renal dialysis services to Pediatric ESRD Patients. To improve payment rate accuracy for Pediatric ESRD Patients, CMS has issued changes to the cost reports for both freestanding ESRD facilities and hospital-based ESRD facilities effective January 1, 2023.[19] [20] [21] These changes include separate categories for labor and supplies used in furnishing renal dialysis services to Pediatric ESRD Patients. These updates are intended to provide data for CMS to more comprehensively estimate the additional costs associated with furnishing renal dialysis services to Pediatric ESRD Patients. However, we estimated it would take approximately 3 years to obtain and analyze the granular data provided by the stratified cost reports data from these changes that we need to consider proposing a more finely tuned payment adjustment.

(2) Alternative Methodology for Estimating Relative Costs for Furnishing Renal Dialysis Services to Pediatric ESRD Patients

As discussed in the CY 2024 ESRD PPS proposed rule, payment accuracy has been historically difficult for pediatric ESRD dialysis because of the small sample size of Pediatric ESRD Patients receiving renal dialysis services paid for under the ESRD PPS. Pediatric ESRD dialysis treatments are also furnished differently from adult ESRD dialysis treatments in several crucial ways. For example, pediatric ESRD facilities are more likely to be hospital-based and, on average, have lower treatment volume and are in higher wage index areas. These systematic differences in treatment, when combined with the small sample size, make it very difficult to obtain low variance estimates of the differences in costs between pediatric and adult ESRD dialysis patients. Even if simple cost models show statistically significant estimates, it is possible that the systematic differences between pediatric and adult ESRD facilities can bias these estimates. Obtaining a reliable estimate of the additional costs that Pediatric ESRD Patients incur would allow us to create a payment adjustment to bring relative Medicare payments more in line with relative costs.

One can account for this bias by selecting a specific sample of ESRD facilities that have similar characteristics except for proportion of dialysis treatments furnished to Pediatric ESRD Patients. This would help to show the additional costs of furnishing dialysis to Pediatric ESRD Patients based on the variation in costs across the ESRD facilities. To achieve this, we would use propensity score matching (PSM).

PSM is a technique that uses regression analysis to account for systematic differences between two populations to isolate the effects of a single variable, in this case percentage of Pediatric ESRD Patients. The PSM regression includes a wide range of ESRD facility-level characteristics including facility type, size, geographic location, and the pediatric ESRD dialysis population nearby the ESRD facility to make a propensity score. This propensity score represents the probability that a given ESRD facility treats a high volume of Pediatric ESRD Patients given its facility-level characteristics.

Once the propensity score for each ESRD facility is determined, each ESRD facility with a significant percentage of Pediatric ESRD Patients (high-pediatric) is matched with the ESRD facility without a significant percentage of Pediatric ESRD Patients (low-pediatric) with the most similar propensity score. We can then compare the relative per-treatment costs of those ESRD facilities to estimate the additional costs an ESRD facility faces when it furnishes renal dialysis services to a higher proportion of Pediatric ESRD Patients, controlling for some important facility-level characteristics. The dependent variable of this regression is the log of the cost per treatment for the ESRD facility. The independent variables are the percent of dialysis treatments that are furnished to Pediatric ESRD Patients, the log of the facility size, the type of ESRD facility (hospital-based, children's hospital-based or freestanding), the log of the wage index for the ESRD facility and the year for the cost report data. The regression equation for cost per treatment given a certain percentage of dialysis treatments furnished to Pediatric ESRD Patients is:

$$\text{Log}\left(\frac{\text{Cost}}{\text{Treatment}}\right) = \text{Pediatric Share} + \log(\text{Facility Size}) + \text{Hospital Type} + \log(\text{wage Index}) + \text{Year Indicator}$$

This cost regression should be unbiased due to the use of PSM. However, PSM also requires a reduction in sample size, because there are relatively few ESRD facilities with a significant number of treatments furnished to Pediatric ESRD Patients that could be matched using PSM. This smaller sample size inherently results in an increase in margin of error. We stated that we believe this is a necessary tradeoff because a biased estimate cannot be relied upon, but we must be cautious while using high-error estimates. The result of this regression is that ESRD facilities that solely serve Pediatric ESRD Patients incur costs that are 40 percent higher per patient for furnishing renal dialysis services than similar ESRD facilities that serve no Pediatric ESRD Patients. The confidence

[19] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r7p242.*

[20] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r18p240i.*

[21] 87 FR 26760 (May 5, 2022). *https://www.federalregister.gov/documents/2022/05/05/2022-09581/agency-information-collection-activities-submission-for-omb-review-comment-request.*

interval of this estimate is 20 percent to 60 percent. Therefore, on average, furnishing renal dialysis services to a Pediatric ESRD Patient costs 40 percent more than furnishing renal dialysis services to an adult patient with ESRD.

(3) Current Medicare Payments for Renal Dialysis Services Furnished to Pediatric ESRD Patients

As discussed in the CY 2024 ESRD PPS proposed rule, the ESRD PPS already accounts for some of the higher costs that ESRD facilities incur while furnishing renal dialysis services to Pediatric ESRD Patients through the case-mix adjusters. Because the analysis described previously uses cost report data, it does not incorporate either the current case-mix adjusters or payment rates for Pediatric ESRD Patients receiving renal dialysis services. We noted that our most recent estimates showed that payments for dialysis treatments furnished to Pediatric ESRD Patients were approximately 10 percent higher than for adult patients with ESRD in CY 2022.

We explained that we are striving for payment accuracy, which is achieved when relative Medicare payments are proportional to relative costs. There are several ways we could adjust ESRD PPS payments to achieve payment accuracy, including calculating the unaccounted-for cost differential, which is the amount by which ESRD PPS payments for pediatric ESRD renal dialysis services must be increased to achieve payment accuracy. We could do this by reducing the cost differential estimate of 40 percent by a factor 1.1 to account for the current payment differential of 10 percent. This would yield an unaccounted-for cost differential of approximately 30 percent (1.4 divided by 1.1 is 1.27 which we are rounding to 1.3). This is a reasonable estimate of the additional labor and supply costs, which are not accounted for by the current case-mix adjusters, incurred by ESRD facilities furnishing renal dialysis services to Pediatric ESRD Patients.

(4) Transitional Pediatric ESRD Add-On Payment Adjustment

As we stated in the CY 2024 ESRD PPS proposed rule, despite the high margin of error of the cost regression using PSM, we believe that 30 percent cost is the most reasonable estimate of the unaccounted-for costs incurred in treating Pediatric ESRD Patients compared to adult ESRD patients. Creating a new add-on payment adjustment using this figure would provide pediatric ESRD facilities with Medicare payments proportional to their estimated costs for a temporary period while we collect additional data. However, due to the high margin of error of the model, increasing Medicare payments to ESRD facilities such that payments are 40 percent higher for Pediatric ESRD Patients compared to all patients would risk making payments higher than appropriate. We noted that when we conduct the analysis with the more comprehensive cost report data provided by the cost report changes implemented for CY 2023, we might find that our analysis overestimated the cost of furnishing renal dialysis services to Pediatric ESRD Patients (that is, that the additional 30 percent payment adjustment was too large). We further stated that if we finalized the transitional add-on payment adjustment for Pediatric ESRD Patients as proposed, pediatric ESRD facilities should be prepared for the possibility that the payment rate for Pediatric ESRD Patients could decrease in the future, should that be indicated by future data analysis and finalized through notice-and-comment rulemaking. We discussed the alternative to propose a smaller, more cautious add-on payment adjustment based on the 20 percent lower bound of the confidence interval, leading to an additional 10 percent transitional add-on payment adjustment after accounting for the current payment rate. This option would still represent a significant increase in Medicare payments to ESRD facilities for Pediatric ESRD Patients without much risk of making payments higher than appropriate. However, this alternative option may lead to underpayment to ESRD facilities serving Pediatric ESRD Patients, which is contrary to our goal of aligning resource use with payment. We invited comments on the most appropriate amount for the proposed transitional add-on payment adjustment.

We proposed in the CY 2024 ESRD PPS proposed rule a new transitional add-on payment adjustment of 30 percent (adjustment factor of 1.3) for dialysis treatments furnished to Pediatric ESRD Patients for 3 CYs, effective January 1, 2024. We stated that based on the time lag for cost report data, 3 years should allow for enough time for CMS to get more detailed data from the changes to the cost reports described previously. After that period, we would evaluate the more comprehensive cost report data from the first year of cost reporting periods beginning on or after January 1, 2023, to refine our methodology for determining the payment rate for pediatric ESRD dialysis. As proposed, this would be a separate, additional add-on payment adjustment of 30 percent of the per treatment payment amount under § 413.230, which reflects the other patient and facility level adjustments. This adjustment would not be part of the case-mix adjusters. This payment adjustment would only apply to the ESRD bundled payment and not to any outlier adjustments. Due to the multiplicative nature of the case-mix adjusters it would function similarly to a 30 percent increase to the expanded bundle case-mix adjusters. For comparison, the effective case-mix adjusters are presented in Table 8.

TABLE 8: Pediatric ESRDB Effective Payment Modifiers

Pediatric ESRDB Effective Payment Modifiers by Age and Modality				
Age	**Modality**	**Current Case- Mix Adjuster (Effective 1/1/2016)**	**30% Increase Effective Case- Mix Adjusters**	**Alternative 10% Increase Effective Case-Mix Adjusters**
<13	PD	**1.063**	1.382	1.169
<13	HD	**1.306**	1.698	1.437
13-17	PD	**1.102**	1.433	1.212
13-17	HD	**1.327**	1.725	1.460

We noted that the exact magnitude of the increase in payment would vary based on the age of the patient and the wage index of a given area; we estimated approximately $80 for (hemodialysis-equivalent) peritoneal dialysis treatments and $100 for hemodialysis treatments. This would represent a substantial increase in payment for renal dialysis services furnished to Pediatric ESRD Patients and would account for the extra costs that this population incurs temporarily until additional cost data is available. This payment adjustment would apply for all dialysis treatments furnished to ESRD patients under the age of 18, not solely treatments furnished in pediatric ESRD facilities. This is warranted because many of the additional costs related to the treatment of Pediatric ESRD Patients are not specific to treatments furnished in pediatric ESRD facilities.

We proposed to call this the Transitional Pediatric ESRD Add-on Payment Adjustment (TPEAPA) and make this adjustment budget neutral. We explained that, in general, add-on payment adjustments under section 1881(b)(14)(D)(iv) of the Act are not statutorily required to be budget neutral under the ESRD PPS, but we stated that we believed in this instance that budget neutrality is appropriate, due to the way this adjustment is derived. We noted that other non-budget neutral add-on payment adjustments that we have established under this authority generally account for costs that were not used for the construction of the ESRD PPS bundled payment, such as the TDAPA for calcimimetics (80 FR 69013 through 69027). We explained that we have also established certain non-budget neutral add-on payment adjustments for items or services that were not commonplace, and therefore not adequately represented in cost reports, such as home dialysis training (75 FR 49063). However, we noted that we have implemented other payment adjustments under this authority in a budget neutral manner; for example, the changes to the wage index in the CY 2023 ESRD PPS final rule were implemented in a budget neutral manner as they represented a shifting of cost allocations, rather than new costs not originally included in the ESRD PPS bundled payment (87 FR 67157). We stated that this TPEAPA is primarily for costs that would have been included in the cost reports used in the analysis conducted when we created the ESRD PPS bundled payment in the CY 2011 ESRD PPS final rule. We explained that the methodology used both in that analysis, and when updating the case-mix adjusters, attributed pediatric ESRD renal dialysis services costs to the general population. Therefore, we explained, it would be appropriate to reduce the ESRD PPS base rate to account for the new allocation of costs. Furthermore, we stated that any changes to the case-mix adjustments are required by section 1881(b)(14)(A)(ii) of the Act to be budget neutral, which means that any future modifications to the pediatric case-mix adjusters would be budget neutral. The proposed budget neutrality adjustment factor for the proposed TPEAPA consisting of 30 percent of the per treatment payment amount was 0.999532. We explained that applying this budget neutrality factor to the proposed ESRD PPS base rate would reduce the ESRD PPS base rate by an estimated $0.12. We stated that under the alternative 10 percent TPEAPA discussed in the proposed rule (88 FR 42464), the budget neutrality factor adjustment would be 0.999847. We explained that applying this budget neutrality factor to the proposed ESRD PPS base rate would reduce the ESRD PPS base rate by an estimated $0.04.

To establish this new TPEAPA, we proposed to amend § 413.235 by splitting current paragraph (b) into paragraphs (b)(1) and (2). Paragraph (b)(1) would set forth the established age and modality of treatment case mix adjustment methodology as currently stated in paragraph (b). Paragraph (b)(2) would state that beginning January 1, 2024, we will provide a per-treatment transitional add-on payment adjustment of 30 percent of the per treatment payment amount under § 413.230 for renal dialysis services furnished to Pediatric ESRD Patients during CYs 2024, 2025, and 2026. We also proposed to revise the current language of § 413.235(b) to use the term ''Pediatric ESRD Patients,'' which is defined at § 413.171, to improve clarity for this section.

(5) Costs and Benefits for a Transitional Pediatric ESRD Add-On Payment Adjustment (TPEAPA)

As we explained in the CY 2024 ESRD PPS proposed rule, we believe CMS could better align the resource use of pediatric ESRD renal dialysis services with payment. Our analysis using the methodology outlined previously found that costs for Pediatric ESRD Patients receiving renal dialysis services are estimated to be 40 percent higher than for adult patients and that the current payment adjusters account for 10 percent higher costs. Implementing a transitional 30 percent add-on payment adjustment for renal dialysis services furnished to Pediatric ESRD Patients would improve payment equity for these patients by increasing payments to align with the estimated costs of treatment more closely. A 30 percent increase in ESRD PPS payments for pediatric ESRD renal dialysis services would represent approximately $80 to $100 per pediatric ESRD dialysis treatment, although the exact magnitude of the increase would depend on age, modality, and the wage index of the area. This payment increase would have beneficial health equity impacts on this population by improving access to care and quality of care. Some ESRD facilities may not be able to absorb the additional expense of the Pediatric ESRD Patient population. Patients may need to travel to a limited number of primarily hospital-based ESRD facilities where pediatric ESRD dialysis is performed. As a result, this population may be underserved and disadvantaged with respect to access to ESRD care. We stated that additional payment to those ESRD facilities treating Pediatric ESRD Patients would thereby benefit this potentially underserved and disadvantaged population of Pediatric ESRD patients. Additionally, this would have a beneficial financial impact on the ESRD facilities, both pediatric and non-pediatric, that serve this pediatric population.

We proposed that this payment adjustment be budget neutral, which would lead to an estimated decrease of $0.12 to the ESRD PPS base rate, corresponding to a budget neutrality factor of 0.99954. This relatively small adjustment would represent less than a twentieth of a percent of the total ESRD PPS base rate. However, we recognized that any decrease in the ESRD PPS base rate would represent a monetary loss to ESRD facilities. As stated previously, our analysis indicated that this transfer would be reasonable given the likelihood that the methodology used in the case-mix adjusters attributed some pediatric costs to the general population. However, we noted, should future analysis of the stratified pediatric cost data indicate that pediatric ESRD renal dialysis services costs are less than 40 percent higher than adult costs, this budget neutral decrease would mean that the treatments for adult patients with ESRD were slightly underpaid during this 3-year period. In either case there would be a risk of underpayment for one group of patients. We stated that we believe using the mean estimate of the analysis will provide us with the best approach for achieving payment accuracy while we collect additional data. Additionally, the health equity

implications of potentially underpaying for Pediatric ESRD Patients receiving dialysis by 20 percent would be significantly higher than the implications of potentially underpaying for adult patients by less than 0.1 percent. We noted that in CY 2021 there were 116 ESRD facilities that furnished more than 2 percent of their dialysis treatments to Pediatric ESRD Patients, out of 7882 total ESRD facilities. These ESRD facilities are a relatively small group, but they are critical for the care of Pediatric ESRD Patients. For these reasons, we stated that we believe the expected benefits for the TPEAPA would outweigh the costs.

We explained that we believe providing this 30 percent TPEAPA for CYs 2024, 2025, and 2026 would be the best approach for improving payment accuracy until more precise data is available. However, we acknowledged that in any case there is a risk of making payments which are higher or lower than appropriate. Therefore, in the CY 2024 ESRD PPS proposed rule we requested comments on our proposal, including on (1) the alternative adjustment amount; and (2) the budget neutrality of the proposal.

We received 30 comments in response to our proposed Transitional Pediatric ESRD Add-on Payment Adjustment (TPEAPA) for pediatric ESRD patients receiving renal dialysis services. Respondents included large and small dialysis organizations, non-profit organizations, an advocacy organization, a coalition of dialysis organizations, a large non-profit health system, and individual providers. The comments on our proposal and our responses are set forth below.

Comment: We received several comments that supported CMS establishing an add-on payment adjustment for pediatric ESRD patients. Most commenters expressed their belief that an add-on payment adjustment of this nature is necessary to support the higher costs associated with providing for the unique care needs and specialized support required for renal dialysis services in the ESRD PPS pediatric population. Physician commenters cited the unique challenges in caring for this population that are not reflected in the current ESRD PPS payment models. Numerous commenters expressed their support for using an ESRD PPS add-on payment adjustment to improve patient access and equity among this vulnerable subpopulation of patients with ESRD. A pediatric ESRD facility noted that money invested in this population lowers avoidable adverse outcomes and complications from ESRD and facilitates a faster path towards transplantation, ultimately yielding both cost savings and healthier adults.

Response: We thank the commenters for their support and dedication to improving access and equity for the pediatric patient population with ESRD receiving renal dialysis services.

Comment: We received several comments regarding the proposed TPEAPA payment amount, calculation, and length of payment period. Most commenters supported the implementation of the 30 percent add-on payment adjustment as a reasonable estimate of the unaccounted-for costs incurred in treating pediatric ESRD patients. An LDO expressed concern that PSM does not provide for an accurate computation of the costs incurred in providing specialized pediatric care; while a pediatric nephrology society agreed that in the absence of accurate pediatric cost data, the PSM methodology seems reasonable. A pediatric nephrology society reported the 30 percent add-on to be consistent with anecdotal cost data collected by the society from around the country. An LDO urged CMS to implement a three-year period of analysis after the proposed 30 percent adjustment. Another LDO requested more transparency on the data and assumptions used to calculate the pediatric adjustment.

Response: We thank the commenters for their support and suggestions. Payment accuracy has been historically difficult for pediatric ESRD dialysis because of the small sample size of pediatric patients receiving renal dialysis services paid for under the ESRD PPS. Obtaining reliable data on the additional costs that pediatric patients with ESRD incur would facilitate the creation of a permanent payment adjustment based on resource use to bring relative Medicare payments more in line with relative costs. We recognize that while our use of PSM unavoidably leads to larger variance in parameter estimates because only a small subset of the broader provider population is utilized in the estimation, this approach is useful because it provides a means of comparison with less biased estimates and as suggested by commenters the 30 percent estimate is in line with anecdotal data. We plan to share data and assumptions through notice-and-comment rulemaking for potential future pediatric payment adjustments to ESRD facilities.

Comment: Most commenters urged CMS to reconsider implementing the payment adjustment as a budget neutral add-on. An LDO expressed that it would be inappropriate to cut payment rates for service provided to adult patients, whose population is comprised of a significant percentage of patients from racial or ethnic minority groups, of low-socioeconomic status, and living in medically underserved areas. A health system expressed concerns that the add-on payment adjustment would shift funding away from ESRD facilities exclusively providing adult services. An LDO expressed that applying the add-on in a budget-neutral manner would effectively penalize all ESRD facilities for the inability of existing cost report data to improve payment accuracy. A nephrology society expressed concerns that while younger patients require more support, that does not mean that adults requiring dialysis require less support than they are already receiving. A non-profit dialysis association expressed that the budget neutral application of the adjustment is contrary to the Administration's stated health equity goals, because it would cut payments for one medically vulnerable group to increase payments for another medically vulnerable group.

Response: We examined the potential impact of the proposed TPEAPA as a budget neutral adjustment. As we noted in the CY 2024 ESRD PPS proposed rule, add-on payment adjustments under section 1881(b)(14)(D)(iv) of the Act are not statutorily required to be budget neutral under the ESRD PPS, but we believe in this instance that budget neutrality is appropriate due to the way this adjustment is derived. As explained in section II.B.1.g.(4) of this final rule, this TPEAPA is primarily for costs that would have been included in the cost reports used in the analysis conducted when we created the ESRD PPS bundled payment in the CY 2011 ESRD PPS final rule. We explained that the methodology used both in that analysis, and when updating the case-mix adjusters, attributed pediatric ESRD renal dialysis services costs to the general population. CMS has therefore determined it to be appropriate to reduce the ESRD PPS base rate to account for the new allocation of costs. We note that the adjustment would decrease the ESRD PPS base rate by a budget neutrality factor of 0.999503, a sum total of $0.14, due to the application of the budget neutrality factor. We further note that the adjustment does not rely on any assumption that resource use by adult patients has decreased over time; rather it assumes that the ESRD PPS payment rate as applied to adults has since its inception incorporated some amount of costs that were more properly attributable to treatment of pediatric

ESRD patients. The TPEAPA therefore makes the ESRD PPS payment more reflective of relative costs by reallocating payments associated with those costs from the payment amounts for adults to pediatric ESRD patients.

Comment: An ESRD facility urged CMS to extend the add-on payment adjustment to pediatric AKI patients to ensure these patients receive the same additional support.

Response: We appreciate the suggestion to apply the TPEAPA to pediatric AKI patients. As we discussed in the CY 2017 ESRD PPS final rule, we have determined that treatment for AKI is substantially different from treatment for ESRD and the case-mix adjustments applied to ESRD patients may not be applicable to AKI patients. Therefore, we have not historically applied these ESRD PPS adjustments and policies to AKI payments (81 FR 77959). We did not propose to apply the TPEAPA to pediatric AKI patients for the same reason.

Comment: We received several additional comments regarding the TPEAPA implementation. Commenters suggested that CMS create and implement pediatric ESRD-specific metrics for the pediatric ESRD programs. A pediatric nephrology society requested CMS utilize means of communication such as the Medicare Learning Network to educate children's hospitals on completing costs reports. A professional nursing association urged CMS to promote a shift towards pediatric ESRD dialysis care moving towards home-based settings. The association also urged investment into the field of pediatric nephrology, as there are limited qualified health care providers and recommended the inclusion (we assume in cost reports) of pediatric nurse practitioners. The association also recommended CMS consider direct patient labor categories when determining costs for pediatrics, as there are additional training and requirements necessary for the pediatric population. As an extension of labor categories, the association noted the shortage of pediatric nephrologists and suggested that CMS include pediatric nurse practitioners who can assist in meeting the needs of the youngest and most vulnerable individuals on dialysis. These commenters did not specify how CMS should include pediatric nurse practitioners or how such inclusion would relate to the ESRD PPS bundled payment.

Response: We thank the commenters for their input. As the TPEAPA is a temporary adjustment until we can fully analyze the costs associated with pediatric dialysis, we did not include any proposals regarding shifts to home-based settings, or the inclusion of a pediatric nurse practitioner in the CY 2024 ESRD PPS proposed rule. However, as we continue to analyze how best to collect pediatric specific metrics and the payment for Pediatric ESRD Patients to facilitate future refinements, we will consider these comments for potential future ESRD PPS payment policies. We appreciate the suggestion about using Medicare Learning Networks to educate children's hospitals on completing costs report. CMS is considering a number of options on how best to provide educational outreach on this topic.

Final Rule Action: We did not receive any comments on our proposal to revise the language of § 413.235(b) to use the term ''Pediatric ESRD Patients'' to improve clarity. As such we are finalizing this change as proposed. In addition, after consideration of the comments received and for reasons outlined in the CY 2024 ESRD PPS proposed rule and previously in this section of the final rule, we are finalizing our proposal to establish this new TPEAPA on a budget-neutral basis. Under our authority at section 1881(b)(14)(D)(iv) of the Act, we will adjust the per treatment base rate for Pediatric ESRD Patients to provide a per-treatment transitional add-on payment adjustment of 30 percent of the per treatment payment amount under § 413.230 for renal dialysis services furnished to Pediatric ESRD Patients during CYs 2024, 2025, and 2026. CMS is codifying this payment adjustment in the regulations at § 413.235(b)(2). The budget-neutrality factor for the CY 2024 TPEAPA is 0.999503. This change will be effective January 1, 2024, as proposed.

h. Reporting Policy for Discarded Amounts of Renal Dialysis Drugs and Biological Products Paid for Under the ESRD PPS

(1) Background

As discussed in the CY 2023 PFS final rule (87 FR 69710), many drugs and biological products that are payable under Medicare Part B are dosed in a variable manner such that the entire amount identified on the vial or package is not administered to the patient. For example, many drugs are dosed based on the patient's body weight or body surface area (BSA). Often, these drugs are available only in single-dose containers. As stated in U.S. Food and Drug Administration (FDA) guidance for

industry,[22] a single-dose container is designed for use with a single patient as a single injection or infusion. The labeling for a drug packaged in a single-dose container typically includes statements instructing users to discard unused portions. When the labeling instructs a health care provider to discard the amount of drug that was unused (that is, the discarded amount) from a single-dose container or other single-use package of a drug after administering a dose to a Medicare beneficiary, the program provides payment for the unused and discarded amount, as well as the dose administered, up to the amount of the drug indicated on the vial or package labeling. On a Medicare Part B claim, the JW modifier (drug amount discarded/not administered to any patient) is a Healthcare Common Procedure Coding System (HCPCS) Level II modifier used to report the amount of a drug that is discarded and eligible for payment.

Beginning on January 1, 2017, CMS revised the Medicare Part B JW modifier policy to require the uniform use of the modifier for all claims for separately payable drugs with discarded drug amounts from single-dose containers or single-use packages payable under Part B, in order to more effectively identify and monitor billing and payment for discarded amounts of drugs.[23] [24] The policy does not apply to drugs that are not separately payable, such as packaged hospital outpatient prospective payment system (OPPS) drugs or those administered in federally qualified health centers (FQHCs) or rural health clinics (RHCs).

In the CY 2023 PFS final rule (87 FR 69718 through 69719), we codified our existing policy as discussed in the prior paragraph in Chapter 17 of the Medicare Claims Processing Manual,[25] and required that billing providers report the JW modifier for all separately payable drugs with discarded drug amounts from single-dose containers or single-use packages payable under Part B, beginning January 1, 2023. These changes were promulgated in connection with the implementation of the discarded drug refund program under section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021). In that same CY 2023 PFS final rule (87 FR 69722), we responded to commenters who requested we exempt drugs paid for under the ESRD PPS bundled payment from the discarded drug refund policy. One commenter expressed concern regarding how implementation of the discarded drug refund might inadvertently impact ESRD products, including those used by home dialysis patients. In response to those comments, we clarified that units for drugs that are packaged under the Medicare ESRD PPS were not subject to the JW modifier policy or the discarded drug refund.

In the same CY 2023 PFS final rule, CMS also finalized a proposal to require billing providers to report the JZ modifier for all such drugs with no discarded drug amounts, beginning no later than July 1, 2023. Specifically, as discussed in the CY 2023 PFS proposed rule (87 FR 46058), we proposed to require the use of a separate modifier, the JZ modifier, to attest that there were no discarded amounts. We stated that to align with the JW modifier policy, the JZ modifier would be required when there are no discarded amounts from single-dose containers or single-use packages payable under Part B for which the JW modifier would be required if there were discarded amounts. Table 9 provides additional information about these modifiers.

TABLE 9 – JW and JZ Short and Long Descriptors

MODIFIER	SHORT DESCRIPTOR (28-character limit)	LONG DESCRIPTOR
JW	Discarded drug not administered	Drug amount discarded/not administered to any patient
JZ	Zero drug wasted	Zero drug amount discarded/not administered to any patient

We explained that on all claims for single-dose containers or single-use packages payable under Part B, either the JW modifier would be used (on a separate line) to identify any discarded amounts or the JZ modifier (on the claim line with the administered amount) would be present to attest that there were no discarded amounts. We noted that we believed the JZ modifier requirement would not increase burden on the provider, because under the current JW modifier policy, the provider already needs to determine whether there are any discarded units from a single-dose container or single-use package, record discarded amounts in the patient medical record, and specify administered and discarded amounts on the claim form. We finalized the JZ modifier requirement in the CY 2023 PFS final rule. Lastly, we noted in the CY 2023 PFS final rule that we would begin claims edits for both the JW and JZ modifier beginning October 1, 2023 (87 FR 69179). Additional details can be found in Chapter 17 of the Medicare Claims Processing Manual and the JW/JZ modifier frequently asked questions (FAQ) document.[26]

(2) Current Reporting of the JW Modifier Under the ESRD PPS

As we discussed in the CY 2024 ESRD PPS proposed rule, the Medicare Part B JW modifier policy generally does not apply to drugs that are not separately payable. The ESRD PPS statute generally requires a single bundled payment for renal dialysis services. Specifically, section 1881(b)(14)(A)(i) requires the Secretary to implement a payment system under which a single payment is made to a provider of services or a renal dialysis facility for renal dialysis services in lieu of any other payment. The only exception is

[22] *https://www.fda.gov/media/117883/download.*

[23] CR6603: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3538CP.pdf.*

[24] MLN Matters® Number MM9603: *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/mm96033.pdf.*

[25] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf.*

[26] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf.*

for oral-only drugs, as defined at § 413.234(a), which are currently paid separately under Medicare Part D. Section 204 of ABLE amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis drugs and biological products cannot be made under the ESRD PPS bundled payment prior to January 1, 2025. We noted that although the ESRD PPS includes certain add-on payment adjustments such as the TDAPA and TPNIES, these are adjustments to the ESRD PPS base rate and therefore part of the single payment made under the ESRD PPS; these payment adjustments are not separate payments. For example, as described in our TDAPA implementation guidance issued August 4, 2017, and updated January 10, 2018, available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R1999OTN.pdf*, the methodology used to calculate the per treatment payment amount incorporates the cost of the drugs that are paid for using the TDAPA.

Although renal dialysis drugs and biological products paid for under the ESRD PPS are not considered ''separately billable'' and are not subject to the general Part B JW modifier policy discussed in the prior paragraph, CMS has previously issued guidance on the use of the JW modifier on ESRD PPS claims for certain circumstances. Chapter 8, section 60.4.5.1 of the Medicare Claims Processing Manual pertains to self-administered supplies of ESAs.[27] Under current guidance, when billing for discarded amounts of drugs in accordance with the policy in chapter 17 of this manual, section 40.1, the provider must bill for discarded amounts on a separate line item with the modifier JW. The line-item date of service should be the date of the last covered administration according to the plan of care or, if the patient dies, use the date of death. More specifically, in Chapter 17, section 40.1 of the Medicare Claims Processing Manual,[28] we state that multi-use vials are not subject to payment for discarded amounts of drug or biological products, with the exception of self-administered ESAs by Method I home dialysis patients, for whom an ESRD facility furnishes and bills for renal dialysis services.[29] Current guidance in Chapter 17, section 40.1 of the Medicare Claims Processing Manual states that the ESRD facility must bill the program using the JW modifier for the amount of ESAs appropriately discarded if the home dialysis patient must discard a portion of the ESA supply due to expiration of a vial, because of interruption in the patient's plan of care, or unused ESAs on hand after a patient's death. We noted that separate payment is not made for ESAs under the ESRD PPS; however, ESAs are eligible for outlier payments when the criteria in § 413.237 are met.

Most recently, the March 15, 2022, Change Request [30] that established the TDAPA for Korsuva® (difelikefalin) instructs facilities to use the JW modifier to report the amount of difelikefalin that is discarded and eligible for payment under the ESRD PPS. We noted that based on the latest available data at the time of the CY 2024 ESRD PPS proposed rule, nearly 40 percent of the TDAPA expenditures for those drugs that were reported in 2022 represented discarded amounts reported using the JW modifier, which represented approximately $1.3 million in TDAPA expenditures for discarded amounts of difelikefalin. Overall, our analysis of Medicare claims data from 2017 to 2021 found that approximately 2 percent of ESRD PPS claims indicate discarded or unused portions of drugs or biological products through use of the JW modifier. We estimated that the total amount of unused product billed from 2017 to 2021 and paid for under the ESRD PPS is approximately $22 million.

We explained in the CY 2024 ESRD PPS proposed rule that, under our current policy, we do not reduce the single payment under the ESRD PPS for any discarded amounts of renal dialysis drugs or biological products that are reported with the JW modifier. Furthermore, when calculating any adjustments to the ESRD PPS base rate for the TDAPA or outlier payments, we include all units of renal dialysis drugs and biological products billed on the claim for which an adjustment is made, including any discarded amounts of such drugs and biological products. Additionally, we have previously established in the CY 2012 ESRD PPS final rule (76 FR 70243 through 70244) that ESRD facilities may only report units and charges for drugs and biological products purchased and may not bill for overfill units of drugs and biological products which exceed the amount indicated on the vial or package labeling.[31] Additionally, we explained that consistent with prior rulemaking, under our authority in section 1881(b)(14)(D)(ii) of the Act, we were adopting the average sales price (ASP) policy on overfill for purposes of calculating the outlier payment. That is, we adopted a policy to exclude overfill units of drugs and biological products which exceed the amount indicated on the vial or package labeling from consideration for the purposes of calculating outlier payments. We stated we believe the use of the ASP policy for purposes of calculating the outlier payment is appropriate because we believe overfill does not represent a cost to the ESRD facility; thus, overfill should not factor into our determination of outlier payments.

In summary, our longstanding policy for payment under the ESRD PPS, including the calculation of the TDAPA and outlier payment adjustments, includes payment for units of renal dialysis drugs and biological products billed with the JW modifier, but does not allow payment for overfill units. That is, the current ESRD PPS payment policy is consistent with the broader Medicare Part B policy to pay for the unused and discarded amount, as well as the dose administered, up to the amount of the drug indicated on the vial or package labeling.

(3) ESRD PPS Policy for Reporting of Discarded Amounts of Renal Dialysis Drugs and Biological Products

As discussed in the CY 2024 ESRD PPS proposed rule (88 FR 42464) and in section II.B.1.j of this final rule, we are undertaking analysis of ESRD PPS claims and cost report data to better understand the patient-specific costs associated with furnishing renal dialysis services to Medicare beneficiaries. We

[27] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c08.pdf.*

[28] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf.*

[29] Prior to the ESRD PPS, a Medicare ESRD beneficiary could elect to obtain home dialysis equipment and supplies from a supplier that was not a Medicare approved dialysis facility. This was referred to as Method II home dialysis. In the CY 2011 ESRD PPS final rule (75 FR 49061), we stated that all costs associated with home dialysis services (both Method I and Method II) are included in the composite portion of the two equation model, and we stated that effective January 1, 2011, all home ESRD patients would be considered Method I home patients and all Medicare payments for home dialysis services would be made to the ESRD facility.

[30] *https://www.cms.gov/files/document/r11295CP.pdf.*

[31] We explained in the CY 2011 PFS final rule (75 FR 73466) that we had become aware of situations where manufacturers intentionally included a small amount of overfill in drug containers, and that this overfill is provided at no extra charge to the provider. We also noted that we understood the intent of the intentional overfill was to compensate for product loss during the proper preparation and administration of a drug. We explained that ASP calculations are based on data reported by manufacturers, including ''volume per item''. Therefore, providers may only bill for the amount of drug product actually purchased and the cost that the product represents (75 FR 73467).

stated in the proposed rule that in considering potential refinements to the ESRD PPS case-mix adjustments in the future, it is important to understand and have consistent data about the costs associated with the quantities of the renal dialysis drugs and biological products that are used by ESRD beneficiaries. This is consistent with our longstanding policy principles, which are reflected by our policy for billing for unused amounts of renal dialysis drugs and biological products under the ESRD PPS. In the CY 2016 ESRD PPS final rule (80 FR 69033), we discussed our existing policy since the inception of the ESRD PPS that all renal dialysis service drugs and biological products prescribed for ESRD patients, including the oral forms of renal dialysis injectable drugs, must be reported by ESRD facilities, and the units reported on the monthly claim must reflect the amount expected to be taken during that month. We stated that ESRD facilities should use the best information they have in determining the amount expected to be taken in a given month, including fill information from the pharmacy and the patient's plan of care. We noted that any billing system changes to effectuate this change needed to be made as soon as possible, as this requirement had been in effect since the ESRD PPS began in 2011. This policy is also discussed in the Medicare Benefits Policy Manual, Pub. 100–02, Chapter 11, section 20.3.C.[32]

Consistent with our longstanding billing policies for unused amounts of drugs and biological products and consistent with the requirements for the uniform use of the JW modifier for all claims for separately payable drugs under Part B since 2017, to more effectively identify and monitor billing and payment for discarded amounts of drugs, in the CY 2024 ESRD PPS proposed rule, we proposed to require ESRD facilities to report accurate and consistent data about discarded amounts of single-dose renal dialysis drugs and biological products paid under the ESRD PPS. Further, section 1881(b)(2)(B) of the Act requires the Secretary to prescribe in regulations any methods and procedures to determine the costs incurred by ESRD facilities in furnishing renal dialysis services to beneficiaries with ESRD, and to determine payment amounts for Part B services furnished by such ESRD facilities.

We noted that, under our longstanding policy, payment is made under the ESRD PPS bundled payment for discarded amounts of renal dialysis drugs and biological products, and such discarded amounts are included in the calculation of the ESRD PPS base rate and any applicable adjustments, such as the TDAPA and the outlier adjustment. Therefore, consistent with the current JW and JZ reporting requirements that were finalized in the CY 2023 PFS final rule for separately payable Part B drugs, we proposed to require that beginning no later than January 1, 2024, ESRD facilities must report information on ESRD PPS claims about the total number of billing units of any discarded amount of a renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS, using the JW modifier (or any successor modifier that includes the same data). We also proposed that ESRD facilities must document any discarded amounts in the beneficiary's medical record. Additionally, we proposed to require ESRD facilities to report the JZ modifier for all such renal dialysis drugs and biological products with no discarded amounts, beginning no later than January 1, 2024. We proposed to codify these reporting requirements in regulation at § 413.198(b)(5) and (6).

We proposed the amount of a renal dialysis drug or biological product from a single-dose container or single-use package that is administered would be billed on one line (reflected as billing units in the unit field) and any discarded amounts would be billed on a separate line with the JW modifier (reflected as billing units in the unit field). If a renal dialysis drug or biological product from a single-dose container or single-use package is administered and there are no discarded amounts, then we proposed that a single line would be billed on the claim form with the JZ modifier and the billing units in the unit field. Therefore, on all claims for renal dialysis drugs and biological products from single-dose containers or single-use packages payable under the ESRD PPS, we proposed that either the JW modifier would be used (on a separate line) to identify any discarded amounts or the JZ modifier (on the claim line with the administered amount) would be present to attest that there were no discarded amounts. We proposed that claims for renal dialysis drugs and biological products from single-dose containers or single-use packages that do not report either the JW or JZ modifier may be returned as un-processable until claims are properly resubmitted.[33] We also stated that if this proposal is finalized, CMS would publish information about which HCPCS codes would be identified as single-dose containers or single-use package renal dialysis drugs and biological products subject to required reporting of the JW or JZ modifier. We also stated that we would plan to issue guidance regarding additional operational considerations and billing instructions specific to the reporting requirements for these products.

We further clarified that, under our proposal, ESRD facilities would not be required to document in the beneficiary's medical record when there are no discarded amounts. We reiterated in the CY 2024 ESRD PPS proposed rule that, as discussed in the CY 2023 PFS final rule (87 FR 69722), units for renal dialysis drugs and biological products that are bundled under the Medicare ESRD PPS would not be subject to the Medicare Part B discarded drug refund program and would continue to be exempted from the Medicare Part B discarded drug refund. We also clarified that for any oral-only drugs, as defined in § 413.234(a), to the extent that any such drugs are produced in single-dose containers or single-use packaging, this proposed reporting requirement would not apply until such drugs are paid for under the ESRD PPS.

We stated that we believe this reporting requirement would enable CMS to obtain more reliable information about the extent to which the costs of providing renal dialysis drugs and biological products represent amounts that beneficiaries use as well as amounts that are discarded. We explained that we believe this is particularly important because under Medicare Part B, beneficiaries are responsible for paying a 20 percent coinsurance. As noted previously, nearly 40 percent of TDAPA expenditures in CY 2022 represented discarded amounts of renal dialysis drugs and biological products. Medicare beneficiaries, therefore, paid approximately $260,000 in copayments for these discarded amounts. While this currently represents a small amount of payments overall, the cost for discarded renal dialysis drugs and biological products is borne by a very small population of beneficiaries. We stated that it is important for CMS to

[32] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c11.pdf.*

[33] Under the basic requirements for all claims at § 424.32(a)(1), a claim must be filed with the appropriate intermediary or carrier on a form prescribed by CMS in accordance with CMS instructions. Chapter 1 of the Medicare Claims Processing Manual, section 70.2.3.1 states that submissions that are found to be incomplete or invalid are returned to the provider (RTP).

understand the full scope of expenditures, including expenditures that may be incurred by beneficiaries, for discarded amounts of renal dialysis drugs and biological products in the future, which may be more expensive or more widely used than the current drug that is being paid for using the TDAPA under the ESRD PPS. Thus, we did not propose in the CY 2024 ESRD PPS proposed rule to alter payments to ESRD facilities based on the amounts of discarded renal dialysis drugs and biological products reported, but noted that data collected through adoption of the JW and JZ modifier reporting requirements discussed in that section of the proposed rule may inform future payment policies, which would be proposed through future notice and comment rulemaking if appropriate.

Based on our analysis of ESRD PPS claims, as well as the billing guidance in sections 8 and 17 of the Medicare Claims Processing Manual, we stated that we believe the JW modifier requirement reflects current practices for ESRD facilities and would not significantly increase burden for ESRD facilities. Additionally, we stated that we believe the JZ modifier requirement would not increase burden on ESRD facilities, because under the current guidance provided regarding use of the JW modifier, the ESRD facility should already have processes in place to determine, in the case of certain drugs and biological products, whether or not there are any discarded units from a single-dose container or single-use package, record discarded amounts in the patient medical record, and specify administered and discarded amounts on the claim form. Furthermore, we noted that while renal dialysis drugs and biological products that are paid under the ESRD PPS are not considered separately payable, ESRD facilities are permitted to bill and receive separate payment using the AY modifier for drugs and biological products that are not related to the treatment of ESRD. Although we noted that renal dialysis drugs and biological products paid under the ESRD PPS are not subject to the Medicare Part B drug refund program or the current JW or JZ reporting requirements, any separately payable drugs, or biological products that ESRD facilities bill for using the AY modifier would be subject to such policies under Medicare Part B. Therefore, we explained that we believe most ESRD facilities should already be reporting the JW and JZ modifiers in such circumstances and would reasonably be able to report these modifiers for renal dialysis drugs and biological products as well. We invited comments on this assumption and on the proposed JW and JZ reporting requirements for the ESRD PPS.

We received public comments on our proposal to require the reporting of the JW and JZ modifiers on ESRD PPS claims. The comments on our proposal and our responses are set forth below.

Comment: Several commenters raised concerns about the lead time needed to operationalize the proposed changes to report the JW and JZ modifiers on ESRD PPS claims. Commenters expressed that a minimum of six months after the publication of detailed guidance would be needed to reprogram systems and train staff to comply with the proposed requirements. Other commenters noted that, especially for independent ESRD facilities, a longer lead time of one year may be appropriate. Specifically, commenters expressed that ESRD facilities would need to implement extensive changes to their policies and procedures, including aligning information from numerous independent medical record systems, and that such activities could not begin in earnest until detailed guidance about these reporting requirements is available. Several commenters urged CMS to commit to publishing guidance by January 1, 2024, and to modify the effective date of the proposed JW and JZ modifier reporting requirement to begin no earlier than January 1, 2025.

Response: We thank commenters for their detailed comments regarding the operational changes needed to comply with the proposed reporting requirement. As commenters pointed out, although ESRD facilities may have processes in place to track amounts of discarded drugs, these processes may not be uniformly applied to all drugs. We recognize the importance of providing ESRD facilities the appropriate amount of time to adjust systems and train staff to expand the scope of drugs to which existing processes are applied. In light of the operational needs that commenters described, we are modifying the effective date of this reporting requirement to begin January 1, 2025, instead of January 1, 2024. Commenters indicated that for certain independent facilities, 1 year would provide sufficient time to train staff and update systems as needed to comply with the reporting requirements we are finalizing in this final rule. We believe extending the effective date of the requirement by 1 year strikes an appropriate balance between the need to collect this data and ESRD facilities' need to make operational changes. We intend to publish detailed operational guidance regarding this requirement no later than January 1, 2024.

Comment: Many commenters stated that although they understand and agree with CMS's need to better understand patient-specific costs associated with furnishing renal dialysis services to Medicare beneficiaries, they did not agree that the proposed collection of information about the JW and JZ modifiers on claims was appropriate or relevant. Several commenters expressed their belief that Medicare beneficiaries do not incur additional coinsurance for renal dialysis drugs and biological products that are paid under the ESRD PPS bundled payment, and therefore information about discarded amounts would not be relevant to ESRD PPS payment. Several commenters encouraged CMS to withdraw the proposed reporting requirement.

Response: We appreciate the concerns raised by commenters. We are not withdrawing the proposed reporting requirement. We do not agree with the commenters' assertion that discarded amounts of renal dialysis drugs and biological products paid under the ESRD PPS have no impact on payment, or that Medicare beneficiaries do not incur additional coinsurance for such discarded amounts. As we discussed in the CY 2024 ESRD PPS proposed rule, certain ESRD PPS payment adjustments, specifically the outlier adjustment and the TDAPA, are dependent upon the amount of renal dialysis drugs and biological products billed on an ESRD PPS claim. For renal dialysis drugs and biological products from single-dose containers or single-use packaging which are eligible for such payment adjustments, discarded amounts contribute directly to increased ESRD PPS payment as well as increased beneficiary copays. Furthermore, because the ESRD PPS base rate includes payment for renal dialysis drugs and biological products, discarded amounts of renal dialysis drugs and biological products from single-dose containers and single-use packaging contribute to overall increases in the ESRD PPS base rate and the amount of beneficiary coinsurance.

Comment: Several commenters expressed concerns about the application of the proposed reporting requirements for home dialysis patients and for any oral-only drugs from single-dose containers or single-use packaging that may, after January 1, 2025, be paid under the ESRD PPS. Commenters expressed concern about ESRD facilities' ability to accurately document the discarded amounts of such drugs and biological products that are not administered at the ESRD facility. One

commenter noted that CMS's current policy applies to a very limited number of patients and ESAs, but the proposed expansion of this policy could apply to a broader range of ESAs, calcimimetics, intravenous iron, and more products. The same commenter noted that most home dialysis patients use multi-use vials, to which the current JW requirement does not apply. Commenters urged CMS to exempt oral-only drugs and renal dialysis drugs and biological products used by home dialysis patients from the proposed reporting requirements or clarify that ESRD facilities can report the amount of such drugs in good faith.

Response: We thank commenters for their detailed comments regarding the applicability of the proposed reporting requirement for renal dialysis drugs and biological products paid under the ESRD PPS that are administered outside of an ESRD facility. Consistent with our longstanding policy discussed in the CY 2016 ESRD PPS final rule (80 FR 69033), all renal dialysis service drugs and biological products prescribed for ESRD patients, including the oral forms of renal dialysis injectable drugs, must be reported by ESRD facilities, and the units reported on the monthly claim must reflect the amount expected to be taken during that month. Accordingly, with respect to reporting discarded amounts of renal dialysis drugs and biological products that are administered to home dialysis patients and oral forms of renal dialysis drugs and biological products, ESRD facilities should use the best information they have in determining the amount expected to be discarded in a given month, including fill information from the pharmacy and the patient's plan of care. Consistent with current guidance in Chapter 17, section 40.1 of the Medicare Claims Processing Manual, ESRD facilities must bill the program using the JW modifier for the amount of ESAs appropriately discarded if the home dialysis patient must discard a portion of the ESA supply due to expiration of a vial, because of interruption in the patient's plan of care, or unused ESAs on hand after a patient's death. In response to the commenter's statement about the use of multi-use vials by home dialysis patients, we are reiterating that discarded amounts should only be reported for drugs and biological products from single-dose containers or single-use packaging. ESRD facilities should not report discarded amounts of renal dialysis drugs or biological products from multi-use vials. Discarded amounts of renal dialysis drugs and biological products from multi-use vials should not be billed on ESRD PPS claims.

Comment: Many commenters requested that CMS provide additional clarity about how information about discarded drug amounts may be used in the future to inform payment policy. Commenters pointed out that packaging for drugs and biological products is controlled by manufacturers and FDA, rather than by ESRD facilities, and expressed concern that data collected under this proposed reporting policy would be used in the future to reduce ESRD PPS payments. Commenters stated that ESRD facilities are already incentivized, by the nature of the ESRD PPS, to minimize the amount of discarded renal dialysis drugs and biological products to the extent possible. One commenter stated that the underlying issue of waste can only be solved by holding the manufacturers responsible. Some commenters requested clarification on whether CMS intends to apply penalties for non-compliance with the JW and JZ modifier reporting requirements.

Response: As we noted in the CY 2024 ESRD PPS proposed rule, we did not propose any reduction to ESRD PPS payments based on the amounts of discarded renal dialysis drugs and biological products reported using the JW modifier. As we noted in the CY 2024 ESRD PPS proposed rule, we intend to analyze information about discarded amounts in the broader context of changes to the ESRD PPS case-mix adjustments and may propose changes in future rulemaking if appropriate. We appreciate and agree with commenters' assertions that ESRD facilities have limited control over the amount of discarded renal dialysis drugs and biological products, and that ESRD facilities are required to discard any remaining amounts from a single-dose container or single-use packaging that are not used by the patient. As we discussed in the CY 2024 ESRD PPS proposed rule, we have previously established in the CY 2012 ESRD PPS final rule (76 FR 70243 through 70244) that ESRD facilities may only report units and charges for drugs and biological products purchased and may not bill for overfill units of drugs and biological products which exceed the amount indicated on the vial or package labeling. We recognize that manufacturers of renal dialysis drugs and biological products are ultimately responsible for decisions about packaging, which drive the magnitude of discarded amounts. As some commenters noted, current provisions at §§ 414.902 and 414.940, which require refunds from manufacturers for discarded amounts of drugs, apply only to separately payable drugs and biological products and do not apply to drugs and biological products paid for under the ESRD PPS. We believe that collecting more complete information about discarded amounts of renal dialysis drugs and biological products from single-dose containers and single-use packaging will help CMS to more fully evaluate the impact that such discarded amounts have on both Medicare payments and beneficiary copayments.

Lastly, we are reiterating that we are not applying any penalties for noncompliance with this reporting requirement for discarded amounts; however, as we noted in the CY 2024 ESRD PPS proposed rule (88 FR 42455), claims for renal dialysis drugs and biological products from single-dose containers or single-use packages that do not report either the JW or JZ modifier may be returned as unprocessable until the claims are properly resubmitted.

Final Rule Action: We are finalizing the proposed reporting requirement for discarded amounts of renal dialysis drugs and biological products from single-dose containers and single-use packaging, with a modified effective date of January 1, 2025. Therefore, consistent with the current JW and JZ reporting requirements that were finalized in the CY 2023 PFS final rule for separately payable Part B drugs, we are finalizing that beginning no later than January 1, 2025, ESRD facilities must report information on ESRD PPS claims about the total number of billing units of any discarded amount of a renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS, using the JW modifier (or any successor modifier that includes the same data). We are also finalizing that ESRD facilities must document any discarded amounts in the beneficiary's medical record. Additionally, we are finalizing that ESRD facilities must report the JZ modifier for all such renal dialysis drugs and biological products with no discarded amounts, beginning no later than January 1, 2025. We are finalizing a modification to the proposed regulation text to clarify that for renal dialysis drugs and biological products from single-dose containers and single-use packaging that are administered to home dialysis patients or that are oral forms of renal dialysis injectable drugs, the ESRD facility should report the amount of such drugs and biological products expected to be discarded. We are finalizing our

proposal to codify these reporting requirements in regulation at § 413.198(b)(5) and (6), with changes to indicate that the January 1, 2025, effective date applies to each of these requirements.

i. New Add-On Payment Adjustment for Certain New Renal Dialysis Drugs and Biological Products After the TDAPA Period Ends

(1) Background on the TDAPA

Section 217(c) of PAMA required the Secretary to establish a process for including new injectable and intravenous (IV) products into the ESRD PPS bundled payment as part of the CY 2016 ESRD PPS rulemaking. Therefore, in the CY 2016 ESRD PPS final rule (80 FR 69013 through 69027), we finalized a process based on our longstanding drug designation process that allowed us to include new injectable and intravenous products into the ESRD PPS bundled payment and, when appropriate, modify the ESRD PPS payment amount. We codified this process in our regulations at § 413.234. We finalized that the process is dependent upon the ESRD PPS functional categories, consistent with the drug designation process we have followed since the implementation of the ESRD PPS in 2011. As we explained in the CY 2016 ESRD PPS final rule (80 FR 69014), when we implemented the ESRD PPS, drugs and biological products were grouped into functional categories based on their action. This was done to add new drugs or biological products with the same functions to the ESRD PPS bundled payment as expeditiously as possible after the drugs are commercially available, so beneficiaries have access to them. As we stated in the CY 2011 ESRD PPS final rule, we did not specify all the drugs and biological products within these categories, because we did not want to inadvertently exclude drugs that may be substitutes for drugs we identified, and we wanted the ability to reflect new drugs and biological products developed or changes in standards of practice (75 FR 49052).

In the CY 2016 ESRD PPS final rule, we finalized the definition of an ESRD PPS functional category in § 413.234(a) as a distinct grouping of drugs or biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD (80 FR 69077). We finalized a policy in the CY 2016 ESRD PPS final rule that if a new renal dialysis injectable or IV product falls within an existing functional category, the new injectable drug or IV product is considered included in the ESRD PPS bundled payment and no separate payment is available. The new injectable or IV product qualifies as an outlier service. We noted in that rule that the productivity-adjusted ESRDB market basket update is used to increase the ESRD PPS base rate annually and accounts for price changes of the drugs and biological products. We also finalized in the CY 2016 ESRD PPS final rule that, if the new renal dialysis injectable or IV product does not fall within an existing functional category, the new injectable or IV product is not considered included in the ESRD PPS bundled payment and the following steps occur. First, an existing ESRD PPS functional category is revised or a new ESRD PPS functional category is added for the condition that the new injectable or IV product is used to treat or manage. Next, the new injectable or IV product is paid for using the TDAPA codified in § 413.234(c). Finally, the new injectable or IV product is added to the ESRD PPS bundled payment following payment of the TDAPA.

In the CY 2016 ESRD PPS final rule, we finalized a policy in § 413.234(c) to pay the TDAPA until sufficient claims data for rate setting analysis for the new injectable or IV product are available, but not for less than 2 years. The new injectable or IV product is not eligible as an outlier service during the TDAPA period. We established that following the TDAPA period, the ESRD PPS base rate will be modified, if appropriate, to account for the new injectable or IV product in the ESRD PPS bundled payment.

In the CYs 2019 and 2020 ESRD PPS final rules (83 FR 56927 through 56949 and 84 FR 60653 through 60677, respectively), we made several revisions to the drug designation process regulations at § 413.234. In the CY 2019 ESRD PPS final rule, we revised the regulations at § 413.234(a), (b), and (c) to reflect that the process applies for all new renal dialysis drugs and biological products that are FDA approved regardless of the form or route of administration. In addition, we revised § 413.234(b) and (c) to expand the TDAPA to all new renal dialysis drugs and biological products, rather than just those in new ESRD PPS functional categories. In the CY 2020 ESRD PPS final rule, we revised § 413.234(b) and added paragraph (e) to exclude from TDAPA eligibility generic drugs approved by FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act and drugs for which the new drug application (NDA) is classified by FDA as Type 3, 5, 7, or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the ''parent NDA'' is a Type 3, 5, 7, or 8, effective January 1, 2020.

Under our current TDAPA policy at § 413.234(c), a new renal dialysis drug or biological product that falls within an existing ESRD PPS functional category is considered included in the ESRD PPS base rate and is paid the TDAPA for 2 years. After the TDAPA period, the ESRD PPS base rate will not be modified. If the new renal dialysis drug or biological product does not fall within an existing ESRD PPS functional category, it is not considered included in the ESRD PPS base rate, and it will be paid the TDAPA until sufficient claims data for rate setting analysis is available, but not for less than 2 years. After the TDAPA period, the ESRD PPS base rate will be modified, if appropriate, to account for the new renal dialysis drug or biological product in the ESRD PPS bundled payment.

As discussed in the CY 2019 and CY 2020 ESRD PPS final rules, for new renal dialysis drugs and biological products that fall into an existing ESRD PPS functional category, the TDAPA helps ESRD facilities to incorporate new drugs and biological products and make appropriate changes in their businesses to adopt such products, provides additional payments for such associated costs, and promotes competition among the products within the ESRD PPS functional categories, while focusing Medicare resources on products that are innovative (83 FR 56935; 84 FR 60654). For new renal dialysis drugs and biological products that do not fall within an existing ESRD PPS functional category, the TDAPA is a potential pathway toward a potential ESRD PPS base rate modification (83 FR 56935). For the complete history of the TDAPA policy, including the pricing methodology, see the CY 2016 ESRD PPS final rule (80 FR 69023 through 69024), CY 2019 ESRD PPS final rule (83 FR 56932 through 56948), and CY 2020 ESRD PPS final rule (84 FR 60653 through 60681).

(2) Request for Information in the CY 2023 ESRD PPS Proposed Rule

In the CY 2023 ESRD PPS proposed rule (87 FR 38522 through 38523), we summarized the concerns of interested parties and issued a request for information about methods that could be used to develop an add-on payment adjustment for certain new renal dialysis drugs and biological products after the end of the TDAPA. We explained that since 2019, dialysis associations and pharmaceutical representatives have expressed concerns

to CMS about payment following the TDAPA period for new renal dialysis drugs and biological products that are paid for using the TDAPA. We noted that these interested parties have asserted that unless money is added to the ESRD PPS base rate for these drugs and biological products, like what occurred with calcimimetics (85 FR 71406 through 71410), then it is unlikely that ESRD facilities would be able to sustain the expense of these drugs and biological products when the TDAPA period ends. Further, these interested parties cautioned that uncertainty about payment could affect ESRD facility adoption of these drugs and biological products during the TDAPA period. We noted that to date, calcimimetics are the only renal dialysis drugs or biological products that have been paid for using the TDAPA and incorporated into the ESRD PPS bundled payment following the TDAPA payment period. We stated that there have been no other renal dialysis drugs or biological products that have completed their TDAPA payment period, and as a result, CMS does not yet have data on other drugs or biological products to evaluate the specific risks and access challenges that interested parties have raised.

We also discussed that, as mentioned in the CY 2019 (83 FR 56941) and CY 2020 (84 FR 60672 and 60693) ESRD PPS final rules, many commenters have suggested a rate-setting exercise at the end of the TDAPA period for all new renal dialysis drugs and biological products. We responded to those comments by noting that we do not believe adding dollars to the ESRD PPS base rate would be appropriate for new drugs that fall into the ESRD PPS functional categories, given that the purpose of the TDAPA for these drugs is to help ESRD facilities incorporate new drugs and biological products and make appropriate changes in their businesses to adopt such products, provide additional payments for such associated costs, and promote competition among the products within the ESRD PPS functional categories. In addition, we explained that the ESRD PPS base rate already includes money for renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category. We stated that under a PPS, Medicare makes payments based on a predetermined, fixed amount that reflects the average patient, and that there would be patients whose treatment costs at an ESRD facility would be more or less than the ESRD PPS payment amount. We noted that a central objective of the ESRD PPS and of prospective payment systems in general is for ESRD facilities to be efficient in their resource use.

We also noted that price changes to the ESRD PPS bundled payment are updated annually by the productivity-adjusted ESRDB market basket update, which includes a pharmaceutical cost category weight. In addition, we explained that our analysis of renal dialysis drugs and biological products paid for under the ESRD PPS has found costs and utilization to have decreased over time for some high volume formerly separately billable renal dialysis drugs, relative to overall ESRDB market basket growth. Therefore, we stated that we believe that any potential methodology for an add-on payment adjustment in these circumstances should adapt to changes in price and utilization over time.

We noted that section 1881(b)(14)(D)(iv) of the Act provides that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate, such as a payment adjustment—(1) for pediatric providers of services and renal dialysis facilities; (2) by a geographic index, such as the index referred to in section 1881(b)(12)(D), as the Secretary determines to be appropriate; and (3) for providers of services or renal dialysis facilities located in rural areas. Regarding the patient access concerns that we discussed in the CY 2023 ESRD PPS proposed rule, we stated that we were considering whether it would be appropriate to establish an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after their TDAPA period ends. We noted that any add-on payment adjustment would be subject to the Medicare Part B beneficiary coinsurance payment under ESRD PPS.

In the CY 2023 ESRD PPS proposed rule, we presented four potential methods that we were considering, which we noted could be used to develop an add-on payment adjustment for these drugs and biological products. We noted that the methods presented differed in terms of which formerly separately billable renal dialysis drugs and biological products would be considered for methodological inclusion in a potential add-on payment adjustment. We further noted that under the potential options presented, we would apply a reconciliation methodology only when an add-on payment adjustment would align resource use with payment for a renal dialysis drug or biological product in an existing ESRD PPS functional category.

Following the discussion in the CY 2023 ESRD PPS proposed rule about these potential methodologies, we issued a request for information within that proposed rule (87 FR 38523) to seek feedback from the public on the need for an add-on payment adjustment of this kind and the potential methodologies for calculating such an add-on payment adjustment. We noted that while we would not be responding to specific comments submitted in response to this RFI, we intended to use this input to inform future policy development. We stated that any potential payment policies related to this RFI would be proposed through a separate notice and comment rulemaking.

We provided a high-level summary of responses to this RFI in the CY 2023 ESRD PPS final rule (87 FR 67219 through 67220) and noted that we would publish more detailed information about the commenters' recommendations in a future posting on the CMS website located at the following link: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources*. We noted that we received 27 public comments regarding our RFI, including from large, small, and non-profit dialysis organizations; an advocacy organization; a coalition of dialysis organizations; a large, non-profit health system; and MedPAC.

In the CY 2023 ESRD PPS final rule, we stated that most commenters expressed their belief that an add-on payment adjustment of this nature is necessary to support the adoption of new renal dialysis drugs and biological products, and that most commenters stated that they supported CMS allowing all new renal dialysis drugs and biological products to be eligible to receive an add-on payment adjustment after the TDAPA period ends. However, we noted that MedPAC opposed this type of add-on payment adjustment by stating that it would undermine competition with existing drugs in the ESRD PPS bundled payment and encourage higher launch prices. We also noted that MedPAC recommended that CMS limit the add-on payment adjustment to new renal dialysis drugs and biological products that show a substantial clinical improvement compared with existing products reflected in the ESRD PPS bundled payment.

We further noted in the CY 2023 ESRD PPS final rule that several commenters stated they supported reconciling the expenditure of the new renal dialysis drug or biological product with any reduction in expenditures for other formerly separately billable renal

dialysis drugs that are clinically or statistically related to the introduction of the new renal dialysis drug in the bundle. Several commenters expressed their belief that the FDA-approved label should be used to determine the primary indication and clinical association, rather than end-action effect. MedPAC expressed opposition to calculating any add-on payment adjustment for new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period ends but noted that if an add-on payment adjustment were applied, it would be appropriate to use an offset, like the approach used with the TPNIES, to avoid duplicative payment for renal dialysis services already included in the ESRD PPS base rate.

(3) Add-On Payment Adjustment for Certain New Renal Dialysis Drugs and Biological Products After the TDAPA Period Ends

As discussed previously, section 1881(b)(14)(D)(iv) of the Act provides that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate. Based on the public comments received regarding the RFI in the CY 2023 ESRD PPS proposed rule,[34] we stated in the CY 2024 ESRD PPS proposed rule (88 FR 42458) that we believe it is appropriate to propose, beginning January 1, 2024, an add-on payment adjustment for new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the end of the TDAPA period. We noted that this proposed payment adjustment would not apply to new renal dialysis drug or biological products used to treat or manage a condition for which there is not an ESRD PPS functional category, because we have already established a policy to modify the ESRD PPS base rate for such products, if appropriate, after the TDAPA period ends, to account for the products in the ESRD PPS bundled payment (§ 413.234(c)(2)(i)).

We stated that we agreed with commenters who expressed concerns that the ESRD PPS' current mechanisms may not fully account for the costs of these new drugs. We noted that several commenters asserted that the outlier adjustment and the ESRDB market basket updates cannot adequately account for these costs, and several organizations noted that if renal dialysis drugs and biological products with significant costs were adopted under the outlier policy, the threshold to qualify for outlier payments would increase dramatically, thus adversely affecting access to products traditionally eligible for the outlier payment adjustment. We described comments which expressed that this increase in the outlier threshold may also raise health equity concerns because, as we noted in the CY 2023 ESRD PPS final rule (87 FR 67170 through 67171), the outlier adjustment protects access for beneficiaries whose care is unusually costly. We stated that we recognize that if the outlier threshold were to increase significantly due to significant use of a new renal dialysis drug or biological product after the end of the TDAPA, then ESRD facilities might be incentivized to avoid treating costlier beneficiaries. Additionally, we described several comments that raised concerns about the ability of the ESRDB market basket update to account for the cost of new renal dialysis drugs and biological products. These commenters referred to a Moran study [35] suggesting that the drug price proxies used in the ESRDB market basket have not adequately accounted for the costs of non-ESA drugs under existing functional categories. We explained that while we continue to believe that the market basket price proxies are the best available information for projecting the future price growth of renal dialysis drugs and biological products, and that they provide an adequate mechanism for projecting future ESRD PPS price growth, we recognize that there is additional uncertainty about future trends in the expenditures for new renal dialysis drugs and biological products, including trends in pricing and utilization of such drugs and any functionally equivalent substitutes such as generic drugs.[36] We stated that we believe these trends could be more effectively analyzed by collecting additional ESRD facility cost data following the 2-year TDAPA period. We stated that we recognize that although the TDAPA for drugs and biological products in existing ESRD PPS functional categories enables ESRD facilities to incorporate new renal dialysis drugs and biological products into their businesses, additional support may be needed to assure continued access to such drugs and biological products for Medicare beneficiaries and to support ESRD facilities' long-term planning and budgeting. We also recognized the importance of providing an appropriate pathway for ESRD facilities to incorporate new renal dialysis drugs and biological products into their business operations. We noted that in the CY 2019 ESRD PPS final rule in which we first established the 2-year TDAPA period for new renal dialysis drugs and biological products in an existing ESRD PPS functional category (83 FR 56934), we acknowledged that ESRD facilities have unique circumstances regarding incorporation of new drugs and biological products into their standards of care. For example, we stated that when new drugs are introduced to the market, ESRD facilities need to analyze their budget and engage in contractual agreements to accommodate the new therapies in their care plans. We noted that newly launched drugs and biological products can be unpredictable regarding their uptake and pricing, which makes these decisions challenging for ESRD facilities. Furthermore, we stated that practitioners should have the ability to evaluate the appropriate use of a new product and its effect on patient outcomes. We noted that we agreed this uptake period would be best supported by the TDAPA pathway because it would help ESRD facilities transition or test new drugs and biological products in their businesses under the ESRD PPS. In the CY 2024 proposed rule, we stated that we continue to believe the 2-year TDAPA period is appropriate and achieves its stated goals. However, we also recognized that continuity and predictability is an integral part of ESRD facilities' ongoing business operations. We stated that we agree with commenters' concerns that a sudden decrease in payments after the end of the TDAPA for these products could result in a decrease in access for these new renal dialysis drugs and biological products. We therefore proposed to establish a new transitional add-on payment adjustment that would provide an appropriate transition of the level of payment following the TDAPA period for these drugs. For ease of reference, we proposed to refer to this add-on payment adjustment as the post-TDAPA add-on payment adjustment. We stated that our goals for the post-TDAPA add-on payment adjustment are to support Medicare beneficiaries' access to new renal dialysis drugs or biological products that are used to treat or manage a condition for which there is an ESRD PPS functional category and that are therefore considered included in the ESRD PPS bundled payment. We

[34] *https://www.cms.gov/files/document/cy-2023-esrd-pps-payment-after-tdapa-rfi-summary-comments.pdf.*

[35] Kidney Care Partners. August 4, 2022. Comment Letter. *https://kidneycarepartners.org/wp-content/uploads/2022/08/KCP-PPS-Comment-Letter-Part-1-Final.pdf.* Accessed May 16, 2023.

[36] *https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers.*

also stated that we want to support ESRD facilities' long-term planning with respect to continuing to budget and plan for new renal dialysis drugs and biological products that ESRD facilities have incorporated into their businesses during the TDAPA period. In addition, we explained that in accordance with the goals of prospective payment under the ESRD PPS, our goal for the post-TDAPA add-on payment adjustment is to incentivize ESRD facilities to be efficient in the use of resources.

We proposed to calculate the post-TDAPA add-on payment adjustment following the methodology described in the following subsections for any new renal dialysis drug or biological product that is paid for using the TDAPA under § 413.234(c)(1). We proposed that the post-TDAPA add-on payment adjustment would be applied for a period of 3 years following the end of the TDAPA period for those products. We stated that we believe a 3-year payment period would provide sufficient time for CMS to analyze cost reports that include costs for the new renal dialysis drug or biological product paid for using the TDAPA under the ESRD PPS, to incorporate changes as appropriate to the ESRDB market basket price proxies. The ESRDB market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres-type price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. We stated that the proposed 3-year payment period for the post-TDAPA add-on payment adjustment would allow CMS to evaluate how the new drug or biological product affects the overall mix of renal dialysis drugs and biological products in the ESRDB market basket and to determine the appropriate price proxies for such new drug or biological product. We noted that for new renal dialysis drugs and biological products that are not considered included in the ESRD PPS base rate, the TDAPA is paid until sufficient claims data for rate setting analysis for the new renal dialysis drug or biological product is available, but not for less than 2 years. Similarly, as described earlier in this paragraph, we proposed a 3-year payment period for the post-TDAPA add-on payment adjustment, which would enable the collection and analysis of sufficient Medicare cost report information and would address the concerns that commenters raised about the effectiveness of the ESRDB market basket price proxies to reflect the prices of new renal dialysis drugs and biological products going forward by allowing CMS to incorporate data showing trends in use over an adequate period of time. Additionally, we stated that we believe a 3-year period for the post-TDAPA add-on payment adjustment would be appropriate and consistent with the transition period that we finalized at the beginning of the ESRD PPS, when ESRD facilities were transitioned from receiving payments under the composite rate payment system to receiving payments under the ESRD PPS (79 FR 49162). We finalized the transition period for CY 2011 through CY 2013 to comply with the requirement of section 1881(b)(14)(E)(i) of the Act to provide a 4-year phase-in of the payment amount under the ESRD PPS, where full implementation of the ESRD PPS payment would occur beginning in the fourth year, CY 2014. We proposed a similar timeline to provide an appropriate transition for new renal dialysis drugs and biological products in existing ESRD PPS functional categories, which are not eligible for a modification to the ESRD PPS base rate. Based on the experience of ESRD facilities during the 4-year phase-in from CY 2011 to CY 2014, ESRD facilities would be familiar with this timeline for phasing in major changes that impact their long-term planning and budgeting. Lastly, in the interest of transparency, we noted that this 3-year period would provide time for analysis of utilization data for public awareness about the potential need for refinements to the ESRD PPS. Therefore, we proposed to calculate and apply the post-TDAPA add-on payment adjustment for a period of 3 years following the end of the TDAPA period, with no post-TDAPA add-on payment adjustment calculated beginning in the 4th year.

We proposed that this post-TDAPA add-on payment adjustment would not be budget neutral, as discussed later in this section of the final rule. We noted that this post-TDAPA add-on payment adjustment, if finalized, would be calculated for Korsuva®, the only renal dialysis drug currently receiving the TDAPA, and that payment of this post-TDAPA add-on payment adjustment, if finalized, would begin April 1, 2024, at the end of the TDAPA period for Korsuva®.

We received several public comments on our proposal to establish a post-TDAPA add-on payment adjustment beginning in CY 2024. The comments on our proposal and our responses are set forth below.

Comment: Many commenters, including LDOs, drug manufacturers, patient advocacy organizations, coalitions of dialysis organizations, and patients, expressed support for establishing a post-TDAPA add-on payment adjustment. Commenters expressed that adequate payment is necessary to support Medicare beneficiaries' access to both current and future new and innovative renal dialysis drugs and biological products.

Response: We appreciate the support for the proposed post-TDAPA add-on payment adjustment. We agree with commenters about the importance of adequate payment. As we discussed in the CY 2024 ESRD PPS proposed rule and in the following section of this final rule, we believe the proposed payment methodology provides a significant level of payment that adequately supports beneficiaries' access to drugs and biological products after the TDAPA period ends, while sharing a significant portion of the cost with ESRD facilities, thereby incentivizing ESRD facilities to allocate resources efficiently.

Comment: MedPAC reiterated several concerns that it previously raised in response to the RFI on this topic in the CY 2023 ESRD PPS proposed rule. First, MedPAC reiterated its strong opposition to the establishment of a post-TDAPA add-on payment adjustment as proposed, stating that such a payment adjustment would be duplicative of payment under the ESRD PPS base rate. MedPAC specifically identified that when Mircera® (an ESA) became available in 2015, beneficiary access to the new drug was not impeded when the agency included it in the ESRD PPS bundled payment (in a budget-neutral manner). Between 2015 and 2020, use of Mircera® significantly and steadily increased. MedPAC further noted that, with respect to Mircera®, one LDO announced its intent to have more than 70 percent of the company's ESA patients (110,000 patients) switched to Mircera® (from epoetin alfa) by the end of the first quarter of 2016, and sources suggest that this LDO reduced its total ESA costs. In addition, MedPAC also reiterated its concerns that CMS would not apply a clinical superiority standard when implementing the post-TDAPA payment adjustment policy and stated that beneficiaries and taxpayers would pay for a new drug without evidence that the new product is an advance in medical technology that substantially improves beneficiaries' outcomes relative to technologies in the ESRD PPS.

Response: We thank MedPAC for its comments. We recognize and agree with MedPAC about the importance of avoiding making payments under a post-TDAPA add-on payment adjustment that would be duplicative of payment under the ESRD PPS base rate

or that would undermine competition between new and existing renal dialysis services. We anticipate that the post-TDAPA add-on payment adjustment will provide appropriate payment that supports Medicare beneficiaries' access to new renal dialysis drugs and biological products, create stability in payments to ESRD facilities after the end of the TDAPA, and appropriately align incentives to promote competition between new and existing renal dialysis services. The proposed post-TDAPA add-on payment adjustment would not be duplicative of payment under the ESRD PPS base rate, because it would specifically support access to new renal dialysis services at the level observed during the most recent 12 months, providing a glidepath for new renal dialysis drugs and biological products in existing functional categories following the TDAPA, since under § 413.234(c)(1), there is no modification to the ESRD PPS base rate. As further discussed below, the proposed application of a risk-sharing methodology would account for existing substitute drugs and biological products included in the ESRD PPS.

There are several important distinctions between the historical inclusion of Mircera® into the ESRD PPS bundled payment and the inclusion of renal dialysis drugs and biological products in existing ESRD PPS functional categories that receive TDAPA payment, for which we have proposed to calculate the post-TDAPA add-on payment adjustment beginning in CY 2024. First, when Mircera® was incorporated into the ESRD PPS bundled payment, CMS had not yet established any TDAPA policies, which are integral to the current ESRD PPS drug designation process. As we previously stated, section 217(c) of PAMA required the Secretary to establish a process for including new injectable and intravenous products into the ESRD PPS bundled payment, which CMS finalized in the CY 2016 ESRD PPS final rule (80 FR 69013 through 69027) and codified in our regulations at § 413.234. Under current law, new renal dialysis drugs and biological products in existing functional categories which qualify for TDAPA payment are generally paid for using the TDAPA for a period of 2 years, after which such drugs and biological products are considered included in the ESRD PPS base rate with no modification to the base rate. As we stated in the CY 2024 ESRD PPS proposed rule, we recognize continuity and predictability are integral parts of ESRD facilities' ongoing business operations. We stated that we agree with commenters' concerns that a sudden decrease in payments after the end of the TDAPA for these products could result in a decrease in access for these new renal dialysis drugs and biological products. We therefore proposed to establish a new transitional add-on payment adjustment that would provide an appropriate transition of the level of payment following the TDAPA period for these drugs.

Importantly, we note that under current regulations at § 413.234, Mircera® would not have been eligible for payment under the TDAPA, because it was approved under an NDA type that is excluded from TDAPA eligibility under § 413.234(e). In contrast to renal dialysis drugs and biological products that are paid for using the TDAPA, Mircera® was seen as a direct and less expensive substitute for existing renal dialysis drugs included in the ESRD PPS, specifically Amgen's anemia management drug Epogen®.[37] Accordingly, as MedPAC noted in its comment letter, ESRD facilities broadly adopted Mircera® into their business practices without the need for additional payment. However, as explained earlier, we do not consider Mircera® to be an appropriate comparison to new renal dialysis drugs and biological products for which we propose to calculate the post-TDAPA add-on payment adjustment, because under current regulation Mircera® would not be eligible to receive either the TDAPA or a post-TDAPA add-on payment adjustment.

As we stated in the CY 2024 ESRD PPS proposed rule, we anticipate that the structure of the proposed post-TDAPA payment methodology will serve to incentivize the use of drugs that represent a substantial improvement over existing drugs, which will promote competition between new and existing renal dialysis drugs and biological products and drive down prices of such new renal dialysis drugs and biological products over time. We expect that our methodology for the post-TDAPA add-on payment adjustment will incentivize ESRD facilities' efficient use of resources, because payment for an individual claim will not be dependent on individual utilization of the new renal dialysis drug or biological product. Accordingly, we anticipate that under our methodology, for new renal dialysis drugs and biological products that are not a substantial clinical improvement over existing renal dialysis drugs and biological products, utilization will diminish over time and the amount of the post-TDAPA add-on payment adjustment will decline accordingly.

In addition, we stated in the CY 2024 ESRD PPS proposed rule that we recognize that continuity and predictability is integral to ESRD facilities' operations, and we do not think that this principle applies only to renal dialysis drugs and biological products that show a substantial clinical improvement. As we previously explained in the CY 2023 ESRD PPS final rule (87 FR 67189), the intent of the ESRD PPS functional category framework is to be broad and to facilitate adding new drugs to the therapeutic armamentarium of the treating physician. As we further explained in the CY 2023 ESRD PPS final rule, the functional category structure helps to ensure the ESRD patient has broad access to all renal dialysis service drugs, which is a distinct benefit to the patient. In addition, the structure of the functional categories helps to ensure the treating physician has a broad array of drugs to meet the specific, individual needs of each ESRD patient, including differing pharmaceutical profiles, comorbidities, contra-indications with other drugs the patient may be taking, and personal patient preference (87 FR 67189). We do not think that limiting the post-TDAPA add-on payment adjustment based on CMS's determination of substantial clinical improvement would align with this stated intent of the ESRD PPS functional category framework to support broad access to all renal dialysis service drugs. We further note that the current TDAPA exclusion criteria under § 413.234(e) consider FDA's determination of the drug's NDA type or approval under section 505(j) of the Federal Food, Drug, and Cosmetic Act, which is less subjective than a determination of substantial clinical improvement. Therefore, we continue to be of the view that the proposed methodology most appropriately balances the need to provide adequate payment with the concerns that MedPAC raised regarding duplicative payment and clinical superiority or substantial clinical improvement.

Comment: Many commenters expressed concerns about the proposed 3-year duration for the post-TDAPA add-on payment adjustment. Several commenters stated that the 3-year period would create a new payment cliff at the end of the 3-year post-TDAPA period and advocated for a permanent, non-budget neutral payment adjustment.

Response: We appreciate the concerns that commenters raised about the

[37] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4090042/.*

proposed 3-year period for the post-TDAPA add-on payment adjustment. We recognize that the policy would not permanently maintain increased payments for new renal dialysis drugs and biological products that receive the TDAPA, and we do not believe that such a permanent increase in payments would be appropriate. The TDAPA for renal dialysis drugs and biological products in existing functional categories is inherently transitional in nature and therefore not permanent. As we discussed in the CY 2019 and CY 2020 ESRD PPS final rules (83 FR 56935; 84 FR 60654), for new renal dialysis drugs and biological products that fall into an existing ESRD PPS functional category, the TDAPA helps ESRD facilities to incorporate the new drugs and biological products and make appropriate changes in their businesses to adopt such products. We also explained that the TDAPA provides additional payments for such associated costs and promotes competition among the products within the ESRD PPS functional categories, while focusing Medicare resources on products that are innovative. Accordingly, we proposed a post-TDAPA add-on payment adjustment beginning in CY 2024 that is similarly transitional in nature and which provides a glidepath for inclusion of such new renal dialysis drugs and biological products into the ESRD PPS. In the CY 2024 ESRD PPS proposed rule, we stated that a 3-year period for the post-TDAPA add-on payment adjustment would be consistent with the transition period that was finalized at the beginning of the ESRD PPS, when ESRD facilities were transitioned from receiving payments under the composite rate payment system to receiving payments under the ESRD PPS (79 FR 49162). We finalized the transition period for CY 2011 through CY 2013, with full implementation in CY 2014, to comply with the requirement of section 1881(b)(14)(E)(i) of the Act to provide a 4-year phase-in of the payment amount under the ESRD PPS. We proposed a similar timeline for the post-TDAPA add-on payment adjustment to provide an appropriate transition for new renal dialysis drugs and biological products in existing ESRD PPS functional categories, which are not eligible for a modification to the ESRD PPS base rate.

Comment: MedPAC encouraged CMS to clarify why an additional period of 3 years is appropriate for the proposed post-TDAPA add-on payment adjustment, as compared to the established 2-year TDAPA period for new renal dialysis drugs and biological products in existing functional categories. MedPAC stated that a post-TDAPA period is not needed to collect and analyze cost report data, and that if CMS has concerns about the price proxies for ESRD drugs used in the ESRDB market basket, CMS can conduct the necessary analyses, without creating the post-TDAPA add-on payment adjustment policy. In addition, MedPAC questioned the utility of current cost reports to evaluate whether the ESRDB market basket accounts for price changes of new ESRD drugs, since Medicare cost reports do not require providers to report the cost of each new item or product paid under a TDAPA or a TPNIES.

Response: As we previously discussed, we proposed to pay the post-TDAPA add-on payment adjustment for a period of 3 years following the payment of TDAPA for 2 years, to allow more complete cost reporting information to become available. CMS routinely rebases and revises the ESRDB market basket and price proxies, usually every four to five years, incorporating more recent cost report information. We agree with MedPAC that a post-TDAPA period is not strictly necessary to collect more recent cost report information. However, as we stated in the CY 2024 ESRD PPS proposed rule, we think that providing a post-TDAPA add-on payment adjustment during this period would provide stability in ESRD PPS payments while CMS analyzes such information.

The existing 2-year TDAPA period provides useful information about ESRD facilities' spending on drugs and biological products paid for using the TDAPA, but due to lags in the timing of when ESRD facilities submit their cost reports, such data would not become available in ESRD facilities' cost report information until after the end of the TDAPA period. For example, CMS generally uses Medicare cost report data that lags by approximately 3 to 4 years prior to the rulemaking year. Therefore, complete Medicare cost report data for CY 2023 or CY 2024 could be used to consider changes to market basket cost categories, cost weights, and price proxies for the CY 2026 or CY 2027 rulemaking cycle. As proposed, the post-TDAPA add-on payment adjustment would begin to be paid on April 1, 2024, based on utilization of Korsuva®, the only renal dialysis drug currently receiving the TDAPA, and would end no later than March 31, 2027. CMS would be able to analyze Medicare cost report data for CY 2023 and CY 2024 to consider changes to the ESRDB market basket for CY 2027 rulemaking, if appropriate. The proposed post-TDAPA add-on payment adjustment would provide appropriate payment stability for ESRD PPS payments to ESRD facilities during the intervening years, which would support beneficiaries' continued access to new renal dialysis drugs and biological products.

With respect to the question of the utility of Medicare cost report data, we think that more recent cost reports, which would include information about total drug spending across categories, would provide meaningful information about how new renal dialysis drugs and biological products affect ESRD facilities' costs. Although TDAPA and TPNIES costs are not reported separately, if spending for new renal dialysis drugs and biological products is driving significant increases in ESRD facilities' costs, more recent Medicare cost report data will inform CMS's understanding of how such spending affects the ESRDB market basket composition. We would also evaluate Part B spending data to determine the mix of the types of drugs and the appropriate price proxy based on changes to the relative mix of drugs used in the ESRD facility setting. Nevertheless, we recognize the limitations of the current Medicare cost reports that MedPAC identified, and we may consider changes in the future to improve the data that we collect through the Medicare cost report.

Final Rule Action: After consideration of the comments, we are finalizing as proposed to establish, beginning for CY 2024, a post-TDAPA add-on payment adjustment for any new renal dialysis drug or biological product that is considered included in the ESRD PPS base rate that is paid for using the TDAPA under § 413.234(c)(1). This post-TDAPA add-on payment adjustment will be applied for a period of 3 years following the end of the TDAPA period for those products.

(a) Calculation of the Post-TDAPA Add-On Payment Adjustment

As discussed earlier in this section of the final rule, we proposed to establish a new add-on payment adjustment for certain new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the end of the TDAPA period. In the CY 2024 ESRD PPS proposed rule, we proposed to apply the post-TDAPA add-on payment adjustment to all ESRD PPS payments beginning at the end of a new renal dialysis drug or biological product's TDAPA period. Specifically, we proposed that the post-TDAPA add-on payment adjustment would begin 8 calendar quarters after the beginning of

the first calendar quarter in which TDAPA payment is made for the new renal dialysis drug or biological product in an existing ESRD PPS functional category and would end no later than the 12th calendar quarter after the last calendar quarter in which TDAPA payment is made. We stated that we believe our calculation of the post-TDAPA add-on payment adjustment would be the most appropriate to address the patient access concerns we discussed in the CY 2023 ESRD PPS proposed rule and in this section of the final rule, and the most consistent with the principles of prospective payment. We stated that this proposal would apply the patient-level adjustment factors to the post-TDAPA add-on payment adjustment amount paid on each claim, which would ensure that ESRD PPS payment would support access to new renal dialysis drugs and biological products for beneficiaries with conditions that are costlier to treat, in alignment with our goals as stated earlier in this final rule. We proposed to codify the payment of the post-TDAPA add-on payment adjustment as part of the per treatment payment amount at § 413.230(f). We proposed to codify the methodology for calculating the post-TDAPA add-on payment adjustment at § 413.234(g). We proposed to make additional changes under § 413.234(b) and (c) to address payment of the post-TDAPA payment adjustment.

In determining the calculation of the post-TDAPA add-on payment adjustment, we considered the comments that we received regarding the RFI in the CY 2023 ESRD PPS proposed rule. Some commenters expressed that new and innovative drugs may only be used by a small percentage of the dialysis population and suggested that an add-on payment adjustment should address patient-specific needs to support access.

First, we considered calculating the post-TDAPA add-on payment adjustment as the average cost for patients that used the new renal dialysis drug or biological product that was previously paid for using the TDAPA under the ESRD PPS and applying the post-TDAPA add-on payment adjustment only to claims that include the new renal dialysis drug or biological product. However, we were concerned that such an approach would not align with the principles of prospective payment under the ESRD PPS. As we noted previously, a central objective of the ESRD PPS (and of prospective payment systems in general) is for ESRD facilities to be efficient in their resource use. Under a PPS, Medicare makes payments based on a predetermined, fixed amount that reflects the average patient, and CMS acknowledges there will be patients whose treatment costs at an ESRD facility will be more or less than the ESRD PPS payment amount. Additionally, we were concerned that such an approach would result in a substantial cost burden for beneficiaries who use the new renal dialysis drug or biological product, because they incur a 20 percent coinsurance under Part B for renal dialysis services. We stated that we do not believe this approach would align with our priorities to reduce drug costs for Medicare beneficiaries. In contrast, our proposed methodology would apply the post-TDAPA add-on payment adjustment to all ESRD PPS payments, which would result in a minimal increase in per-treatment coinsurance amounts for all beneficiaries. As discussed later in this section, we proposed to apply the ESRD PPS patient-level adjustments to the post-TDAPA add-on payment adjustment for each treatment.

Next, we considered applying the post-TDAPA add-on payment adjustment based only on claims from ESRD facilities that used the new renal dialysis drug or biological product during the TDAPA period. However, like the previous option, we stated that we believe limiting application of this add-on payment adjustment to claims from ESRD facilities that include the new renal dialysis drug or biological product would be inconsistent with the principles of prospective payment. As we discussed in the CY 2011 ESRD PPS final rule, there are patients whose medical treatment results in more costly care as well as those with less costly care, and the ESRD PPS bundled base rate reflects Medicare payment for the average ESRD patient (75 FR 49045). Further, we were concerned that limiting the post-TDAPA add-on payment adjustment to claims from ESRD facilities that use the new renal dialysis drug or biological product could result in substantial overestimation of the post-TDAPA add-on payment adjustment, if more ESRD facilities begin using the new renal dialysis drug or biological product. As we discuss later in this final rule, we proposed to apply this post-TDAPA add-on payment adjustment in a non-budget neutral manner. Therefore, we stated in the CY 2024 ESRD PPS proposed rule that we were concerned that an overestimation of the post-TDAPA add-on payment adjustment could result in an inappropriate increase in Medicare expenditures. As we discussed in the CY 2019 and CY 2020 ESRD PPS final rules (83 FR 56935; 84 FR 60654), for new renal dialysis drugs and biological products that fall into an existing ESRD PPS functional category, the TDAPA helps ESRD facilities to incorporate the new drugs and biological products and make appropriate changes in their businesses to adopt such products, provides additional payments for such associated costs, and promotes competition among the products within the ESRD PPS functional categories, while focusing Medicare resources on products that are innovative. We stated that we believe after the end of the TDAPA period, ESRD facilities will have made appropriate changes in their business models to adopt such products, and therefore any approach to a post-TDAPA add-on payment adjustment should apply equally to all ESRD PPS treatments, in order to apply the appropriate incentive structures for ESRD facilities' utilization of renal dialysis drugs and biological products and to continue to promote competition among the products within the ESRD PPS functional categories, including the new renal dialysis drug or biological product that was previously paid for using the TDAPA under the ESRD PPS. Furthermore, we stated that we believe that such an approach would help to support access to new renal dialysis drugs and biological products to the widest scope of beneficiaries. This is in line with CMS's commitment to advance health equity by supporting access to renal dialysis services.

Accordingly, we proposed to apply the post-TDAPA add-on payment adjustment to each ESRD PPS treatment, and to adjust it for patient characteristics. In other words, the post-TDAPA add-on payment adjustment would be multiplied by the ESRD PPS patient-level adjustments under § 413.235. We stated that we believe this approach would appropriately adjust aggregate ESRD PPS payment to account for the new renal dialysis drugs and biological products in a way that is consistent with the principles of prospective payment and would support beneficiary access to new renal dialysis drugs and biological products by recognizing the additional patient-specific needs associated with the existing ESRD PPS case-mix adjusters. We noted that to calculate an appropriate post-TDAPA add-on payment adjustment, we would apply a case-mix standardization factor to the post-TDAPA add-on payment adjustment amount as discussed in the following paragraphs.

In addition, we explained that we considered the public comments regarding the need to reconcile

estimated expenditures for a new renal dialysis drug or biological product with the declines in expenditures for related drugs. We noted that commenters expressed support for establishing a methodology that would consider the decline in estimated expenditures for drugs that are clinically or empirically related to the new renal dialysis drug or biological product. We explained that such a methodology would be highly complex and less transparent than other potential options that commenters suggested. We also explained that commenters in the past noted various ideas that CMS would need to consider when attempting to establish the offsetting financial effects of drugs and biological products that are either clinically or empirically related to the new renal dialysis drug or biological product. For example, most commenters suggested that CMS use drugs with the same FDA clinical indication to offset the payment adjustment, in the interest of transparency and objectivity. However, some commenters, including MedPAC, noted that they do not believe that FDA determinations or ESRD PPS functional categories should be the basis of eligibility for the post-TDAPA payment adjustment, as CMS should make these determinations based on the specific needs of the Medicare population. We stated that we believe such considerations based on specific population needs could be less transparent than alternative approaches, especially in situations when there could, in the future, be multiple new renal dialysis drugs or biological products for which we would be calculating multiple offset adjustments. We stated that we anticipate it would be challenging for CMS to determine, within the annual rulemaking timeframes, the extent to which changes in the utilization of existing renal dialysis drugs and biological products are clinically or empirically related to utilization of a new renal dialysis drug or biological product paid for using the TDAPA. We noted that the latest available data at the time of the proposed rulemaking included less than a full year of TDAPA utilization. We explained that we anticipate that as additional data are collected, CMS will be able to analyze trends and may be able to retrospectively determine the extent of any substitution effects between new and existing renal dialysis drugs and biological products. Furthermore, we noted that the calculation of these offsets could involve multiple overlapping periods of time, which would further increase complexity and reduce transparency. As an alternative, we explained that we considered MedPAC's suggestion to align the methodology closer to that of the ESRD PPS TPNIES, wherein CMS pays a reduced percentage of the estimated incremental cost of a new product as a risk-sharing mechanism with ESRD facilities and to provide a disincentive for significant increases in drug prices. Under the TPNIES, CMS calculates the TPNIES amount as 65 percent of the MAC-determined price for certain new and innovative equipment and supplies (§ 413.236(f)). We stated that we believe this approach would have the same general effect of accounting for declines in other drug expenditures, while being significantly less complex and more transparent. In the CY 2020 ESRD PPS final rule that established the 65 percent cost-sharing proportion for the TPNIES, we stated that the goal of the TPNIES was to support ESRD facility use of new and innovative renal dialysis equipment and supplies (84 FR 60692). In that same CY 2020 ESRD PPS final rule, we further stated in response to comments that we believe that we need to balance this goal with sharing risk for the new product (84 FR 60697). We noted that one goal of the post-TDAPA add-on payment adjustment is to support continued access to new renal dialysis drugs and biological products and to support ESRD facilities' long-term planning and budgeting for such drugs after the TDAPA period. Additionally, we stated that our goal is also to incentivize efficient use of resources, consistent with the principles of prospective payment under the ESRD PPS. We explained that we believe applying a cost-sharing proportion of 65 percent to the post-TDAPA add-on payment adjustment would effectively achieve these goals, because it would provide a significant level of payment that supports access for beneficiaries and long-term planning for ESRD facilities, while incentivizing ESRD facilities to efficiently allocate resources by sharing a significant portion of the cost with ESRD facilities. Furthermore, we stated that this 65 percent cost-sharing factor would serve to further reduce the minimal cost-sharing burden of new renal dialysis drugs and biological products for beneficiaries, under the post-TDAPA add-on payment methodology. Lastly, we noted that for home dialysis machines that are capital-related assets that qualify for the TPNIES, our policy is to apply an offset to account for such capital-related assets in the ESRD PPS base rate. As we discussed previously, we considered applying an offset to the post-TDAPA add-on payment adjustment; however, we believe that considerations based on specific population needs could be less transparent than applying a simple 65-percent risk-sharing percentage. Additionally, we noted that in the future, there could be multiple new renal dialysis drugs or biological products for which we would be calculating multiple offset adjustments, which would further increase complexity and reduce transparency. We solicited comments on whether there are other ways CMS could consider calculating an offset amount for the post-TDAPA payment adjustment. Alternatively, we sought comment on if there are other ways CMS could ensure any growth in post-TDAPA add-on payment adjustment amounts is reasonable, such as not allowing increases to exceed inflation or other relevant metrics.

We proposed to calculate the post-TDAPA add-on payment adjustment annually, based on the latest available full calendar quarter of average sales price (ASP) data, which would be consistent with the current policy for determining the basis of payment for the TDAPA. We stated that under current policy, finalized in the CY 2020 ESRD PPS final rule (84 FR 60679), we pay the TDAPA based on 100 percent of ASP. If ASP is not available, we base the TDAPA payment adjustment on wholesale acquisition cost (WAC), and if WAC is not available, then we base payment on invoice pricing. As we stated in the CY 2020 ESRD PPS final rule, we continue to believe that after the TDAPA period, calculating the post-TDAPA add-on payment adjustment for new renal dialysis drugs based on ASP, as compared to WAC or invoice pricing, would be the most appropriate choice for the ESRD PPS, and would strike the right balance in supporting ESRD facilities in their uptake of innovative, new renal dialysis drugs and biological products and limiting increases to Medicare expenditures. We proposed to address the annual calculation of the post-TDAPA add-on payment adjustment in the annual proposed and final ESRD PPS rules for future years.

As discussed in the CY 2024 ESRD PPS proposed rule (88 FR 42472), under current TDAPA policy, if CMS stops receiving ASP during the TDAPA period, then CMS will stop paying the TDAPA after 2 calendar quarters. Similarly, we explained that if drug manufacturers were to stop submitting ASP data for products that are included in the calculation of the post-TDAPA add-on payment adjustment, and we had to revert to basing calculation of the post-TDAPA add-on payment

adjustment on WAC or invoice pricing, we believe we would be overpaying for the add-on payment adjustment. Therefore, we proposed to make payment of the post-TDAPA add-on payment adjustment conditional on receiving ASP data. Because the post TDAPA add-on payment adjustment would be calculated annually rather than quarterly, we proposed that if CMS does not receive the latest full calendar quarter of ASP data for a drug that would be included in the calculation of the post-TDAPA add-on payment adjustment, then CMS would not include that drug in the calculation of the post-TDAPA add-on payment adjustment for any future years. We also proposed that if CMS stops paying the TDAPA for a drug or biological product because CMS stops receiving the latest full calendar quarter of ASP data, then we would not include that drug or biological product in the calculation of the post-TDAPA add-on payment adjustment for the next CY or any future CY. Consistent with our policy for calculating the TDAPA, as discussed in section II.B.1.k of the proposed rule, we proposed that in situations when a manufacturer reports zero or negative sales, we would consider CMS to have received the latest full calendar quarter of ASP data, but we would calculate the post-TDAPA payment adjustment based on WAC, or if WAC is not available, on invoice pricing, in such circumstances.

Finally, we proposed that for each of the 3 years for which this post-TDAPA add-on payment adjustment would be paid, we would update the amount of the post-TDAPA add-on payment adjustment by the productivity-adjusted ESRDB market basket update to account for estimated future input price changes faced by ESRD facilities. We solicited comment on whether it would be more appropriate to consider using the growth in the price proxy for the pharmaceuticals cost category in the ESRDB market basket, rather than the productivity-adjusted ESRDB market basket update. We also provided a detailed set of steps for calculating the amount of the proposed post-TDAPA add-on payment adjustment for CY 2024, which we calculated at $0.0961 for the proposed rule. We solicited comments on this proposed methodology for a post-TDAPA add-on payment adjustment and its appropriateness for CY 2024 and future years.

We received public comments on our proposed methodology for calculating the post-TDAPA add-on payment adjustment. The comments on our proposal and our responses are set forth below.

Comment: Many commenters, including LDOs, drug manufacturers, and patient advocacy organizations, expressed concerns that the proposed methodology would not support access to new and innovative renal dialysis drugs and biological products. Commenters stated that the proposed amount would provide a level of funding that supports the provision of drugs and biological products currently paid for using the TDAPA to only a small proportion of patients and would not support expanded access to such drugs. One commenter stated that CMS policy must recognize that practice follows payment and provided an example of certain payment policy changes in the SNF PPS, specifically the recent transition from the SNF Resource Utilization Group payment system to the Patient-Driven Payment Model (83 FR 39162), which the commenter stated drove subsequent utilization patterns in that system by reducing incentives for overutilization of certain rehabilitative therapies.

Response: We disagree with commenters who stated that the amount of the proposed post-TDAPA add-on payment adjustment would not support access to new and innovative renal dialysis drugs and biological products. Because the proposed methodology is based on the latest available price and utilization information, we believe it provides an adequate level of funding to maintain access to new renal dialysis drugs and biological products after the end of the TDAPA period. We note that the proposed amount of the post-TDAPA add-on payment adjustment for CY 2024 reflects utilization of current TDAPA drugs by a small proportion of ESRD beneficiaries, amounting to less than 1 percent of all treatments. Although the payment per treatment is a relatively small amount, an ESRD facility's aggregate payments under the proposed post-TDAPA add-on payment adjustment methodology would nonetheless help to support the utilization for new renal dialysis drugs and biological products at the level of utilization observed during the TDAPA period. We note that, as discussed later in this final rule, we are calculating the final amount of the post-TDAPA add-on payment adjustment for CY 2024 to be significantly higher than the CY 2024 ESRD PPS proposed rule, based on the latest available price and utilization data.

Lastly, we appreciate the concerns that the commenter raised regarding utilization patterns as the result of payment policies, and we are acutely aware of the importance of establishing payment adjustments in the ESRD PPS that are aligned with the principles of prospective payment. We anticipate that the post-TDAPA payment methodology that we are finalizing will provide an appropriate level of funding to support access to new renal dialysis drugs and biological products after the end of the TDAPA, without providing a direct incentive to use any particular new drug or biological product, which we anticipate could result in overutilization.

Comment: MedPAC stated that although it strongly disagrees with the implementation of a post-TDAPA add-on payment adjustment, it recognizes that CMS's proposed per claim add-on payment approach provides better incentives for more judicious use of a new renal dialysis drug rather than a per use add-on payment approach. MedPAC reiterated that paying on a per unit basis for a drug incentivizes its use (to the extent clinically possible) and recommended that if CMS finalizes the post-TDAPA add-on payment adjustment, the agency should proceed with a per claim add-on payment. MedPAC also expressed support for the proposed 65 percent risk-sharing percentage as an incentive for price competition.

Response: We appreciate MedPAC's qualified support for the proposed methodology. We agree with MedPAC that the proposed per-treatment methodology would appropriately align incentives for ESRD facilities to be efficient with their resources, and as a result it would foster competition between new and existing renal dialysis drugs and biological products. We also agree that the proposed application of a risk-sharing percentage would provide a further incentive for price competition between drugs within an ESRD PPS functional category. As we discussed in the CY 2024 ESRD PPS proposed rule (88 FR 42462), we anticipate that the proposed risk sharing percentage of 65 percent would be appropriate, as it would provide a significant level of payment that supports access for beneficiaries and long-term planning for ESRD facilities, while incentivizing ESRD facilities to allocate resources efficiently.

Comment: Several commenters advocated for an alternative methodology that would calculate an add-on payment adjustment based on the average cost for patients that use the new renal dialysis drug or biological product. Commenters stated that the proposed methodology for the post-TDAPA add-on payment adjustment, and the structure of the ESRD PPS overall, do not address the needs of the non-average patient. Several

commenters drew parallels to the comprehensive ambulatory payment classification (C–APC) complexity adjustment in the Hospital OPPS as an example of a payment policy that adjusts payment based on patient characteristics.

Response: We appreciate the suggested methodology for which these commenters advocated but do not agree that such a methodology would be appropriate, because it would directly incentivize utilization of a particular drug or biological product, which can result in overutilization. As we discussed earlier in this final rule, we believe that the proposed methodology provides the most appropriate incentives for ESRD facilities to be efficient with resources, while providing an appropriate level of payment that supports access to new renal dialysis drugs and biological products.

Additionally, we disagree with several of the premises that commenters offered with respect to the proposed methodology for calculating the post-TDAPA add-on payment adjustment. Specifically, commenters stated that both the proposed post-TDAPA methodology and the ESRD PPS are designed to meet the needs of the average patient and do not meet the needs of the non-average patient. In fact, the ESRD PPS base rate is not constructed to address the needs of the average patient, but rather to provide a level of payment that reflects the average per-treatment costs of renal dialysis services. As we discussed in the CY 2011 ESRD PPS final rule (75 FR 49037), in response to concerns that bundling payment for drugs like EPO and oral medications would limit nephrologists from prescribing what is necessary, we stated that the ESRD PPS would establish a bundled payment system based on the average cost of care with adjustments that target more payment to more resource intensive ESRD patients. We further explained that in situations where costs for treating patients exceed an established threshold, the outlier policy would apply. Later in the same CY 2011 ESRD PPS final rule (75 FR 49047) we explained that the ESRD PPS provides an opportunity for ESRD facilities to make financially sound decisions while providing necessary care, recognizing that some patients may utilize less renal dialysis items and services while others may use more. In other words, while some patients cost more than average and others cost less, an ESRD facility's aggregate payments under the ESRD PPS are reflective of the overall cost of providing renal dialysis services to its patients. The ESRD PPS includes patient-level and facility-level adjustments that better align payment with resource use for facilities that incur higher costs due to their patient population or geographic location.

We do not believe that the OPPS C–APC complexity adjustment is an appropriate comparison to the proposed post-TDAPA payment amount, which as we previously noted will be applied in a non-budget-neutral manner and is intended to provide a transitional level of payment that supports ESRD facilities' long-term planning and budgeting and supports beneficiaries' access to new renal dialysis drugs and biological products. In contrast, the OPPS C–APC complexity adjustment is budget neutral under the OPPS and is intended to provide increased payment when certain service combinations represent a complex, costly, or more resource-intensive version of the primary service. As an example, we believe a more appropriate payment mechanism to recognize the additional costs of treating ESRD patients with pruritus may be a patient-level adjustment under the ESRD PPS. As we discuss in section II.B.1.j of this final rule, we are collecting additional information on dialysis duration and may consider future revisions to the ESRD PPS case-mix adjustments, if appropriate.

Comment: Several commenters responded to our comment solicitation on the methodology for applying the productivity-adjusted ESRDB market basket update, or an alternative update factor, to the proposed post-TDAPA add-on payment adjustment. Commenters generally advocated for applying a pharmaceutical price proxy, rather than the productivity-adjusted ESRDB market basket update, stating that a pharmaceutical price proxy would be more representative of anticipated future price growth for new renal dialysis drugs and biological products. Commenters requested clarification about whether CMS would recalculate the post-TDAPA add-on payment adjustment annually for each of the three years, in addition to applying an update factor as proposed. Several commenters requested that CMS calculate the post-TDAPA add-on payment adjustment at the end of the TDAPA period, and then annually update that amount based on an update factor such as a pharmaceutical price proxy. MedPAC expressed concern about a payment methodology in which the payment amount would only increase and suggested alternative approaches to update the amount of the post-TDAPA add-on payment adjustment annually.

Response: We thank commenters for their comments regarding the proposed update methodology for the post-TDAPA add-on payment adjustment. We proposed to use the most recent available price and utilization information to determine a per-treatment amount for each of the three years during which a post-TDAPA add-on payment adjustment would apply. We are clarifying in this rule that we would annually recalculate the post-TDAPA add-on payment adjustment, based on the most recent available price and utilization information at the time of rulemaking. Accordingly, the post-TDAPA add-on payment adjustment amount could increase or decrease from year to year, depending on changes in pricing and utilization. We note that although we proposed to apply the productivity-adjusted ESRDB market basket update, we proposed to do so only for the purpose of updating the post-TDAPA add-on payment adjustment to reflect anticipated prices in the target year. We did not propose, and are not finalizing, the application of an update factor to update the amount of the post-TDAPA add-on payment adjustment from one payment year to the next.

We appreciate the comments recommending the use of the pharmaceutical price proxy rather than the productivity-adjusted market basket update. We agree with commenters that a pharmaceutical price proxy would more effectively track the change in prices for new renal dialysis drugs and biological products than would the market basket update. We are finalizing that for each year that we calculate a post-TDAPA add-on payment adjustment, we will apply the projected growth in the ESRDB market basket price growth for pharmaceuticals, which reflects the weighted blend of the ESA and non-ESA price proxies in the 2020-based ESRDB market basket, to reflect anticipated pricing for the target year. We refer readers to the CY 2023 ESRD PPS final rule (87 FR 67149) for a detailed discussion of the construction of this price proxy.

Comment: Several commenters opposed the application of a 65 percent risk sharing percentage and urged CMS to instead calculate and apply an offset based on actual utilization of related drugs. Many commenters suggested that CMS limit the calculation of an offset to the post-TDAPA add-on payment adjustment that accounts for the actual spending for products that are in the same ESRD PPS functional category as the new renal dialysis drug or biological

product and are directly impacted by the drug or biological product.

Response: As we discussed in the CY 2024 ESRD PPS proposed rule, we did not propose to calculate an offset based on utilization, because we are concerned that this approach would be more burdensome and less transparent than the proposed 65 percent risk-sharing percentage. We do not believe it would be appropriate to limit the calculation of an offset to just drugs and biological products in the same functional category, because we recognize that utilization of drugs in one functional category can affect the utilization of drugs in other functional categories. For example, utilization of drugs in the bone and mineral metabolism functional category can indirectly affect the incidence of itching among dialysis patients. However, if we were to apply a per-treatment offset based on changes in spending for all formerly separately billable drugs and biological products, it would be difficult to determine definitively which reductions in spending were related to a new renal dialysis drug or biological product.

Comment: One commenter pointed out that the CY 2024 ESRD PPS proposed rule does not indicate whether the ESRD PPS outlier adjustment would apply to products for which a post-TDAPA add-on payment adjustment is calculated.

Response: We appreciate the request for clarification regarding outlier eligibility for drugs and biological products during the post-TDAPA period. Under current policy, after the end of the TDAPA period, a drug or biological product is considered an eligible outlier service only if it meets the requirements of § 413.237(a)(1). We are clarifying that any renal dialysis drug or biological product included in the calculation of the post-TDAPA add-on payment adjustment would be considered an eligible ESRD outlier service only if it meets the requirements of § 413.237(a)(1). However, we are further clarifying that under current policy, Korsuva®, the only renal dialysis drug whose TDAPA period will end in CY 2024, will not be considered an eligible outlier ESRD service after the end of its TDAPA period, because it is a substitute for diphenhydramine hydrochloride, which was included in the composite rate prior to 2011, and therefore does not meet the requirements of § 413.237(a)(1) (that is, it would not have been, prior to January 1, 2011, separately billable under Medicare Part B).

Final Rule Action: After considering the comments, we are finalizing as proposed the methodology to calculate the amount of the post-TDAPA add-on payment adjustment, except that, as noted previously, we will apply the price growth of the pharmaceutical cost category, reflecting a weighted blend of the ESA and non-ESA price proxies in the 2020-based ESRDB market basket, to adjust the amount of the post-TDAPA add-on payment adjustment to reflect anticipated pricing for the target year rather than using the productivity-adjusted ESRDB market basket update. Therefore, we will use the following calculation to determine the amount of the post-TDAPA add-on payment adjustment to be applied to each ESRD PPS treatment.

- Step 1, using the most recent available 12 months of claims data, calculate the total expenditure of the new renal dialysis drug or biological product being paid for using the TDAPA under the ESRD PPS. Total expenditure is calculated by multiplying the latest available full calendar quarter of ASP data for the new renal dialysis drug or biological product by the quantity of units billed. If CMS does not receive the latest available calendar quarter of ASP data for a drug or biological product, then CMS would not apply the post-TDAPA add-on payment adjustment for that drug or biological product. As we noted earlier, if the latest available full calendar quarter of ASP data reflects zero or negative sales, CMS will calculate the post-TDAPA add-on payment adjustment based on WAC, or if WAC is not available, invoice pricing.
- Step 2, divide the total expenditure of the new renal dialysis drug or biological product from Step 1 by the total number of ESRD PPS treatments furnished during the same 12-month period as used in Step 1. The resulting quotient from Step 2 is the post-TDAPA add-on payment adjustment amount for each treatment, before applying the reduction factor to account for case-mix standardization, as described in Step 4.
- Step 3, calculate the dollar amount of the total aggregate case-mix adjusted post-TDAPA add-on payment adjustment amount by multiplying the post-TDAPA add-on payment adjustment amount from Step 2 by the applicable patient-level adjustments for each ESRD PPS treatment furnished during the 12-month period.
- Step 4, divide the aggregate case-mix adjusted add-on payment adjustment amount from Step 3 by total expenditure from Step 1. The resulting quotient is the reduction factor applied to the post-TDAPA add-on payment adjustment amount to account for case-mix standardization.
- Step 5, apply the reduction factor from Step 4 to the post-TDAPA add-on payment adjustment amount from Step 2.
- Step 6, apply the 65 percent risk-sharing factor to the amount from Step 5 to calculate the case-mix adjusted post-TDAPA add-on payment adjustment amount.
- Step 7, multiply the case-mix adjusted post-TDAPA add-on payment adjustment amount by the growth in the ESRDB market basket price proxy for pharmaceuticals to account for anticipated price growth to the target year.

We are amending § 413.234 by revising § 413.234(c)(1)(i) and adding regulations at § 413.234(b)(1)(iii), (c)(1)(ii), (c)(3), and (g) that describe the post-TDAPA add-on payment adjustment and the calculation we will use to determine the post-TDAPA add-on payment adjustment amount, as described previously. In addition, we are amending § 413.230 by adding reference to the post-TDAPA add-on payment adjustment in the calculation of the ESRD PPS per treatment payment amount.

We will follow these steps to calculate the case-mix adjusted post-TDAPA add-on payment adjustment amount for CY 2024 and future years, when appropriate. We will include in the calculation of the case-mix adjusted post-TDAPA add-on payment adjustment amount any new renal dialysis drugs and biological products in existing ESRD PPS functional categories that are eligible for payment using the TDAPA described in § 413.234(c). We will begin making payment under this new post-TDAPA add-on payment adjustment 8 calendar quarters after the beginning of the TDAPA payment period for the new renal dialysis drug or biological product. Payment of the post-TDAPA add-on payment adjustment will end no later than 12 calendar quarters after the end of the TDAPA payment period for the new renal dialysis drug or biological product.

(b) Example of the Final Post-TDAPA Add-On Payment Adjustment Calculation for CY 2024

Following the methodology finalized in the previous section, we will apply a post-TDAPA add-on payment adjustment to all ESRD PPS treatments beginning April 1, 2024, when the TDAPA payment period for Korsuva® ends. We will calculate the amount of this post-TDAPA add-on payment adjustment based on the most recent available 12 months of utilization data for Korsuva® and the most recent

available 12 months of ESRD PPS claims data for this final rule. As we proposed, we will use updated data for this ESRD PPS final rule. We will apply the ESRD PPS patient-level adjustment factors for determining the amount of the post-TDAPA add-on payment adjustment for each ESRD PPS claim.

Based on the latest available data, which includes utilization of Korsuva® from July 2022 through June 2023, we estimate that total expenditure for Korsuva® is $11,948,389 and that 28,450,178 total ESRD PPS treatments were furnished during the same time period. In addition, as discussed earlier in this final rule, we are finalizing the application of the growth in the ESRDB market basket price proxy for pharmaceuticals to adjust the amount of the post-TDAPA add-on payment adjustment to reflect anticipated pricing for CY 2024. The ESRDB pharmaceutical price proxy used for this CY 2024 ESRD PPS final rule is 1.3 percent. Accounting for the existing ESRD PPS patient-level adjustment factors and the TPEAPA as discussed in section II.B.1.g of this final rule, the reduction to the post-TDAPA add on payment adjustment to account for case-mix standardization for this time period is 0.901653. Accordingly, we will calculate a case-mix adjusted post-TDAPA add-on payment adjustment for CY 2024 equal to (($11,948,389)/(28,450,178)) × (0.901653) × (0.65) × (1.013) = $0.2493. Estimates for the impact of this post-TDAPA add-on payment adjustment for CY 2024 are included in section VII.D.5 of this final rule.

(c) Considerations Related to Budget Neutrality for the Post-TDAPA Add-On Payment Adjustment

As discussed in the CY 2024 ESRD PPS proposed rule and earlier in this final rule, the ESRD PPS includes other add-on payment adjustments based on the authority in section 1881(b)(14)(D)(iv) of the Act, which are not statutorily required to be budget neutral. In the case of existing add-on payment adjustments under the ESRD PPS, these generally account for costs that were not included in cost reports used for the construction of the ESRD PPS bundled payment. These include items that either did not exist at the time of the construction of the ESRD PPS bundled payment, like new drugs and equipment, or services that were not commonplace that the add-on payment adjustment is meant to encourage, like home dialysis training. In the proposed rule, we stated that we expect this increased payment would support ESRD facilities in providing the new renal dialysis drug or biological product to all beneficiaries for whom it is reasonable and medically necessary. We noted that we believe it is also important to support access to new renal dialysis drugs and biological products while minimizing the financial impact to beneficiaries, who incur a 20 percent coinsurance for renal dialysis services under the ESRD PPS.

As discussed previously, we considered and proposed this new post-TDAPA add-on payment adjustment in response to concerns that a sudden decrease in payment for certain new renal dialysis drugs and biological products after the end of the TDAPA period could negatively affect Medicare beneficiaries' access to such new renal dialysis drugs and biological products. Although we have noted that the ESRD PPS base rate already includes money for renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category, we stated that proposing a budget neutral payment adjustment would not be appropriate for the post-TDAPA add-on payment adjustment. Because we proposed to apply the post-TDAPA add-on payment adjustment to every ESRD PPS treatment, budget neutralizing this final add-on payment adjustment would effectively undo the adjustment and leave aggregate payments at the same level they would have been without an adjustment, which as we previously noted could negatively affect beneficiaries' access to such drugs and biological products. In contrast, applying this add-on payment adjustment in a non-budget neutral manner would increase aggregate ESRD PPS expenditures to a level that reflects the most recent 12 months' utilization of the new renal dialysis drug or biological product, which we believe would support beneficiary access. By applying the post-TDAPA add-on payment adjustment in a non-budget neutral way, we would effectively maintain expenditures for these new renal dialysis drugs and biological products at 65 percent of the level of expenditures paid during the TDAPA period. We stated that we believe this approach would provide consistency and predictability in a way that would support beneficiaries' continued access to new renal dialysis drugs and biological products, while appropriately reducing expenditures for such drugs after the TDAPA period ends both for the Medicare program and for individual beneficiaries, as discussed earlier in this section. Accordingly, we proposed that this post-TDAPA add-on payment adjustment would not be budget neutral. We invited comments on the budget neutrality aspect of this proposal.

Comment: Several commenters expressed support for applying the post-TDAPA add-on payment adjustment in a non-budget neutral way. These commenters agreed with CMS that calculating the post-TDAPA add-on payment budget neutrally would be counterproductive, as it would effectively undo the impact of the proposed adjustment.

Response: We agree, and we thank the commenters for their support.

Final Rule Action: After considering the comments we received, we are finalizing the application of the post-TDAPA add-on payment adjustment as a non-budget neutral payment adjustment, beginning for CY 2024.

j. Requirement of ''Time on Machine'' Hemodialysis Treatment Data as a Recordkeeping and Cost Reporting Requirement for Outpatient Maintenance Dialysis

We proposed certain new recordkeeping and cost reporting requirements for outpatient maintenance dialysis at proposed § 413.198(b)(5). Specifically, we proposed to require patient-level reporting on resource use involved in furnishing hemodialysis treatment in-center in ESRD facilities that would serve to apportion composite rate costs for use in the case-mix adjustment. Importantly, this new data would be used to disaggregate facility-level composite rate costs (as obtained from the cost reports) and assign them to the patient-month level, which would enable a refined single-equation estimation methodology. The integrity of the ESRD PPS is dependent on our ability to monitor payment accuracy and make refinements to the payment system, as needed. Under this proposal, CMS would require ESRD facilities to report information on ESRD PPS claims for renal dialysis services about the duration of time in minutes that ESRD beneficiaries spend in center receiving hemodialysis treatment (hereafter referred to in this section as ''time on machine''). We would use time on machine data to help us evaluate and monitor the accuracy of our payments for patient-level adjustment factors. CMS would also evaluate whether the data could be used to inform future refinements to the existing patient-level adjustment factors set forth at § 413.235(a), which include patient age, body mass index (BMI), body surface area (BSA), and co-morbidities such as sickle cell anemia. Finally, CMS would review the data for its potential to

identify any disparities from a health equity perspective that may support proposing in future rulemaking new patient-level adjustment factors, including potential social determinants of health (SDOH) factors. As described in section II.B.1.h of this final rule, we proposed the addition of § 413.198(b)(5), which states that ESRD facilities must submit data and information in the formats established by CMS for the purpose of estimating patient-level and facility level variation in resource use. Under this paragraph, we proposed to require ESRD facilities to report ''time on machine'' as when a patient the begins dialysis treatment and ends dialysis treatment. We proposed to require ESRD facilities to report this information using the D6 value code on ESRD PPS claims.

(1) Background

(a) Statutory Authorities for Recordkeeping, Cost Reporting, and Case-Mix Adjustments Under the ESRD PPS

Section 1881(b)(2)(B) of the Act generally directs the Secretary to prescribe in regulations any methods and procedures to determine the costs incurred by providers of services and renal dialysis facilities in furnishing covered services to individuals with ESRD, and to determine, on a cost-related or other economical and equitable basis, payment amounts for Medicare part B services furnished by such providers and facilities to individuals with ESRD. To that end, CMS promulgated § 413.198,[38] which specifies certain recordkeeping and cost reporting requirements for ESRD facilities that meet the conditions for coverage under 42 CFR part 494.[39] The recordkeeping and cost reporting requirements at § 413.198 enable CMS to determine the costs incurred in furnishing outpatient maintenance dialysis and support the two-equation payment model that is currently used as the basis for the ESRD PPS.

Section 1881(b)(14)(D)(i) of the Act requires that the ESRD PPS include a payment adjustment based on case-mix that may consider patient weight, BMI, comorbidities, length of time on dialysis, age, race, ethnicity, and other appropriate factors. We implemented this statutory requirement in § 413.235, which sets forth certain patient characteristics for which the per treatment ESRD PPS base rate may be adjusted, specifically where those patient characteristics result in higher costs for ESRD facilities. The patient characteristics at § 413.235(a) include: patient age, BSA, low BMI, onset of renal dialysis (new patient), and co-morbidities. The Secretary is also authorized, under section 1881(b)(14)(D)(iv) of the Act, to apply such other payment adjustments under the ESRD PPS as the Secretary determines appropriate. Per § 413.196, we publish notice of any proposed changes to payment adjustments, including adjustments to the composite rate,[40] in the **Federal Register**. We last updated the payment multipliers for the ESRD PPS patient-level adjustment factors in the CY 2016 ESRD PPS final rule (80 FR 68968, at 68973 through 68984), for age, BSA, low BMI, sex, four co-morbidity categories (that is, pericarditis; gastrointestinal tract bleeding with hemorrhage; hereditary hemolytic or sickle cell anemias; and myelodysplastic syndrome), and the onset of renal dialysis. We also established payment adjustments for pediatric patients and for facilities treating a low volume of patients with ESRD.

Finally, the collection of data from ESRD claims, cost reports and record keeping, has been instrumental in identifying underserved populations and establishing that ESRD disproportionately affects African American/Black men relative to their share of the total population. The proposal to collect and evaluate time on machine data would provide additional information concerning resource use to enable CMS to identify, assess, and address potential health disparities. This proposal therefore may support the Secretary's efforts to evaluate race and ethnicity data and provide recommendations for improving the quality of the data, as required under section 1809 of the Act, previously discussed in the CY 2011 ESRD PPS final rule (75 FR 49030 at 49108 through 49113).

In the CY 2024 ESRD PPS proposed rule (88 FR 42464 through 42472), we noted that, if the proposed requirement to collect time on machine data were to be finalized, we would issue corresponding guidelines. We stated that such guidance would provide instructions regarding the applicable administrative requirements for reporting a value code on an electronic claim, here value code D6, connected to the number of minutes of hemodialysis treatment provided in-center in an ESRD facility. We further noted that the National Uniform Billing Committee (NUBC) has approved and is prepared for ESRD facilities' use of value code D6 on claim form CMS–1450 (UB–04) (OMB–0938–0997) to report the total number of minutes of hemodialysis provided during the billing period.

(b) Case-Mix Adjustments Background and the Two-Equation ESRD PPS Model

The ESRD PPS includes patient-level adjustments that adjust the ESRD PPS base rate for certain patient characteristics. The current ESRD PPS case-mix adjustments are derived from a case-mix adjustment model involving two equations. In the CY 2011 ESRD PPS final rule (75 FR 49083), we discussed the two-equation methodology used to develop the adjustment factors that would be applied to the ESRD PPS base rate to calculate each patient's case-mix adjusted payment per treatment. The two-equation approach used to develop the ESRD PPS included a facility-based regression model for services historically paid for under the composite rate as indicated in ESRD facility cost reports, and a patient-month-level regression model for services historically billed separately. One significant limitation, which in large part drove the development of the two-equation model, was that there was no way to reliably identify, using claims data, the costs for composite rate services—that is, items and services such as staff labor, dialysate, capital-related assets such as renal dialysis machines, and certain drugs and laboratory tests that are used in the provision of outpatient maintenance dialysis for the treatment of ESRD and that were included in the composite payment system established under section 1881(b)(7) of the Act and the basic case-mix adjusted composite payment system established under section 1881(b)(12) of the Act.

In the CY 2016 ESRD PPS final rule, we updated the payment multipliers for the ESRD PPS patient-level adjustment factors for age, BSA, low BMI, sex, four co-morbidity categories (that is,

[38] We note that § 413.198 was promulgated prior to the establishment of the ESRD PPS. It was initially set forth in 1983 at 42 CFR 405.441 (48 FR 21254), to implement section 2145 of the Omnibus Budget Reconciliation Act of 1981 (Pub. L. 97–35). Section 405.441 was later redesignated in 1986 as 42 CFR 413.174 (51 FR 34790–01), and the requirements were moved again, from § 413.174 to § 413.198, in a reorganization of subpart H of part 413 (62 FR 43657).

[39] Likewise, under section 1881 of the Act, CMS established related data and information requirements at 42 CFR 494.180(h).

[40] As explained in the CY 2011 ESRD PPS final rule (75 FR 49030 at 49032), the composite rate is the method by which CMS determines prospectively the amounts of payments for renal dialysis services furnished by providers of services and by renal dialysis facilities to individuals in a facility and to such individuals at home. The composite rate is a single composite weighted formula that is combined with separately billable services under a single payment, adjusted to reflect patient differences in resource needs or case-mix.

pericarditis; gastrointestinal tract bleeding with hemorrhage; hereditary hemolytic or sickle cell anemias; and myelodysplastic syndrome), and the onset of renal dialysis. We also established payment adjustments for pediatric patients and for ESRD facilities treating a low-volume of ESRD patients (80 FR 68968 at 68973 through 68984). In that CY 2016 ESRD PPS final rule, we discussed and responded to several public comments in which commenters expressed concerns about the continued use of the two-equation model (80 FR 68974 through 68976). One comment from MedPAC suggested that CMS develop a one-equation model for the ESRD PPS. In response, we noted that the ESRD PPS is not currently able to utilize a one-equation method, because ESRD facilities do not report charges associated with the components of renal dialysis treatment costs that vary across patients such as time on machine. In other words, patient-level claims provide line-item detail on the use of the formerly separately billable services but do not provide any information regarding variation across patients in the use of the formerly composite rate services. In addition, we stated that we believed that capturing the resource cost for furnishing renal dialysis services is complex since Medicare has historically paid an ESRD PPS base rate (that is, composite rate payment) to account for those costs that were never itemized on a claim but were reported through the cost report (80 FR 68975 through 68976).

(c) Background on CMS Efforts To Explore the Use of ''Time on Machine'' Data To Refine the Case-Mix Adjustment Model

Interested parties, including MedPAC, have long expressed concerns about the complexity of the two-equation model underpinning the ESRD PPS and have questioned the validity of assuming that the composite rate costs for all patients at an ESRD facility are the same. Interested parties have encouraged CMS to develop a patient cost model that is based on a single patient-level cost variable that accounts for all composite rate and formerly separately billable services. Additionally, interested parties have expressed concerns that the existing case-mix adjustors might not correlate well with the current cost of renal dialysis treatment and have encouraged CMS to explore a refinement.

In response, CMS has explored the feasibility of collecting time on machine data on patient claims from ESRD facilities and the potential for using such data. These efforts include: a Technical Expert Panel (TEP) held on December 6, 2018, a Request for Information (RFI) published in the ESRD PPS CY 2020 ESRD PPS proposed rule (84 FR 38399), and more recently, an RFI published in the ESRD PPS CY 2022 proposed rule (86 FR 36322, 36399 through 36400). In addition, CMS issued sub-regulatory guidance in Transmittal 10368, from September 24, 2020, to begin collecting time on machine data, but it later rescinded that guidance.

(i) Technical Expert Panel (TEP) December 2018

As we discussed in the CY 2020 ESRD PPS proposed rule (84 FR 38396 through 38400), a TEP was held on December 6, 2018, to discuss options for improving data collection to refine the ESRD PPS case-mix adjustment model. In that CY 2020 ESRD PPS proposed rule, we discussed the purpose of the TEP and the topics that were discussed, including several data collection options.[41]

In the CY 2020 ESRD PPS proposed rule, we noted that CMS's data contractor's pre-TEP analysis of CY 2016 cost report data showed that composite rate costs comprise nearly 90 percent of average total treatment costs, with capital, direct patient care labor, and administrative costs representing approximately 88 percent of total average composite rate cost per treatment. The data contractor provided examples of ways that longer duration of renal dialysis time might be associated with increased treatment costs, including utility costs, accelerated depreciation on equipment, and lower daily census counts, which, among other things, would result in increased per-treatment capital costs. The analysis suggested that additional labor hours for a patient with longer treatments on average could increase per-treatment labor costs, and that patients with increased use of dialysate and water treatment supplies or equipment likely have higher average per-treatment supply costs. We noted that, under current reporting practices, there are no data on the patient-and treatment-level variation in the cost of composite rate items and services. We explained that these findings underscore the importance of identifying variation in these costs to inform the development of a refined case-mix adjustment model.

CMS published the findings from the December 2018 TEP in a report dated June 2019.[42] The 2018 TEP report provided examples of ways that extended treatment duration could affect cost components. First, an imputed cost per treatment was calculated using a combination of treatment duration data from CROWNWeb[43] (now the ESRD Quality Reporting System, or EQRS) and facility cost per-minute data from cost reports to infer differences in costs reported across patient-months. An average interquartile range of 34.6 minutes was observed from CROWNWeb duration data, indicating significant within-facility variation in dialysis treatment time. Significant variation in average imputed cost per hemodialysis sessions also was observed, with an across-facility interquartile range of $62.62. Overall, it was found that costs increased with longer treatment times, and this pattern was consistent for the individual cost report components as well. Facilities with a higher proportion of beneficiaries receiving treatments ≥ 4.5 hours duration were found to have higher average costs for each cost component, except for cost report drugs.[44]

CMS presented further discussion into collection of time on machine data for each dialysis session in the CY 2020 ESRD PPS proposed rule (84 FR 38396 through 38400), where we further identified this potential data set as a singular option that would provide sufficient data to develop a refined case-mix adjustment model. If renal dialysis session time were reported for each renal dialysis treatment, cost report and treatment-level data could be integrated to infer differences in composite rate costs across patients. In this paradigm, patient-level differences in composite rate costs could be attributed to two discrete categories: differences due to renal dialysis treatment duration (measured in units of time); and differences unrelated to treatment duration. To alleviate concerns from interested parties, we noted that time on machine data would not be used to

[41] The final TEP report from December 2018 and other materials can be found at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources.*

[42] The final TEP report from December 2018 is found directly at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/esrdpayment/downloads/esrd-pps-tep-summary-report-june-2019.pdf.*

[43] In 2008, CMS introduced an electronic Web-based data collection system, Consolidated Renal Operations in a Web-enabled Network (CROWNWeb) which was designed to collect clinical performance measures data from dialysis facilities (73 FR 20370, at 20372). CrownWeb is now ''EQRS''—that is, the ESRD Quality Reporting System (OMB Control Number 0938–1289).

[44] Acumen LLC. ESRD PPS Case-Mix Adjustment Technical Expert Panel (TEP). Slide Presentation Slide 42. December 2018. See *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/ESRD-PPS-TEP-Presentation.pdf.*

directly adjust ESRD PPS payment, rather, it would be used to apportion composite rate costs (currently only observable at the facility level to the patient or treatment level) for use in the case-mix adjustment. Time on machine data would allow for a higher proportion of composite rate costs to be allocated to patients with longer renal dialysis treatment times, and ultimately inform CMS refinements to existing patient-level adjusters, including age and comorbidities.

We further explained that, in the December 2018 TEP, the data contractor proposed two approaches to collect time on machine data: (1) Use existing data from Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) (now EQRS) on delivered renal dialysis minutes during the monthly session when a laboratory specimen is drawn to measure blood urea nitrogen (BUN); or (2) have ESRD facilities report time on machine data on Medicare claims. For the latter, we suggested that time on machine data could be reported by using a new HCPCS or revenue center code to indicate units of treatment time for each renal dialysis treatment or by updating the definition of the existing revenue center code for renal dialysis treatments so that the units correspond to treatment time instead of the number of treatments. We noted that ESRD facilities already reported to CMS a single monthly treatment time in CROWNWeb for in-facility treatments, indicating that ESRD facilities currently collect time on machine data.[45] Moreover, we stated that we were aware that many ESRD facilities' electronic health records (EHR) systems automatically collect this information for every renal dialysis treatment, minimizing additional burden of reporting this metric on claims.

The December 2018 TEP participants preferred that the data be collected on Medicare claims (84 FR 38398). They did not support using the then-existing CROWNWeb data for time on machine data, as there were too many questions about its completeness and timeliness. They agreed that if time on machine data is collected on claims that it should be reported in actual minutes dialyzed and not, for example, in 15-minute increments. We explained that the TEP participants cautioned that reporting time on renal dialysis on the claims would place additional burden on ESRD facilities. However, we stated that we believed that, for ESRD facilities with EHRs, the burden associated with the collection of renal dialysis treatment time is expected to be small and temporary, because the information is already being collected. We noted that collecting time on machine data could be difficult to accomplish for ESRD facilities that do not use EHRs. Lastly, we stated that some participants maintained that certain factors related to patient complexity—such as comorbidities and mental health status—that are associated with treatment costs are unrelated to treatment duration.

(ii) Request for Information (RFI) in the CY 2020 ESRD PPS Proposed Rule

In addition to presenting the findings from the December 2018 TEP, we solicited comments in the CY 2020 ESRD PPS proposed rule (84 FR 38399) on the option of collecting time on machine data. As discussed in the CY 2020 ESRD PPS final rule (84 FR 60648, 60782), commenters responding to the RFI opposed the use of time on machine data, maintaining that other factors were more directly related to cost of treatment. Commenters claimed that many subgroups of patients are challenged to stay on renal dialysis for the prescribed treatment time because of their physical status or other limitations, leading to more frequent treatment and/or higher costs related to patients' special circumstances and comorbidities and not to treatment duration. Regarding patient-level factors contributing to high costs of care, commenters expressed that patient-level adjusters should be based on sound, empirical evidence of their contribution to cost of care and opposed the use of time on machine data as a single, patient-level factor to estimate variation in composite rate costs. Some commenters expressed the objection that use of this measure would not be productive because there was great homogeneity in treatment times across patients.

(iii) CMS Sub-Regulatory Guidance in Transmittal 10368 (September 24, 2020) (Now Rescinded)

In Transmittal 10368, published September 24, 2020, CMS instructed the MACs to implement a new value code D6, which reflects the total number of minutes of dialysis provided during the billing period. See Transmittal 10368, CR 11871 (*Changes to the End Stage Renal Disease (ESRD) PRICER to Accept the New Outpatient Provider Specific File Supplemental Wage Index Fields, the Network Reduction Calculation and New Value Code for Time on Machine*), effective January 1, 2021. At the same time, CMS announced a new requirement for ESRD facilities to report value code D6 on ESRD claims, for in-facility or home hemodialysis maintenance, training, or retraining treatments. Shortly after making these contractor directions public, CMS issued a Medicare Learning Network (MLN) Matters guidance document (MLN Matters No. MM11871) advising ESRD facilities of the new requirement to include treatment time on claims. However, after a large dialysis organization submitted a petition [46] pursuant to the HHS Good Guidance Practices Regulation,[47] HHS issued a finding that notice-and-comment rulemaking was required for CMS to impose such a requirement. Consequently, CMS rescinded Transmittal 10368 and replaced it with Transmittal 10576, dated January 20, 2021, withdrawing the requirement for reporting time on the dialysis machine with value code D6. Although the guidance to report time on machine data was rescinded, the value code D6 for the time on machine in minutes remains approved by the NUBC and remains on CMS's claim form CMS–1450 (UB–04) (OMB–0938–0997), in a deactivated status.

(iv) Request for Information (RFI) in the CY 2022 ESRD PPS Proposed Rule

CMS revisited the topic of time on machine in the 2020 TEP and discussed the case-mix adjusters.[48] Interested parties continued expressing concerns that the existing case-mix adjustors might not align with resource-intensive patient-level services such as isolation rooms, behavioral issues, or neurocognitive issues. We sought additional public input in the ESRD PPS CY 2022 proposed rule, requesting information on the methodology used to calculate the case-mix adjustment (86 FR 36322, 36399 through 36400) and the methodology to collect data to reflect patient-level differences in composite rate costs, including the use of a value

[45] Centers for Medicare & Medicaid Services (CMS) End-Stage Renal Disease Quality Incentive Program (ESRD QIP) Payment Year (PY) 2021 Measure Technical Specifications. Page 23. Available at: *https://www.cms.gov/files/document/cy-2021-final-technical-specifications-20201130.pdf.*

[46] The petition (dated December 23, 2020) is attached as Exhibit A to HHS's petition response (January 8, 2021) which can be found at *https://www.hhs.gov/sites/default/files/davita-petition-response-and-exhibit.pdf.*

[47] The HHS ''Good Guidance Practices'' final rule appeared in the **Federal Register** on December 7, 2020 (85 FR 78770) and was later rescinded July 25, 2022 (87 FR 44002).

[48] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf.*

code to collect time on machine on the claim.[49]

We received similar comments on this RFI to those expressed in response to the CY 2020 ESRD PPS proposed rule. As discussed in the CY 2022 ESRD PPS final rule, commenters cited concerns that apportioned composite rate costs (such as labor and capital related costs) from the cost reports, used in the case-mix adjustments, were currently only observable at the facility-level and did not include patient or treatment-level variations.

Like previously mentioned concerns regarding the collection of time on machine data, commenters suggested this data element would be burdensome and complex (especially for those dialyzing at home) and would not identify high-cost patients. They stated that what little variation might be identified would not be worth the burden of collecting the information. In addition, these commenters stated that ESRD facilities' staffing is based on prescribed time, not on the actual time a patient is on the machine. They stated that the prescription approach is the most rational way to determine staffing levels, because ESRD facilities do not have time on machine in advance. According to these commenters, ESRD facilities would only have the prescribing physician's prescription to use.

A provider advocacy organization opposed the use of time on machine data for purposes of ESRD PPS primarily because certain patients benefit from shorter, more frequent dialysis, such as patients with catheter-related access issues, non-compliant patients, patients with chronic pain or diarrhea, and patients suffering from certain comorbidities. They expressed significant concern that use of time on machine data for differentiating treatment cost variability creates inappropriate incentives for certain ESRD facilities to ''game the system'' by: (1) putting patients on renal dialysis longer than necessary; or (2) placing patients on the cheapest dialyzer and keeping them on it for all five possible hours of dialysis. Another small renal dialysis organization agreed, pointing out that most renal dialysis treatments, regardless of time, will have similar composite rate costs. In other words, they asserted that if a treatment is 3.5 hours compared to 5 hours, the composite rate costs for those treatments will be very similar. The only difference in cost between those two treatments would be 1.5 hours more use of utilities, dialysate and bicarbonate solution, machine depreciation, and a small amount of labor to check on the patient. Most of the labor for renal dialysis treatments is putting the patient on and taking the patient off dialysis. Therefore, in both previously described scenarios, the commenter asserted that cost would remain the same. Further, they pointed out that some patients will not remain for their full renal dialysis treatment, and they generally cannot force a patient to remain for their full prescribed treatment time. Therefore, in their view, using actual treatment time for cost allocation is not realistic.

A small renal dialysis organization within a large non-profit health system commented that reporting treatment times would be difficult and confusing and identified many factors that would need to be addressed by CMS, including: identifying renal dialysis start time, early removal from renal dialysis, inadvertent lack of time on machine information, data inclusion on a claim form, and staff training. They also expressed concern about the reporting of time on machine creating opportunities for ESRD facilities to game the system by having the renal dialysis run a few extra minutes to move into the next highest level.

Several commenters recommended changes or removal of the case-mix adjusters, including refinement of the age and weight (BSA and BMI) adjustments and removal of the comorbidity adjustments, based on declining frequency of claims containing comorbidities. Some comments recommended removal of the comorbidity adjustments, because they report the adjustments are not utilized. They recommended CMS refine the age and weight (BSA and BMI) adjusters to better capture and designate higher cost patients. Many commenters expressed the belief that the comorbidity categories no longer protect beneficiary access and no longer correlate with increased costs. A non-profit renal dialysis association recommended that CMS minimize resources devoted to adjusters. The commenters suggested including only the minimum needed to deliver quality patient care, restore significant funding to the ESRD PPS base rate for the benefit and care of all beneficiaries, and focus retained adjusters only on those that are clearly linked to patient cost of care or clear barriers to access. Specifically, they recommended that CMS: retire the remaining comorbid case mix adjusters; revise the weight adjusters to maintain a low-BMI adjuster; create a high-BMI adjuster; eliminate the BSA adjuster; retire the age adjuster (which they believe is not methodologically sound and does not resonate with clinician or renal dialysis facility experience of care); maintain the adjuster for low volume facilities; consider expanding the adjuster to a second tier of facilities providing fewer than 6,000 treatments per year; eliminate the rural adjuster; and maintain the onset of renal dialysis adjuster to support the resource intensive needs of patients starting dialysis. Other commenters stated it would be too preliminary to eliminate the case-mix adjusters entirely, and instead they recommended that CMS initiate a discussion of the adjusters that are true drivers of high costs and how the use of adjusters can be operationalized for practical purposes. One payment adjustment that was universally supported by commenters was the onset adjustment.

MedPAC recommended that CMS develop a one-equation regression model in place of the two-equation model currently used as the basis for the ESRD PPS. MedPAC also recommended that CMS consider removing the comorbidity adjustments and revise the body size adjustment. MedPAC further recommended that CMS address the inherent correlation between BSA and BMI by jointly estimating the association of BSA and BMI with treatment cost. Both BSA and BMI are calculated based on patient height and weight. MedPAC's analyses found that BSA and BMI values are correlated such that patients with low BMI also tend to have low BSA, and that these variables have a joint effect on treatment costs that is different from the sum of independent effects as currently implemented. We reiterated in the CY 2022 ESRD PPS final rule our current inability to implement such a model given the absence of data on the charges associated with the components of renal dialysis treatment costs that vary across patients in the use of the formerly composite rate services. A non-profit renal dialysis association agreed with MedPAC.

(2) Health Equity Considerations Supporting the Proposed Collection of Time on Machine Data

In the CY 2024 ESRD PPS proposed rule (88 FR 42468), we stated that CMS prioritizes expansion of the collection, reporting, and analysis of standardized data as a key means to advance health

[49] We published a summary of the responses to the CY 2022 ESRD PPS RFI (86 FR 36322, 36399 through 36400) for the current case-mix methodology in the ESRD PPS CY 2022 final rule (86 FR 61874, 61997) and provided greater detail on CMS's website at *https://www.cms.gov/files/document/cy-2022-esrd-pps-rfi-summary-comments.pdf.*

equity.[50] We explained that by increasing our understanding of the needs of those we serve, CMS aims to ensure all individuals have access to equitable care and coverage. We noted that CMS's proposal to collect time on machine data supports these priorities. We stated that we believe the proposed data reporting requirements would support our ability to assess whether, and to what extent, our programs and policies may perpetuate or exacerbate systemic barriers to opportunities and benefits for underserved communities.

As noted previously, as part of CMS's December 2018 TEP and in the ESRD PPS CY 2020 final rule, CMS's EQRS data (formerly collected under CROWNWeb) is reported once per patient-month. CMS's proposal to collect time on machine data, which would require duration of treatment data reported for every renal dialysis treatment, would provide a more granular set of standardized data for analyzing (and potentially apportioning) composite rate costs for use in the case-mix adjustment. We noted that we would also look to time on machine data as a source to monitor claims data and identify disparities in care that could be mitigated by potential future adjustments that would incentivize equitable care within the framework of the ESRD PPS.

As we noted in the CY 2024 ESRD PPS proposed rule, ESRD PPS reform is an ongoing multi-year effort to refine payment adjustments and methodologies under the ESRD PPS. Section 1881(b)(2)(B) of the Act provides that the Secretary shall prescribe in regulations any methods and procedures to determine the amounts of payments to be made for part B services (which include renal dialysis services), on a cost-related basis or other economical and equitable basis. Section 1881(b)(14)(D) of the Act requires the ESRD PPS to include a payment adjustment based on case mix that may consider various patient characteristics and other appropriate factors.

Since the establishment of the ESRD PPS in the CY 2011 ESRD PPS final rule (75 FR 49030), CMS has been engaged in ongoing monitoring and analysis of the ESRD PPS. CMS publishes these monitoring results regularly.[51] CMS's monitoring activities have involved analysis of ESRD facility cost reports and patient claims to determine the most accurate adjustments and methodologies as well as to identify trends in beneficiary health outcomes. Similarly, we noted that the proposal in the CY 2024 ESRD PPS proposed rule to collect more-detailed standardized data (that is, the proposed time on machine reporting) than is presently available for analysis supports our ability to evaluate potential disparities in health care provided to our beneficiaries.

Presently, CMS adjusts the per-treatment ESRD PPS base rates to account for variation in the case mix, as set forth in § 413.235. These adjustments account for patient age, BSA, low BMI, onset of renal dialysis (new patient), and comorbidities (for example, sickle cell anemia), as specified by CMS. We explained in the CY 2024 ESRD PPS proposed rule that the data and information that inform these adjustments are derived from cost reports, which are submitted to CMS on the facility level. However, we noted that time on machine data would be provided to CMS at the patient level on patient claims. This change would shift CMS's focus to a more patient-centered paradigm. We stated that we believe time on machine data would provide the insights we need to develop (and propose) potential amendments to the payment multipliers for the current, and potential future, patient-level adjustments, including new SDOH factors or health conditions (such as profound post-dialytic exhaustion) as patient-level adjustments. More immediately, however, time on machine data would significantly enhance CMS's insight into whether our current payment adjusters are appropriately aligning with actual resource use for individuals and communities who are underserved or disadvantaged and who may have multiple patient-level characteristics that necessitate longer renal dialysis times.

For example, CMS is aware of anecdotal evidence and published studies showing that patients with the comorbidity of sickle cell anemia may need a longer renal dialysis treatment time as well as additional resources from medical staff to attend to the manifestations of sickle cell that occur during dialysis. In fact, renal dialysis patients with sickle cell anemia may have frequent pain attacks during the actual renal dialysis treatment.[52] Such an attack, known as a vaso-occlusive pain crisis, precipitates a series of medical interventions involving intravenous fluids, analgesia, as well as the treatment of any precipitant and/or acute comorbid state.[53] CMS would be able to use time on machine data for patients with sickle cell anemia to evaluate its alignment with the patient-level adjuster for the corresponding co-morbidity.

In addition to re-evaluating and potentially updating the payment multiplier for the patient-level adjuster for the co-morbidity of sickle cell anemia, we noted that we anticipate that there could be other instances where patients need more time on renal dialysis to avoid uncomfortable post-dialytic sequela, such as profound post-dialytic exhaustion. In instances of profound post-dialytic exhaustion, for example, CMS would evaluate the forthcoming time on machine data for the potential correlations between additional hemodialysis treatment time and decreased incidence of profound post-dialytic exhaustions, which may have cost implications. We stated that we are aware there may be a need for a future patient-level payment adjuster associated with post-dialysis fatigue.

(3) Requirement for Reporting Time on Machine Data To Evaluate Accuracy of Current Payment Adjusters Aligned With Resource Use

In the CY 2024 ESRD PPS proposed rule (88 FR 42469), we proposed to require patient-level reporting on resource use involved (time on machine) in furnishing in-center hemodialysis treatment in ESRD facilities, which would serve as a proxy to apportion composite rate costs (capital, labor, and administrative costs, as well as drugs, laboratory tests, and supplies necessary to administer the dialysis treatment) for use in the case-mix adjustment. This would allow us to more precisely estimate the average costs of the various earlier-mentioned components of a renal dialysis treatment that cannot currently be captured because payment for these items is bundled, and claims data do not contain detail on the use of these items and services. We stated that CMS would review the patient-level resource use data, including time on machine data, to evaluate and monitor the accuracy of the methods and procedures, including the payment methodology for the patient-level adjustment factors,

[50] *https://www.cms.gov/about-cms/agency-information/omh/health-equity-programs/cms-framework-for-health-equity.*

[51] Since the implementation of the ESRD PPS in January 2011, CMS has monitored outcomes, through a claims-based monitoring program, for Medicare beneficiaries receiving outpatient maintenance dialysis. See *https://www.cms.gov/medicare/medicare-fee-for-service-payment/esrdpayment/esrd-claims-based-monitoring.*

[52] Benjamin Jacob et al. Management of the Dialysis Patient with Sickle Cell Disease (Seminars in Dialysis 14 July 2015, *https://doi.org/10.1111/sdi.12403*).

[53] Derebail VK, Lacson EK Jr, Kshirsagar AV, Key NS, Hogan SL, Hakim RM, et al.: Sickle trait in African American hemodialysis patients and higher erythropoiesis-stimulating agent dose. *J Am Soc Nephrol* 25: 819–826, 2014.

enhancing the integrity of the ESRD PPS. In addition, we stated that CMS would evaluate whether the data could be used to inform future refinements to the existing patient-level adjustment factors set forth at § 413.235(a), which may include age, BMI, BSA, and co-morbidities such as sickle cell anemia. Finally, we stated that CMS would review the data for its potential to identify any disparities from a health equity perspective and to support the future proposal of any new patient-level adjustment factors, including potential SDOH factors. We noted that such data may also be used to inform potential future refinements to the facility-level adjustment factors, if appropriate. We stated that per § 413.196, we would publish notice of any proposed changes to payment adjustments, including adjustments to the composite rate, in the **Federal Register**.

(a) Changes to 42 § 413.198

We proposed to amend § 413.198 by adding language at § 413.198(b)(5) that would require each ESRD facility to submit data and information, under existing paragraph § 413.198(b)(3) describing allowable costs, of the types and in the formats established by CMS, for the purpose of estimating patient-level and facility-level variation in resource use, such as data and information on the duration of hemodialysis treatment (that is, time on machine data) involved in furnishing hemodialysis treatment in center in an ESRD facility. For additional context, we noted that, under § 413.198(b)(3), allowable cost is the reasonable cost related to renal dialysis treatments. Reasonable cost includes all necessary and proper expenses incurred by the ESRD facility in furnishing the renal dialysis treatments, such as administrative costs, maintenance costs, and premium payments for employee health and pension plans. Reasonable cost includes both direct and indirect costs and normal standby costs.

We also proposed to update § 413.198(a) by adding a reference to section 1881(b)(14) of the Act to acknowledge the statutory provisions for the ESRD PPS.

(b) Additional Background Considerations for, and Comments and Responses Thereto on, the Proposed Reporting of Time on Machine Data

As we noted in the CY 2024 ESRD PPS proposed rule, CMS reviewed past comments from its TEPs and RFIs and considered the approach of our now-rescinded sub-regulatory guidance in Transmittal 10368 and the complexities of reporting the number of minutes of hemodialysis treatment on patient claims. With this background in mind, we further refined our proposed requirements at § 413.198(b)(5) in a way that would result in the reporting of the most useful, high value data.

Considering past comments questioning the feasibility and accuracy of time on machine reporting for home dialysis patients, we proposed a reporting requirement that would only apply to patients receiving an in-center hemodialysis treatment. We explained that we believe this approach would ensure greater uniformity to the recording process and thus greater consistency in the data reported.

CMS also considered past comments responding to its RFI in the CY 2020 ESRD PPS final rule (84 FR 60648, 60782) regarding patient-level factors that contribute to high costs of care. We stated that we agree with commenters that expressed that patient-level adjusters should be based on sound, empirical evidence of their contribution to cost of care.

We noted in the CY 2024 ESRD PPS proposed rule that we agree that the payment multipliers for patient-level adjusters should be grounded in strong evidence, and we recognize that each patient will have unique needs, with some being more costly to treat and others with fewer costs, given their medical backgrounds. We emphasized and again clarified that time on machine data would not be directly used to determine payment for renal dialysis services, nor would higher payments be made for longer treatments.

We also considered comments suggesting that a ''time on machine'' data element would not identify high-cost patients and comments suggesting such a data element would not be productive as described earlier in this section. We stated that we agree with commenters that treatment times and costs may be similar across most patients based on our analysis and the comments of TEP participants. However, we would not expect to find that ESRD facilities are treating ESRD patients in a homogeneous fashion, but on a case-by-case basis determined by patient-centered plans of care. We noted that a review of CY 2016 cost report data, conducted as part of the December 2018 TEP,[54] showed that overall costs of renal dialysis services (within the ESRD facility cost reports) increased with longer treatment times, and that this pattern was consistent for the individual cost report components.

We stated in the CY 2024 ESRD PPS proposed rule that we anticipate that the data that would become available under the proposed requirement, if finalized, for reporting time on machine data would provide insight into meaningful, measurable variabilities in certain costs associated with patient-level characteristics.

We stated that the significance of the time on machine data is dependent upon the collection of data from a preponderance of patient claims for in-facility hemodialysis. We further noted that while most patient claims may come from patients with similar profiles and treatment plans, the needs of the more complex and resource-intensive patients can only be identified by CMS through the collection of patient-level data from across the ESRD PPS patient population. We stated that complex and resource-intensive patients are frequently encountered in the ESRD dialysis treatment setting, but it is not possible to obtain precise estimates of the higher costs of these patients' hemodialysis treatments from currently reported data. We identified that cost reports and claims are the two data sources from which per treatment costs can be estimated. Since cost reports aggregate data at the facility level, we explained that patient-level differences in resource use are not detectable as higher medical needs, and related costs are masked by averages. Further, analysis of claims data from 2016 found that roughly 99 percent of ESRD facilities reported 10 or fewer distinct charge values across all patients and treatment modalities.[55] Routinely collected, ESRD patient population-based data on time on machine for each in-facility hemodialysis treatment would enable CMS to assess variation in the use of composite rate items and services at the patient level and to identify high-need and high-cost patients. In addition, the time on machine data set would enable CMS to further determine what trends or causal relationships may exist between certain patient-level characteristics and the

[54] As presented on Slide 42 from the December 2018 TEP, overall costs of renal dialysis services (within the ESRD facility cost reports) increased with longer treatment times. See *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/ESRD-PPS-TEP-Presentation.pdf.*

[55] See page 9 of the December 2018 TEP Report at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/ESRD-PPS-TEP-Summary-Report-June-2019.pdf.* See also Slide 27 from the December 2018 TEP Presentation at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/ESRD-PPS-TEP-Presentation.pdf.*

And see Slide 30 from the December 2019 TEP Presentation at *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-presentation-december-2019.pdf.*

number of minutes of hemodialysis treatment received by such patients. CMS would evaluate whether specific patient characteristics are associated with increased length of dialysis treatment, which contribute to cost.

We also considered comments that the costs to ESRD facilities for providing dialysis treatment could be better measured by looking at costs based on prescribed time, and not on the actual time a patient is on the dialysis machine. The commenters stated their view that looking to prescribed time(s) would be the most rational way to determine staffing levels (and costs), because ESRD facilities plan for dialysis session length based on the prescribed time. Although CMS recognizes ESRD facilities' labor practices to align staffing with the stated prescription times, CMS is concerned that, for some patients, their prescription times are not aligning with actual usage and thus may not be the best predictor of ESRD facilities' costs. For example, we noted that we are aware that patients who experience severe itching or have certain psychological disorders may be less likely to receive dialysis for the full prescribed time. For such patients, only the collection of time on machine data for the number of minutes of hemodialysis treatment received would facilitate CMS's understanding of their complex needs and the implications for the ESRD PPS. For such patients, a pattern of shorter treatment times may ultimately result in worse patient outcomes and higher patient costs to the ESRD facility as well as to Medicare. We stated that CMS is also aware that patients with certain characteristics, such as higher BSA quartiles, may be more likely to need longer dialysis times.[56] Additionally, CMS has been made aware of instances in which ESRD facilities may avoid treating complex patients or patients with higher costs generally (thereby favoring average or lower cost patients). We noted that prescribed dialysis times would not provide insight into costs for dialysis sessions for patients whose individual needs or circumstances might necessitate a dialysis treatment time that differs in practice from the prescribed dialysis time. Therefore, identifying actual resource usage, as correlated with the needs, health outcomes, and patient-level characteristics of complex patients would enable CMS to better align the payment multipliers with resource use within the ESRD PPS.

We stated that we anticipate that our proposed requirement would generate the data we would need to evaluate a potential adjustment of the payment multipliers for patient level adjustments, thereby allowing us to counteract possible financial disincentives to serving those patients. We noted that we expect that such adjustments may thereby enhance access to renal dialysis services for such resource-intensive patients. We also believe that collecting time on machine data is preferable to collecting prescribed times, since we recognize that patients' actual experiences do not always align with their doctors' orders.

We recognized that a new reporting requirement would require uniformity in its implementation across ESRD facilities. We noted that the proposed ''time on machine'' requirement is for the reporting of the number of minutes of hemodialysis treatment a beneficiary receives, and it refers to only the minutes (reported in whole minutes) spent dialyzing, while the patient is connected to the dialysis machine. We stated that we would address such details in operational guidance.

We received numerous public comments on our proposal in the CY 2024 ESRD PPS proposed rule to require reporting of time on machine data from a broad array of interested parties. Commenters included professional associations, advocacy organizations, large dialysis organizations, independent and regional dialysis providers, individual physicians, other healthcare providers, and patients.

The majority of the commenters generally opposed the requirement, but some commenters expressed support. Many commenters were supportive of CMS's effort to develop a patient cost model and to pursue future refinements that would advance health equity in the ESRD PPS. However, commenters questioned the utility of time on machine data and expressed concern for the additional administrative burden collecting and reporting the data would entail. Commenters expressed concerns about the adverse effects on specific populations. The comments on our proposal and our responses are set forth below.

Comment: Some commenters expressed support for establishing a patient cost model that is based on a single patient-level cost variable. MedPAC reiterated its support for collection of time on machine data, which the commission previously noted in their comments on the CY 2022 ESRD PPS proposed rule. MedPAC agreed with CMS that these data could be used in the future to apportion composite rate costs (including labor and capital-related costs) that are currently only observable at the facility-level to the patient- or treatment- level for use in case-mix adjustment. One large dialysis organization expressed appreciation for CMS's acknowledgement that the current two-equation payment model has intricacies that can be mitigated by moving toward a single patient-level cost variable. This commenter asserted that using a patient-level cost variable would more accurately align treatment cost to payment. Further, the commenter urged transparency and inclusion of the dialysis community in moving forward with the development of a patient-level cost variable.

Response: CMS appreciates the support expressed by MedPAC and other commenters for moving toward a patient cost model. As we discussed in the CY 2024 ESRD PPS proposed rule and reiterate in this final rule, the proposed requirement for reporting time on machine data is the first step toward creating the kind of patient cost model that commenters acknowledged would have advantages over the current cost model. As we discuss later in this final rule, we intend to analyze time on machine data for the purposes of creating a patient-level cost variable for potential future refinement to the ESRD PPS case mix adjusters. We intend to undertake further rulemaking in subsequent years to address various considerations, including the methodology for allocating composite rate costs to patients for the development of a patient-level cost variable. Interested parties would have the opportunity to comment on the methodology used in CMS's analysis to support such development at that time. We look forward to actively engaging with the public throughout that process in the future.

Comment: Several commenters, including a network of dialysis organizations, State regional offices, a non-profit organization of ESRD networks, an individual commenter, a national organization of patients and kidney health care professionals, MedPAC, an ESRD facility, and patients advocated for evaluating disparities in the ESRD PPS, to refine case-mix adjusters in a way that would improve payment accuracy, promote health equity, and ensure quality of patient care. A national organization of patients and kidney health care professionals voiced support for aligning patient characteristics and co-morbidities more accurately to case-mix adjusters to

[56] See slide 31 from the 2020 ESRD TEP presentation, which can be found here: *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-presentation-december-2020.pdf.*

establish that patients are receiving patient-centered care.

One commenter explained that his research has demonstrated that slower, longer dialysis sessions have a positive impact on patient health and mortality. In addition, several commenters described serious issues with shortened dialysis treatments contributing to reduced quality of care. One patient reported an incident in which they lost consciousness during treatment and no staff member responded. Several patients indicated they did not receive education regarding home modalities for years after beginning dialysis treatment. Two patients reported disregard and lack of education by physicians. Several patients reported additional quality of care issues, including starting dialysis treatment late or being removed from dialysis treatment early, being requested to move their treatment time frequently, being moved to another ESRD facility for treatment, and even being requested to skip dialysis treatment.

Response: We appreciate the support for advancing health equity and quality of care through refinements to the ESRD PPS case mix adjusters. We believe that time on machine data, which we proposed to collect beginning January 1, 2025, would support CMS's analysis of disparities and support potential future refinements to advance health equity. Time on machine data can help inform CMS's understanding of the relationship between resource use and many of the issues reported by patients related to lack of staff time to address education or side effects of dialysis treatments. Monitoring time on machine data will enable CMS to address patient concerns about the possibility of being removed from treatment early or started late and receiving shortened treatments. Any potential new case-mix adjusters or changes to the case-mix adjusters would be the subject of separate rulemaking, and as we noted earlier in this final rule, interested parties would have the opportunity to comment on the methodology used in CMS's analysis to support such development at that time.

Comment: MedPAC recommended that CMS consider the collection of time on machine data for Medicare Advantage (MA) dialysis beneficiaries, as the share of dialysis beneficiaries enrolled in MA plans now exceeds 40 percent. Doing so, MedPAC explained, would enable the agency to identify, assess, and address potential health disparities among both FFS and MA beneficiaries.

Response: We appreciate the recommendation from MedPAC to collect time on machine data for MA beneficiaries, but we note that the collection of data related to services provided to beneficiaries enrolled in MA is outside the scope of this final rule.

Comment: Several commenters, including a coalition of dialysis organizations, a non-profit kidney care alliance, and a non-profit dialysis organization, raised various concerns about the validity and sufficiency of time on machine data for the purpose of measuring patient resource use. One large dialysis organization requested details about how CMS would validate the time on machine data it proposes to collect. Several commenters claimed that shorter time on machine does not correlate with lower costs, and that time on machine data is not an accurate predictor of facility-level composite rate costs, since time on machine does not capture the full scope of services rendered. Specifically, commenters noted that time on machine fails to capture services provided before and after the actual dialyzing time, such as time spent working with social workers. Commenters expressed concern that use of such data would misinform payment model refinements.

Commenters also noted that patient characteristics such as pain, co-morbidities, or an inability to adhere to the prescribed length of dialysis time, all contribute to variation in time on machine. A coalition of dialysis organizations asserted that the costs of all these patients would remain the same regardless of their time on machine. Several commenters expressed concern regarding the accuracy of data for patients that require the dialysis treatment to be suspended or for dialysis treatment to be ended early due to medical or other needs. One non-profit treatment and research center expressed that some patients may have personal needs that require working with staff while they are not connected to a dialysis machine, that some patients may need to have dialysis treatment interrupted for a variety of needs, such as mechanical issues, bathroom breaks, and blood pressure issues; therefore, some patients do not complete the full dialysis treatment ordered by the physician.

Various commenters, including a professional organization of nephrologists, a non-profit dialysis association, and a large dialysis organization, suggested that CMS exclude certain types of dialysis from the proposed reporting requirement because of concerns about data quality. Commenters suggested excluding time on machine data collection for home dialysis patients, AKI patients, and nocturnal dialysis patients. Furthermore, several commenters expressed their concern that underserved or disadvantaged populations would be allocated fewer resources because of inaccuracies in time on machine data. Specifically, commenters noted that pediatric patients require highly individualized prescription time due to patient size and blood volume, which would not be indicative of health disparities. Lastly, one large dialysis organization requested that CMS track disasters and remove any data related to shortened treatments from the data.

Response: We appreciate the concerns that commenters raised regarding the validity and sufficiency of the data. Many of the concerns that commenters raised about potential issues of data quality can be addressed through CMS's analysis of the data. We note that methodological considerations related to allocating costs based on time on machine data or any other data would be addressed in future notice and comment rulemaking.

First, regarding the question about how CMS intends to validate the data, it is not clear whether the commenter is referring to validating that ESRD facilities are reporting accurate and complete information, or ensuring the statistical validity of aggregated data CMS uses for analysis. In the former case, as we noted in the CY 2024 ESRD PPS proposed rule, requiring reporting of time on machine data on a claim, by definition, would involve an attestation that the information submitted is correct and that the items represent expenses for medically necessary services. CMS reserves the right to request documentation from the provider validating the time on machine data, and to recoup payment if this documentation is not provided or supportable, as well as to take other administrative actions, as appropriate. We note that prescription data and historically reported monthly time on machine data is available in EQRS and can be used for the purposes of comparison. In the case of ensuring the statistical validity of data used for future analysis, we note that CMS has historically applied statistical trims to remove outlier values and erroneous data and could employ similar methods for future analyses.

As commenters rightly pointed out, time on machine data does not account for costs that ESRD facilities incur before and after the time spent dialyzing. As we previously discussed in the CY 2020 ESRD PPS proposed rule (84 FR 38396 through 38400), patient-level differences in composite rate costs could be attributed to two discrete

categories: differences due to renal dialysis treatment duration (measured in units of time); and differences unrelated to treatment duration. The collection of time on machine data for each dialysis session would support the development of a patient-level cost model, with respect to the portion of composite rate costs that are attributable to dialysis duration. We would consider additional data and information to inform our allocation of costs that are not related to dialysis duration, such as time spent with social workers. Importantly, however, without a measure of dialysis duration, which we have proposed to collect as time on machine data reported on claims, it would not be possible to develop a comprehensive patient-level cost model in the future.

We disagree with the commenter that the cost to care for patients is unchanged regardless of pain, co-morbidities, or adherence to prescribed dialysis treatment schedule based on time on machine. CMS published the findings from the December 2018 TEP in a report dated June 2019.[57] The 2018 TEP report provides clear evidence that in general, longer treatment duration is associated with higher costs. First, as discussed in the 2018 TEP report, an imputed cost per treatment was calculated using a combination of treatment duration data from CROWNWeb [58] (now EQRS) and facility cost per-minute data from cost reports to infer differences in costs across patient-months. An average interquartile range of 34.6 minutes was observed from CROWNWeb duration data, indicating significant within-facility variation in dialysis treatment time. Significant variation in average imputed cost per hemodialysis sessions also was observed, with an across-facility interquartile range of $62.62. Overall, it was found that costs increased with longer treatment times, and this pattern was consistent for the individual cost report components as well. Facilities with a higher proportion of beneficiaries receiving treatments ≥4.5 hours duration were found to have higher average costs for each cost component, except for cost report drugs.[59]

Lastly, we recognize that the unique needs of particular subpopulations such as pediatric patients, AKI patients, nocturnal patients, and patients with social needs may affect time on machine data. We intend to consider such patient characteristics when proposing a methodology for allocating composite rate costs in the future. We do not believe it would be appropriate to exclude these subpopulations from the analysis entirely, because doing so would result in refinements to the ESRD PPS that in no way account for the unique needs of these subpopulations. Rather, we intend to look for ways to analyze and understand the impacts of such patient characteristics on treatment duration. For example, because commenters have indicated time on machine may be shortened due to social factors, we would encourage ESRD facilities to use Z codes when submitting ESRD PPS claims as appropriate to note when social factors affect treatment time or other aspects of treatment. For instance, if a patient has transportation issues necessitating removal from treatment early, the ESRD facility could include Z59.82 (Transportation insecurity), or if the patient has difficulty in understanding the education provided related to the importance of completing treatments the ESRD facility could use Z55 (Problems related to education and literacy) to indicate the psychosocial need to be addressed. The coding of this type of information, when clinically appropriate, would support CMS's efforts to understand the impact of social determinants of health, and other factors, on treatment duration and patient-level cost.

Comment: Many commenters stated that collecting time on machine data would place a significant administrative burden on ESRD facilities, including for facilities that utilize EHR systems, but especially for smaller facilities and facilities that lack EHR capabilities. Commenters expressed that the time-consuming task of reporting time on machine would add to ESRD facilities' costs and would have a negative impact on time available for patient care during a prolonged period of workforce shortage.

Several commenters suggested alternative data sources that CMS could consider using in order to avoid the burden associated with the proposed collection of time on machine on claims. Some commenters suggested that existing CrownWeb (now EQRS) clinical data on time on machine, collected once monthly in conjunction with blood urea nitrogen (BUN) laboratory testing, could be used instead, reducing the burden on providers to collect data for each treatment. A non-profit kidney care alliance indicated while time on machine data may be interesting, there may be superior alternatives as a proxy to apportion composite rate costs; however, they did not provide any alternatives to time on machine as a proxy. Some commenters encouraged the use of physician prescribed time, rather than actual time on machine, as it reflects how ESRD facilities are staffed. One commenter suggested defining time on machine as blood volume processed >0, as this would enable CMS to capture resources expended on sequential ultrafiltration.

Several other commenters suggested limiting the scope of the proposed data collection to reduce burden. Some commenters suggested limiting time on machine data collection to a subset of dialysis facilities or treatments. MedPAC urged CMS to be mindful of the potential for increased administrative burden on ESRD facilities and consider collecting these data for a finite period of time, only as long as needed to explore refining the payment adjustment factors.

Response: We acknowledge that collecting time on machine data will increase administrative burden for ESRD facilities, especially those for whom the collection of such data will have to be done manually. However, we do not agree that the proposed reporting requirement will substantially impact time available for patient care, as some commenters suggested. We anticipate that ESRD facilities will employ medical records technicians or similar non-direct-care staff to aggregate time on machine data and report it on claims. Furthermore, as we stated in the CY 2024 ESRD PPS proposed rule (88 FR 42466), for facilities that have already automated the collection of machine-generated data directly into the patient electronic medical record, this burden should be minimal. CMS will work to provide timely operational guidance about the reporting requirement for time on machine information so that facilities may prepare their information technology (IT) or EHR systems or other processes to collect and report complete time on machine data by January 1, 2025. We have revised our burden estimate in the regulatory impact

[57] The final TEP report from December 2018 is found directly at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/esrdpayment/downloads/esrd-pps-tep-summary-report-june-2019.pdf.*

[58] In 2008, CMS introduced an electronic Web-based data collection system, Consolidated Renal Operations in a Web-enabled Network (CROWNWeb) which was designed to collect clinical performance measures data from dialysis facilities (73 FR 20370, at 20372). CROWNweb is now ''EQRS''—that is, the ESRD Quality Reporting System (OMB Control Number 0938–1289).

[59] Acumen LLC. ESRD PPS Case-Mix Adjustment Technical Expert Panel (TEP). Slide Presentation Slide 42. December 2018. See *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/ESRD-PPS-TEP-Presentation.pdf.*

analysis in section VII.D.2.a of this final rule to reflect the additional burden associated with aggregating time on machine data from the patient record and reporting it on the claim.

We appreciate commenters' suggestions regarding alternative sources of data. As we discuss earlier in this final rule, we believe time on machine is the most appropriate source of data for our proposed purpose. In contrast to the sources that commenters suggested, time on machine data would provide more comprehensive information about the actual quantity of dialysis that a patient receives each month. As we have previously noted, past analysis has demonstrated a statistically significant relationship between a patient's total time on machine and resource utilization.

In addition, we appreciate the suggestion to limit time on machine data collection to a subset of dialysis facilities to drive the revision of case-mix adjusters. However, we believe this would be counterproductive, because analysis of a subset of facilities could skew the data and impact the accuracy of case-mix adjusters for the ESRD PPS in its entirety. We also appreciate the recommendation from MedPAC to limit the duration of data collection to the length of time necessary to develop methodology to use for case-mix adjustment. Without collection, review, and assessment of the time on machine data, we cannot provide an estimate of the length of time CMS will need to collect the data. We will consider the recommendation from MedPAC and the level of burden that reporting places on ESRD facilities in the future. We intend to monitor and potentially propose modifications to this policy, as appropriate, through future notice and comment rulemaking.

(c) Using a Medicare Claims Data Field To Report Time on Machine Data

In the CY 2024 ESRD PPS proposed rule (88 FR 42471), we proposed that ESRD facilities report the number of minutes of hemodialysis treatment received in center in an ESRD facility using the D6 value code on the Medicare 72X type of bill (TOB) that is part of CMS's claim form CMS–1450 (UB–04) (OMB–0938–0997). While our proposal limited the time on machine reporting requirement to in-center claims, to address the concerns previously raised by interested parties about the burden and complexity of home dialysis reporting, we noted that time on machine for home dialysis data could nonetheless be voluntarily reported using the D6 value code on claims.

This approach would address long-standing concerns, including such concerns raised by MedPAC and other interested parties, that CMS should move to a one-equation model. We stated that we agree with interested parties that a single-equation model, to be constructed at the patient level, would reduce the complexity of the current model, and would better align payment with costs. The current two-equation model's payment adjusters are derived using weighted averages of the coefficients from the facility-level and patient-level equations. Because the composite rate items currently comprise roughly 90 percent of the payment, we stated that we are seeking a more detailed understanding of patients' utilization of such treatment resources. We noted that we anticipate that the time on machine data would provide a useful proxy for these composite rate items.

Furthermore, we noted that the proposal to collect time on machine data on patient claims would address past comments on whether such a reporting requirement could create perverse incentives for ESRD facilities to amend actual reported time on machine. Another past commenter expressed concern about whether an ESRD facility might have the renal dialysis run a few extra minutes to increase the payment. However, we noted that requiring the reporting of time on machine data on a claim, by definition, would involve an attestation that the information submitted is correct and that the items presented represent medically necessary expenses. The False Claims Act (31 U.S.C. 3729 to 3733) establishes civil liability for knowingly presenting a false or fraudulent claim to the government for payment.

We noted that if the requirement to report time on machine information on claims is finalized, we would issue operational guidance in support of the requirement. We stated that such guidance would describe the applicable instructions for reporting a value code (in this case, the D6 [60] value code) connected to the number of minutes of hemodialysis treatment provided to a patient in center.

The majority of the commenters expressed concerns about the need for specific operational guidance and about exclusions and missing data. The comments on our proposal and our responses are set forth below.

[60] Value code D6 on claim form CMS–1450 (UB–04) (OMB–0938–0997), for reporting the total number of minutes of dialysis provided during the billing period.

Comment: Several commenters, including a non-profit kidney care alliance, a coalition of dialysis providers, and large dialysis organizations requested clarification about the scope and specifications of the proposed reporting requirement. Commenters requested CMS to clarify its proposed definition of time on machine and how ESRD facilities would be expected to collect and report such data under the proposed requirement. A coalition of dialysis providers stated that there are inconsistencies in the methodology used across health care providers for the collection of time on machine data and that CMS will need to provide guidance to ensure data is accurately provided. Two large dialysis organizations recommended CMS define time on machine data collection using an approach like that used in the ESRD Measures Specification Manual associated with the ESRD QIP.[61] One large dialysis organization recommended using ''clock time'' to measure time on machine. We note that the commenter did not specify a meaning for the term ''clock time''; however, we interpret this to mean the total number of minutes between the beginning of dialysis and the end of dialysis, without accounting for any interruptions. Clock time, the commenter suggested, could be utilized by all ESRD facilities, since it would not require networked electronic medical records. Another large dialysis organization requested confirmation that ESRD facilities would be required to report time on machine for all in-center dialysis treatments, including those provided under special circumstances for patients who normally perform dialysis treatments at home.

Response: We appreciate these requests for clarification from the commenters. Although we intend to publish detailed operational guidance, we are taking the opportunity in this final rule to respond directly to the questions that commenters posed. First, while we appreciate the recommendation that we use the ESRD Measures Specification Manual as a guide to define data collection, we note that the manual does not define time on machine in a way that is useful for our purposes. Rather, for the purposes of this reporting requirement, we are clarifying that we generally define time on machine as the total number of minutes between the beginning of dialysis and the end of dialysis, without accounting for any interruptions, which

[61] *https://www.cms.gov/files/document/cy-2023-final-technical-specifications-20230613.pdf.*

we believe one commenter referred to as ''clock time'', as noted earlier. We do not intend for ESRD facilities to track minutes for interruption during dialysis due to frequent alarms or when a patient is removed from dialysis treatment to go to the bathroom, nor do we expect facilities to subtract those minutes of interruption from the time on machine that is reported. We expect these episodes to be infrequent and time-limited, and generally not a significant driver of aggregate variation in total time on machine between patients. Thus, time on machine for each dialysis treatment can be calculated by subtracting the time the dialysis treatment started from the time the treatment ended. For each ESRD PPS claim, the ESRD facility should report in the D6 value code the total number of minutes across all treatments provided to the patient during the billing period, which is typically a month. Lastly, regarding the comment about in-center dialysis treatments provided under special circumstances for patients who normally perform dialysis treatments at home, we are clarifying that time on machine data must be reported for all dialysis treatments that are provided in-center, even if the patient usually uses a home modality. In such circumstances, the ESRD facility should be billing for in-center dialysis treatments on a separate claim from any home dialysis treatments, with the appropriate indicators to reflect that the treatment is being provided in-center.

Comment: Several commenters requested clarification about how to report time on machine in various exceptional circumstances. One large dialysis organization stated that CMS should provide guidance regarding how to report time on machine during certain infrequent anomalous circumstances such as power outages, network failures, mechanical issues or failures, or emergency circumstances when treatments must be shortened. One large dialysis organization requested CMS to differentiate between when time on machine data is captured manually and when it is captured electronically. Commenters also expressed concern about whether ESRD facilities would be paid for treatments for which time on machine was missing and requested that payment should not be withheld for missing time on machine data (that is, claims with no D6 value). One large dialysis organization requested CMS consider allowing an error rate of ten percent of total treatments to allow for unforeseen circumstances.

Response: We appreciate the concerns that commenters raised about exceptional circumstances. We recognize that circumstances such as power outages, network failures, mechanical issues or failures, emergency circumstances, and human error can result in disruptions to standard workflows and consequently, missing time on machine data for individual dialysis treatments. We are clarifying that since data for time on machine is reported as an aggregate value for all dialysis treatment sessions in one month, we will not return claims that lack reporting of individual sessions. We will only return claims that have nothing reported in the D6 value code. Therefore, although we appreciate the suggestion to allow a ten percent error rate, we believe it is neither necessary nor appropriate to do so.

At this time, we have not established any specific indicators to differentiate between time on machine that is collected manually versus electronically. Nor have we established any identifiers for circumstances when a patient needs to end his or her dialysis session earlier than the prescribed time; however, as we discussed earlier in this final rule, we believe additional information already reported on claims, such as ICD–10 codes, could provide relevant context for such circumstances. We may consider developing additional indicators to identify circumstances like the ones that commenters described, and we would discuss any such changes in future notice and comment rulemaking.

(d) Use of Time on Machine Data for the ESRD PPS

In our CY 2024 ESRD PPS proposed rule (88 FR 42470), we emphasized and again clarified that time on machine data would not be directly used to determine payment for renal dialysis services, nor would higher payments be made for longer treatments. Rather, we stated that time on machine data would allow for patient-specific calculation of costs for composite rate services, including labor costs, costs for the use of renal dialysis machines and related equipment, and costs for such items as dialysate and other essential supplies. We noted that, in this way, time on machine data would be used to disaggregate facility-level composite rate costs (as obtained from the cost reports) and assign them to the patient-month level, which would enable a refined, single-equation estimation methodology. The refined, single-equation regression analysis (currently under development) would still be used to determine the inclusion/exclusion and magnitude of payment multipliers for patient-level case-mix flags that are associated with higher costs. We wrote that final payment adjustments would still only depend on existing patient-level case-mix adjustors, rather than a factor directly derived from time on machine data.

Several of the commenters expressed concerns about how the resultant time on machine data would be used in the model refinement process to potentially determine payment. The comments on our proposal and our responses are set forth below.

Comment: Several commenters requested further clarification about how CMS intends to use the time on machine data. A not-for-profit dialysis organization expressed concern that reporting time on machine data would lead to a payment methodology based on minutes of dialysis provided.

Response: In the proposed rule and this final rule, we have clearly stated how data collected from time on machine will be used. We will use time on machine data to help us evaluate and monitor the accuracy of our payments for patient-level adjustment factors. CMS will also evaluate whether the data could be used to inform future refinements to the existing patient-level adjustment factors set forth at § 413.235(a), which include patient age, BMI, BSA, and co-morbidities such as sickle cell anemia. Finally, CMS will review the data for its potential to identify any disparities from a health equity perspective that may support proposing, in future rulemaking, new patient-level adjustment factors, including potential SDOH factors.

(e) Request for Information About Effective Date

In the CY 2024 ESRD PPS proposed rule, we proposed a January 1, 2025, effective date for this new reporting requirement. We stated that we are aware that all ESRD facilities record the time a patient has received hemodialysis treatment into a patient's medical record, and that, for most ESRD facilities, this time is automatically recorded into the patient's EHR. We noted that we further understand that ESRD facilities can transfer data from EHRs into the patient-specific claims that are submitted to Medicare for payment. However, we recognized that some ESRD facilities with limited resources may need to make modifications to their record keeping and reporting systems to facilitate the transfer of a patient's recorded hemodialysis treatment time in the patient's medical record to the Medicare claim. Although we did receive a past comment indicating that a facility's

implementation time would involve training staff on how to count and track time, we stated that we do not expect that the manual recording of a patient's hemodialysis treatment time into their health record is widespread. Finally, we noted that ESRD facilities are already reporting extensive information from patient EHRs into Medicare institutional claim form CMS–1450 (UB–04) (OMB–0938–0997), and we would not expect implementation to be overly burdensome to ESRD facilities. We stated that we recognize that some ESRD facilities would need to establish a new pathway from patient EHRs to the Medicare claim form, in addition to making simpler programming updates to add a field for the total number of minutes of dialysis provided during the billing period. Based on our findings in the TEP from December 2018, we noted that we anticipate that the implementation challenges that ESRD facilities might experience would be small and temporary, as a patient's time receiving dialysis treatment is already collected for the patient's medical record. We solicited comment on whether an earlier effective date, such as January 1, 2024, would be feasible and would provide ESRD facilities with adequate time to implement this new reporting requirement.

The majority of the commenters expressed concerns about the ability to make the necessary changes to internal IT systems by a January 1, 2024, reporting requirement. The comments on our proposal and our responses are set forth below.

Comment: Commenters expressed strong opposition to any start date earlier than January 1, 2025. A large dialysis organization expressed that making the necessary operational changes to report time on machine data would require considerable effort and would not be possible prior to January 1, 2025. Several commenters called for CMS to allow for at least one year before implementation for ESRD facilities, including large dialysis organizations, to program the new requirements into their IT and EHR systems, and to provide comprehensive guidance before finalizing this policy. A few commenters also suggested that operational guidance be issued in conjunction with the CY 2024 ESRD PPS final rule, and that implementation of the proposed time on machine reporting requirement be delayed until interested parties have an opportunity to comment on such guidance.

Response: CMS understands the concerns that commenters raised regarding lead time needed to develop IT systems and processes in order to collect and report accurate and complete time on machine data. As we noted in the CY 2024 ESRD PPS proposed rule, we have proposed an implementation date of January 1, 2025, for this reporting requirement to provide what we believe will be sufficient lead time for ESRD facilities to make these necessary changes to their systems and operations. Commenters indicated that it would take 1 year for ESRD facilities to update their systems after the provision of operational guidance due to systems updates and staff education. We believe that the 1 year implementation timeline strikes a balance between the need to collect this data and ESRD facilities' need to make operational changes.

We also appreciate the concerns of commenters who requested specific operational guidance, and the opportunity to comment on such guidance, before the effective date of the proposed reporting requirement. In this final rule, we have addressed many of the operational questions that commenters posed. Additionally, as we noted earlier in this final rule, we intend to issue detailed operational guidance no later than January 1, 2024. This operational guidance will address topics such as instructions for the collection and reporting of time on machine data, detailed billing requirements, including the types of ESRD PPS claims subject to required reporting of the D6 value code, and guidance on how to proceed when time on machine for a qualifying treatment is missing or otherwise unavailable. The proposed 1-year lead time between the issuance of detailed operational guidance and the effective date of the proposed reporting requirement will afford CMS the opportunity to engage in further dialogue with interested parties about such guidance during the CY 2025 rulemaking cycle. CMS has responded to specific concerns about operational guidance earlier in this section of this final rule. Further guidance will be provided by the MACs. Additionally, interested parties may reach out to CMS to request meetings to discuss and resolve specific concerns.

Final Rule Action: We are finalizing our proposal to require the reporting of in-center hemodialysis duration on ESRD PPS claims, beginning January 1, 2025. Specifically, we are finalizing our proposal to require ESRD facilities to report ''time on machine,'' with certain changes to clarify that ESRD facilities are required to report the number of minutes between the start and end of hemodialysis treatment, without accounting for interruptions, a beneficiary receives during the billing period in center in an ESRD facility. We are finalizing our proposal to require ESRD facilities to report this information using the D6 value code on ESRD PPS claims. We are codifying this requirement in regulation at § 413.198(b)(5)(i). As discussed in section II.B.1.h of this final rule, we are finalizing the addition of § 413.198(b)(5), which states that ESRD facilities must submit data and information in the formats established by CMS for the purpose of estimating patient-level and facility level variation in resource use.

(4) Technical Change to § 413.198

We proposed to fix a typographical error in § 413.198(b)(3)(iii), which currently refers to ''luxury items or servicess''. We proposed to change this to ''luxury items or services''. CMS did not receive any comments regarding correcting this typographical error in § 413.198(b)(3)(iii). We are finalizing our proposal to revise the typographical error in § 413.198(b)(3)(iii), which currently refers to ''luxury items or servicess'' to ''luxury items or services''.

k. Clarification to TDAPA Average Sales Price (ASP) Policy

In the CY 2020 ESRD PPS final rule, we finalized a conditional policy for TDAPA payment based on the availability of ASP data (84 FR 60679). In that final rule, we explained that if drug manufacturers were to stop submitting full quarters of ASP data for products that are eligible for the TDAPA, and we had to revert to basing the TDAPA on the wholesale acquisition cost (WAC) or invoice pricing, we believed we would be overpaying for the TDAPA for those products. We stated that we would no longer apply the TDAPA for a new renal dialysis drug or biological product if a drug manufacturer submits a full calendar quarter of ASP data into CMS within 30 days after the last day of the 3rd calendar quarter after the TDAPA is initiated for the product, but at a later point during the applicable TDAPA period specified in § 413.234(c)(1) or (2), stops submitting a full calendar quarter of ASP data into CMS. We explained that once we determine that the latest full calendar quarter of ASP is not available, we would stop applying the TDAPA for the new renal dialysis drug or biological product within the next 2-calendar quarters. For example, we stated that if we began paying the TDAPA on January 1, 2021 for an eligible new renal dialysis drug or biological product, and a full calendar quarter of ASP data is made available to CMS by October 30, 2021 (30 days after

the close of the 3rd quarter of paying the TDAPA), but a full calendar quarter of ASP data is not made available to CMS as of January 30, 2022 (30 days after the close of the 4th quarter of paying the TDAPA), we would stop applying the TDAPA for the product no later than June 30, 2022 (2 quarters after the 4th quarter of paying the TDAPA).

We adopted this conditional policy to avoid overpaying for the TDAPA on an ongoing basis and to ensure that TDAPA payment is based on the most appropriate data, that is, ASP. Specifically, we explained in the CY 2020 ESRD PPS proposed rule (84 FR 38349) and final rule (84 FR 60680) that we were concerned about (1) increases to Medicare expenditures due to the TDAPA for calcimimetics; (2) drug manufacturers not reporting ASP data for products eligible for TDAPA; and (3) our TDAPA policy potentially incentivizing drug manufacturers to withhold ASP data from CMS.

In the CY 2024 ESRD PPS proposed rule (88 FR 42472), we discussed that our existing regulation at § 413.234(c) does not specifically address the application of the TDAPA conditional policy in situations in which the manufacturer of the new renal dialysis drug or biological product submitted ASP data to CMS and reported zero or negative sales. Zero or negative sales may occur for a variety of reasons, including no sales, recalls of a product, or repurchases of sold products. In the CY 2012 PFS final rule (76 FR 73296), CMS clarified that zero or negative values are valid for ASP, ASP units, and WAC. Therefore, when such a scenario occurs for separately payable Medicare Part B drugs, we consider the submission of zero or negative sales to fulfill the reporting requirements of manufacturer ASP data to CMS as set forth in sections 1927(b)(3)(A)(iii) and 1847A(f) of the Act. We noted that in situations when zero sales are submitted, CMS guidance [62] instructs the manufacturer to report ''0.000'' for the ASP and the number of ASP units. The payment allowance limits for drugs and biologicals that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified Pricing File, other than new drugs that are produced or distributed under a new drug application (or other application) approved by the U.S. FDA, are based either on the published WAC or invoice pricing (except under OPPS, where the payment allowance limit is 95 percent of the published average wholesale price (AWP)). In determining the payment limit based on WAC, the contractors follow the methodology specified in Publication 100–04, Chapter 17, section 20.4 Drugs and Biologicals, for calculating the AWP, but substitute WAC for AWP. The payment limit is 106 percent of the lesser of the lowest-priced brand or median generic WAC.[63] Therefore, for purposes of the TDAPA conditional policy, in circumstances where a manufacturer submitted ASP data reflecting zero or negative sales during the TDAPA period, we clarified that we consider CMS to have received the latest full calendar quarter of ASP data, and we would not discontinue TDAPA payment under the conditional policy in § 413.234(c). Consistent with the pricing methodologies for separately payable Medicare Part B drugs, we would set the TDAPA payment amount based on WAC, or if WAC is not available, invoice pricing, for the quarter in which zero or negative sales were reported.

Comment: We received two comments on our proposal to clarify the ASP data submission requirement. Both commenters, a coalition of dialysis organizations and a drug manufacturer, agreed with CMS that a submission reflecting zero or negative sales should not lead to a discontinuation of TDAPA payment. Both commenters supported this clarification. The comment from the coalition of dialysis organizations stated that this policy would support continued patient access to a drug or biological product that is in the TDAPA period. The comment from the drug manufacturer expressed further support for the use of WAC, or if WAC is not available, invoice pricing, when ASP data is not usable for the purposes of determining the TDAPA payment amount and post-TDAPA payment amount.

Response: We thank commenters for their support and for their insight into the importance and impact of this policy.

Final Rule Action: We are finalizing the clarification to the TDAPA ASP payment policy as proposed; for purposes of the TDAPA conditional policy, in circumstances where a manufacturer submitted ASP data reflecting zero or negative sales during the TDAPA period, we consider CMS to have received the latest full calendar quarter of ASP data, and we will not discontinue TDAPA payment under the conditional policy in § 413.234(c). Consistent with the pricing methodologies for separately payable Medicare Part B drugs, in such circumstances, we will set the TDAPA payment amount based on WAC, or if WAC is not available, invoice pricing, for the quarter in which zero or negative sales were reported.

C. Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) Clarifications and Application for CY 2024 Payment

1. Background

In the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), CMS established the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) under the ESRD PPS, under the authority of section 1881(b)(14)(D)(iv) of the Act, to support ESRD facility use and beneficiary access to these new technologies. We established this add-on payment adjustment to help address the unique circumstances experienced by ESRD facilities when incorporating new and innovative equipment and supplies into their businesses and to support ESRD facilities transitioning or testing these products during the period when they are new to market. We added § 413.236 to establish the eligibility criteria and payment policies for the TPNIES.

In the CY 2020 ESRD PPS final rule (84 FR 60650), we established in § 413.236(b) that for dates of service occurring on or after January 1, 2020, we would provide the TPNIES to an ESRD facility for furnishing a covered equipment or supply only if the item: (1) has been designated by CMS as a renal dialysis service under § 413.171; (2) is new, meaning granted marketing authorization by the FDA on or after January 1, 2020; (3) is commercially available by January 1 of the particular CY, meaning the year in which the payment adjustment would take effect; (4) has a Healthcare Common Procedure Coding System (HCPCS) application submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular CY; (5) is innovative, meaning it meets the substantial clinical improvement criteria specified in the Inpatient Prospective Payment System (IPPS) regulations at § 412.87(b)(1) and related guidance; and (6) is not a capital-related asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired).

[62] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Downloads/ASP_Data_Collection_Validation_Macro_User_Guide.pdf.*

[63] Medicare Claims Processing Manual Chapter 17, section 20.1.3 *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf.*

Regarding the innovation requirement in § 413.236(b)(5), in the CY 2020 ESRD PPS final rule (84 FR 60690), we stated that we would use the following criteria to evaluate substantial clinical improvement for purposes of the TPNIES under the ESRD PPS based on the IPPS substantial clinical improvement criteria in § 412.87(b)(1) and related guidance:

A new technology represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. First, CMS considers the totality of the circumstances when making a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. Second, a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries means one of the following:

- The new renal dialysis equipment or supply offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments; or
- The new renal dialysis equipment or supply offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods, and there must also be evidence that use of the new renal dialysis service to make a diagnosis affects the management of the patient; or
- The use of the new renal dialysis equipment or supply significantly improves clinical outcomes relative to renal dialysis services previously available as demonstrated by one or more of the following: (1) a reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; (2) a decreased rate of at least one subsequent diagnostic or therapeutic intervention; (3) a decreased number of future hospitalizations or physician visits; (4) a more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; (5) an improvement in one or more activities of daily living; an improved quality of life; or (6) a demonstrated greater medication adherence or compliance; or,
- The totality of the circumstances otherwise demonstrates that the new renal dialysis equipment or supply substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries.

Third, evidence from the following published or unpublished information sources from within the United States or elsewhere may be sufficient to establish that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries: Clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.

Fourth, the medical condition diagnosed or treated by the new renal dialysis equipment or supply may have a low prevalence among Medicare beneficiaries.

Fifth, the new renal dialysis equipment or supply may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new renal dialysis equipment or supply.

In the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), we also established a process modeled after IPPS's process of determining if a new medical service or technology meets the substantial clinical improvement criteria specified in § 412.87(b)(1). As we discussed in the CY 2020 ESRD PPS final rule (84 FR 60682), we believe it is appropriate to facilitate access to new and innovative equipment and supplies through add-on payment adjustments similar to the IPPS New Technology Add-On Payment and to provide stakeholders with standard criteria for both inpatient and ESRD facility settings. In § 413.236(c), we established a process for our announcement of TPNIES determinations and a deadline for consideration of new renal dialysis equipment or supply applications under the ESRD PPS. We would consider whether a new renal dialysis equipment or supply meets the eligibility criteria specified in § 413.236(b) and summarize the applications received in the annual ESRD PPS proposed rules. Then, after consideration of public comments, we would announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS in the ESRD PPS final rule. In the CY 2020 ESRD PPS final rule, we also specified certain deadlines for the application requirements. We noted that we would only consider a complete application received by February 1 prior to the particular CY. In addition, we required that FDA marketing authorization for the equipment or supply must occur by September 1 prior to the particular CY. We also stated in the CY 2020 ESRD PPS final rule (84 FR 60690 through 60691) that we would establish a workgroup of CMS medical and other staff to review the materials submitted as part of the TPNIES application, public comments, FDA marketing authorization, and HCPCS application information and assess the extent to which the product provides substantial clinical improvement over current technologies.

In the CY 2020 ESRD PPS final rule, we established § 413.236(d) to provide a payment adjustment for certain new and innovative renal dialysis equipment or supplies. We stated that the TPNIES is paid for two CYs. Following payment of the TPNIES, the ESRD PPS base rate will not be modified, and the new and innovative renal dialysis equipment or supply will become an eligible outlier service as provided in § 413.237.

Regarding the basis of payment for the TPNIES, in the CY 2020 ESRD PPS final rule, we finalized at § 413.236 that the TPNIES is based on 65 percent of the price established by the MACs, using the information from the invoice and other specified sources of information.

In the CY 2021 ESRD PPS final rule (85 FR 71410 through 71464), we made several changes to the TPNIES eligibility criteria at § 413.236. First, we revised the definition of new at § 413.236(b)(2) as within 3 years beginning on the date of the FDA marketing authorization. Second, we changed the deadline for TPNIES applicants' HCPCS Level II code application submission from September 1 of the particular CY to the HCPCS Level II code application deadline for biannual Coding Cycle 2 for durable medical equipment, orthotics, prosthetics, and supplies (DMEPOS) items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the CY. In addition, a copy of the applicable FDA marketing authorization must be submitted to CMS by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the

CMS website in order for the equipment or supply to be eligible for the TPNIES the following year. Third, we revised § 413.236(b)(5) to remove a reference to related guidance on the substantial clinical improvement criteria, as the guidance had already been codified.

Finally, in the CY 2021 ESRD PPS final rule, we expanded the TPNIES policy to include certain capital-related assets that are home dialysis machines when used in the home for a single patient. We explained that capital-related assets are defined in the Provider Reimbursement Manual (chapter 1, section 104.1) as assets that a provider has an economic interest in through ownership (regardless of the manner in which they were acquired). We noted that examples of capital-related assets for ESRD facilities are dialysis machines and water purification systems. We explained that, although we stated in the CY 2020 ESRD PPS proposed rule (84 FR 38354) that we did not believe capital-related assets should be eligible for additional payment through the TPNIES because the cost of these items is captured in cost reports, they depreciate over time, and are generally used for multiple patients, there were a number of other factors we considered that led us to consider expanding eligibility for these technologies in the CY 2021 ESRD PPS rulemaking. We explained that, following publication of the CY 2020 ESRD PPS final rule, we continued to study the issue of payment for capital-related assets under the ESRD PPS, taking into account information from a wide variety of stakeholders and recent developments and initiatives regarding kidney care. For example, we considered various HHS home dialysis initiatives, Executive Orders to transform kidney care, and how the risk of COVID–19 for particularly vulnerable ESRD beneficiaries could be mitigated by encouraging home dialysis.

After closely considering these issues, we proposed a revision to § 413.236(b)(6) in the CY 2021 ESRD PPS proposed rule to provide an exception to the general exclusion for capital-related assets from eligibility for the TPNIES for capital-related assets that are home dialysis machines when used in the home for a single patient and that meet the other eligibility criteria in § 413.235(b), and finalized the exception as proposed in the CY 2021 ESRD PPS final rule. We finalized the same determination process for TPNIES applications for capital-related assets that are home dialysis machines as for all other TPNIES applications; that we will consider whether the new home dialysis machine meets the eligibility criteria specified in § 413.236(b) and announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS. In accordance with § 413.236(c), we will only consider, for additional payment using the TPNIES for a particular CY, an application for a capital-related asset that is a home dialysis machine received by February 1 prior to the particular CY. If the application is not received by February 1, the application will be denied and the applicant is able to reapply within 3 years beginning on the date of FDA marketing authorization to be considered for the TPNIES, in accordance with § 413.236(b)(2).

In the CY 2021 ESRD PPS final rule, at § 413.236(f), we finalized a pricing methodology for capital-related assets that are home dialysis machines when used in the home for a single patient, which requires the MACs to calculate the annual allowance and the preadjusted per treatment amount. The pre-adjusted per treatment amount is reduced by an estimated average per treatment offset amount to account for the costs already paid through the ESRD PPS base rate.[64] We finalized that this amount would be updated on an annual basis so that it is consistent with how the ESRD PPS base rate is updated.

We revised § 413.236(d) to reflect that we would pay 65 percent of the pre-adjusted per treatment amount minus the offset for capital-related assets that are home dialysis machines when used in the home for a single patient.

We revised § 413.236(d)(2) to reflect that following payment of the TPNIES, the ESRD PPS base rate will not be modified, and the new and innovative renal dialysis equipment or supply will be an eligible outlier service as provided in § 413.237, except a capital-related asset that is a home dialysis machine will not be an eligible outlier service as provided in § 413.237.

In summary, under the current eligibility requirements in § 413.236(b), CMS provides for a TPNIES to an ESRD facility for furnishing a covered equipment or supply only if the item: (1) has been designated by CMS as a renal dialysis service under § 413.171; (2) is new, meaning within 3 years beginning on the date of the FDA marketing authorization; (3) is commercially available by January 1 of the particular CY, meaning the year in which the payment adjustment would take effect; (4) has a complete HCPCS Level II code application submitted in accordance with the HCPCS Level II coding procedures on the CMS website, by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the CY; (5) is innovative, meaning it meets the criteria specified in § 412.87(b)(1); and (6) is not a capital-related asset, except for capital-related assets that are home dialysis machines.

2. Clarifications Regarding CMS's Evaluation of the TPNIES Eligibility Criteria

This section of the final rule discusses clarifications to our policies for evaluating the TPNIES eligibility criteria under § 413.236(b).

a. Sequential Order of CMS Review of the TPNIES Eligibility Criteria (§ 413.236(b))

As stated previously, we consider whether a new renal dialysis supply or equipment meets the TPNIES eligibility criteria as part of the annual ESRD PPS rulemaking and announce the results in ESRD PPS final rule. To qualify for the TPNIES, an applicant must meet each of the TPNIES eligibility criteria set forth in § 413.236(b)(1) through (6). An applicant that fails to demonstrate that it meets each of the six eligibility criteria is not eligible for the TPNIES.

In the CY 2021 ESRD PPS final rule, we focused our analysis of the TPNIES eligibility criteria on those that were not met. That is, for the Theranova Dialyzer, we included our analysis of how the applicant did not meet the innovation criterion under § 413.236(b)(5), and for the Tablo® cartridge, we included our analysis of how the applicant did not meet the newness criterion under § 413.236(b)(2) and innovation criterion under § 413.236(b)(5) (85 FR 71444 through 71464). In the CY 2022 and CY 2023 ESRD PPS final rules, we expanded our analysis to include our determination as to whether the applicants met each of the six criteria. In doing so, we analyzed the TPNIES eligibility criteria in the sequence that is provided in § 413.236(b)(1) through (6) (86 FR 61889 through 61906 and 87 FR 67193 through 67216).

In the CY 2024 ESRD PPS proposed rule (88 FR 42475 through 42476), we stated that we are clarifying that our analysis of the TPNIES eligibility criteria would continue to proceed in sequential order. Specifically, in the annual ESRD PPS proposed rule, we would continue to summarize the information from the application regarding each of the six eligibility criteria and include any questions or

[64] The CY 2023 TPNIES offset amount was $9.79. CMS finalized a CY 2024 TPNIES offset amount of $10.00, as discussed in section II.B.1.e of this final rule.

concerns that we identify during our analysis of the application.

Based on information provided by the applicant and from public comments during the annual ESRD PPS rulemaking cycle, we would continue to analyze the TPNIES eligibility criteria in sequential order in the annual ESRD PPS final rule. However, the change that we proposed is that once it has been established that one criterion has not been met, we would not discuss or make specific determinations on the subsequent criteria for that item in the annual ESRD PPS final rule. We noted that the criteria set forth in § 413.236(b) are intentionally listed in the order in which they appear. The first criterion is foundational in that an equipment or supply that is not a renal dialysis service would not be paid for under the ESRD PPS and therefore would not fit within the TPNIES payment pathway. As such, it would not be pertinent to evaluate the remaining TPNIES criteria for that item. TPNIES criteria two through four are objective and not subject to interpretation in that they each require date evidence to demonstrate newness, commercial availability, and the submission of a HCPCS application, respectively. The TPNIES innovation criterion under § 413.236(b)(5) requires the most significant CMS evaluation. We explained that, under our TPNIES policy and § 412.87(b)(1)(i), CMS is required to consider the totality of the circumstances when making a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. In doing so, we consider various non-objective circumstances in our review of the TPNIES applications, including the state of the ESRD landscape and the particular challenges and vulnerabilities of patients with ESRD (86 FR 61905). We noted that we believe it is prudent to reserve our in-depth analysis of the TPNIES innovation criterion only for applications that provide the necessary evidence to demonstrate that they meet the earlier foundational and objective TPNIES criteria.

As described previously in the background section of this final rule, the TPNIES innovation criterion in § 413.236(b)(5) incorporates the substantial clinical improvement criteria in the IPPS regulations at § 412.87(b)(1) for the new technology add-on payment (NTAP). This sequential approach for reviewing eligibility criteria is also in place for the NTAP pathway. The FY 2009 IPPS final rule (73 FR 48561 through 48563) discussed the way in which CMS evaluates the NTAP eligibility criteria for new medical service or technology add-on payment applications. That is, we first determine whether a medical service or technology meets the newness criterion, and only if so, do we then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. The NTAP cost criterion is not applicable in analyzing TPNIES eligibility. However, consistent with our approach under NTAP, we stated that we believe that the most prudent use of CMS resources would be to reserve our analysis and determination regarding whether a new equipment or supply meets the TPNIES innovation criterion by representing a substantial clinical improvement over existing technologies until after we determine the new equipment or supply meets the earlier criteria.

Under this proposal, we would first determine whether an equipment or supply meets the renal dialysis service criterion in § 413.236(b)(1) and present our analysis of this first criterion in the final rule. In instances where CMS determines that § 413.236(b)(1) has been met, we would proceed in assessing the newness criterion in § 413.236(b)(2) and present our analysis of this second criterion in the final rule. In instances where CMS determines that § 413.236(b)(2) has been met, we would proceed in assessing whether the commercial availability criterion in § 413.236(b)(3) has either been met or the applicant expects that it will be met by January 1 of the particular CY and present our analysis of this third criterion in the final rule. In instances where CMS determines that § 413.236(b)(3) has been met or the applicant expects that it will be met by January 1 of the particular CY, we would proceed in assessing the HCPCS Level II code application criterion in § 413.236(b)(4) and present our analysis of this fourth criterion in the final rule. In instances where CMS determines that § 413.236(b)(4) has been met, we would proceed in assessing the innovation criteria in §§ 413.236(b)(5) and 412.87(b)(1) and present our analysis of this fifth criterion in the final rule. In instances where CMS determines that § 413.236(b)(5) has been met, we would proceed in assessing the non-capital-related asset (except home dialysis machines) criterion in § 413.236(b)(6) and present our analysis of this sixth criterion in the final rule. In instances where CMS determines that § 413.236(b)(6), as well as each of the five preceding criteria in § 413.236(b)(1) through (5) as discussed previously have been met, the equipment or supply would qualify for and would be paid for under the ESRD PPS using the TPNIES per § 413.236(d) beginning in the year that is the subject of the rulemaking.

In summary, we proposed to clarify that as CMS proceeds through the sequential analysis of the six TPNIES eligibility criteria in the ESRD PPS final rule for a particular equipment or supply, once we determine that the item has failed to demonstrate having met one of the eligibility criteria, the item would be ineligible for the TPNIES. We would limit our analysis in the final rule to the TPNIES criterion that is not met and any preceding criteria that have been determined to have been met. We would not include the analysis of the remaining criteria in the final rule. This policy would be effective January 1, 2024 and would apply to our analysis of TPNIES applications for CY 2025 payment.

We received six comments regarding our proposed clarification of the sequential order of CMS review of the TPNIES eligibility criteria at § 413.236(b). These comments and CMS's responses are set forth below.

Comment: One commenter supported our proposal with the understanding that all criteria would be discussed in full in the annual ESRD PPS proposed rule. Other commenters requested CMS confirmation that we would continue to summarize the information from each TPNIES application, including any questions and concerns regarding each of the six eligibility criteria, in the annual CY ESRD PPS proposed rule. Commenters also requested clarification that in the annual CY ESRD PPS final rule, CMS would limit its analysis to the criterion not met as well as any preceding criteria that are met. Several other commenters expressed concern that our proposal would deny applicants CMS's analysis of each criterion, eliminating the opportunity for the public to review the latter eligibility criteria and limiting applicants' ability to correct deficiencies prior to the next TPNIES application cycle.

Response: We thank the commenters for their input and confirm that we will continue to include our analysis of each TPNIES eligibility criterion in sequential order in the annual CY ESRD PPS proposed rule. We believe that identifying our comments or concerns with each of the eligibility criteria in the proposed rule provides the public with sufficient information and ample opportunity to review and respond to

our analysis and provides the applicant with the opportunity to correct deficiencies, as needed.

If a TPNIES applicant who is denied reapplies in a later application cycle, we will continue to provide a full analysis of all the eligibility criteria once again in the annual ESRD PPS proposed rule to allow the applicant an opportunity to correct any additional deficiencies for all the eligibility criteria, as needed.

As stated in the CY 2024 ESRD PPS proposed rule (88 FR 42475), an applicant that fails to demonstrate that it meets each of the six eligibility criteria is not eligible for the TPNIES. Therefore, we believe that reviewing the TPNIES eligibility criteria in sequential order allows CMS to reserve our in-depth analysis of the TPNIES innovation criterion only for applications that provide the necessary evidence to demonstrate that they meet the earlier foundational and objective TPNIES criteria. This approach is consistent with the way that NTAP applications are assessed in the annual IPPS rule.

Final Rule Action: After consideration of the public comments received, we are finalizing our clarification regarding the sequential order of CMS review of the TPNIES eligibility criteria as proposed. In the annual ESRD PPS proposed rule, we will continue to summarize the information from the application regarding each of the six eligibility criteria and include any questions or concerns that we identify during our analysis of the application. As CMS proceeds through the sequential analysis of the six TPNIES eligibility criteria in the ESRD PPS final rule for a particular equipment or supply, once we determine that the item has failed to demonstrate having met one of the eligibility criteria, the item will be ineligible for the TPNIES. We will limit our analysis in the final rule to the TPNIES criterion that is not met and any preceding criteria and will not include the analysis of the remaining criteria in the final rule. This policy will be effective January 1, 2024 and will apply to our analysis of TPNIES applications for CY 2025 payment.

b. Clarifications Regarding the TPNIES Newness Criterion (§ 413.236(b)(2))

As stated previously, applicants must meet the newness criterion in § 413.236(b)(2) to qualify for the TPNIES. CMS defines the TPNIES newness criterion at § 413.236(b)(2) as within 3 years beginning on the date of the FDA marketing authorization. In the CY 2024 ESRD PPS proposed rule (88 FR 42476), we clarified two distinct aspects of the criterion that are consistent with our current TPNIES policies and would not represent any changes to the eligibility criteria: (1) the 3-year newness period and (2) FDA marketing authorization.

First, with respect to the 3-year newness period, we stated in the CY 2021 ESRD PPS final rule that by defining new as within 3 years beginning on the date of the FDA marketing authorization, we limit eligibility for the TPNIES to new technologies but allow prospective TPNIES applicants 3 years beginning on the date of FDA marketing authorization in which to submit their applications (85 FR 71410 through 71464).

To further clarify the timeframe during which a prospective TPNIES applicant is eligible to apply, in the CY 2024 ESRD PPS proposed rule (88 FR 42476), we proposed to modify our regulation to specify that the applicant would have 3 years from the date of FDA marketing authorization to apply for the TPNIES, based on the date the application is submitted. We noted that this modification is consistent with current policy, and while it is not a change in policy, we believe that clarifying the regulation text would help to eliminate any confusion about the 3-year newness period. As indicated in § 413.236(c), February 1 prior to the particular CY is the annual TPNIES application submission deadline. We proposed to clarify that the 3-year newness period is only for submission of the complete application. An applicant does not have to ensure that CMS renders its determination through notice and comment rulemaking within the 3-year newness period. Specifically, we proposed to revise § 413.236(b)(2) to clarify that the equipment or supply is new if a complete application has been submitted to CMS under § 413.236(c) within 3 years of the date of the FDA marketing authorization.

Second, with respect to the requirement in § 413.236(b)(2) that the equipment or supply must have FDA marketing authorization, we proposed to clarify that an equipment or supply with FDA Exempt status would not meet the newness criterion and therefore would not be eligible for the TPNIES. As described on the FDA website, the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act established three regulatory classes for medical devices: Class I, Class II, and Class III. The three classes are based on the degree of control necessary to assure the various types of devices are safe and effective.[65] Most Class 1 and some Class II devices, as noted on FDA's website, are exempt from premarket notification (510(k)) requirements, subject to certain limitations.[66] As we stated in the CY 2023 ESRD PPS final rule (87 FR 67202 through 67023), devices that receive FDA marketing authorization have met regulatory standards that provide a reasonable assurance of safety and effectiveness for the devices. For exempt devices, FDA has determined that a premarket notification is not required to provide a reasonable assurance of safety and effectiveness for the devices. However, generally a Class I or Class II device that is exempt from 510(k) requirements still must comply with certain regulatory controls (known as ''general controls'') to provide a reasonable assurance of safety and effectiveness for such devices. In limiting the TPNIES policy to items that have received FDA marketing authorization, we intended to exclude devices that lack FDA marketing authorization (87 FR 38511). In the absence of evidence that the renal dialysis equipment or supply is new, meaning a complete application has been submitted to CMS under § 413.236(c) within 3 years of the date of the FDA marketing authorization, the equipment or supply would not meet the TPNIES newness criterion under § 413.236(b)(2).

We received 11 comments on our proposed clarifications regarding the TPNIES newness criterion at § 413.236(b)(2). These comments and CMS's responses are set forth below.

Comment: In general, commenters supported both TPNIES clarifications. Commenters supported our proposal to revise § 413.236(b)(2) to clarify that the equipment or supply is new if a complete application has been submitted to CMS under § 413.236(c) within 3 years of the date of the FDA marketing authorization and stated that basing the three-year newness period on the date of the TPNIES application submission, and not the date of CMS's determination through notice and comment rulemaking would ensure that months of eligibility are not taken up by the determination process.

With respect to our proposal that an equipment or supply with FDA Exempt status would not meet the newness criterion and therefore would not be

[65] Food & Drug Administration. Learn if a Medical Device Has Been Cleared by FDA for Marketing. Available at: *https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing.* Accessed on March 14, 2023.

[66] Food & Drug Administration. Class I and Class II Device Exemptions. Available at: *https://www.fda.gov/medical-devices/classify-your-medical-device/class-i-and-class-ii-device-exemptions.* Accessed on May 30, 2023.

eligible for the TPNIES, one commenter stated that this policy would limit access to the TPNIES. The commenter stated that because exempt devices must still comply with general controls to provide a reasonable assurance of safety and effectiveness, these devices have no need to apply for FDA marketing authorization, and an FDA determination should not exclude these devices from the TPNIES. This commenter asserted that CMS should incentivize innovation in the ESRD space by allowing all relevant and appropriate technologies an opportunity to apply for the TPNIES.

Response: We appreciate the commenters' overall support for our clarifications regarding the TPNIES newness criterion. Regarding our proposed clarification that an equipment or supply with FDA Exempt status would not meet the newness criterion, we emphasize that for the purposes of the TPNIES, we rely on FDA marketing authorization to ensure that devices have met regulatory standards that provide a reasonable assurance of safety and effectiveness. While a Class I or Class II device that is exempt from 510(k) requirements still must comply with certain regulatory controls (known as ''general controls'') to provide reasonable assurance of safety and effectiveness for such devices, we do not believe devices with Exempt status offer the level of assurance that is provided with FDA marketing authorization. As such, we maintain that our original intent was to exclude devices that lack FDA marketing authorization (87 FR 38511).

Final Rule Action: After considering public comments, we are finalizing as proposed our proposal to revise § 413.236(b)(2) to clarify that the equipment or supply is new if a complete application has been submitted to CMS under § 413.236(c) within 3 years of the date of the FDA marketing authorization. We are also finalizing as proposed our proposed clarification that an equipment or supply with FDA Exempt status would not meet the newness criterion and therefore would not be eligible for the TPNIES. In the absence of evidence that the renal dialysis equipment or supply is new, meaning a complete application has been submitted to CMS under § 413.236(c) within 3 years of the date of the FDA marketing authorization, the equipment or supply would not meet the TPNIES newness criterion under § 413.236(b)(2).

We received one application for the TPNIES for CY 2024. A discussion of the application is presented below.

3. CY 2024 TPNIES Application for Buzzy® Pro

Pain Care Labs™ submitted an application for the TPNIES for Buzzy® Pro for CY 2024. Buzzy® Pro is one of several models of the Buzzy® device. The Buzzy® device is intended to control pain associated with needle procedures and for temporary relief of minor injuries. Buzzy® Pro is a palm-sized external use vibration device used with unique ice packs and is intended to temporarily desensitize and physiologically block pain associated with dialysis cannulation. The applicant stated that dialysis cannulation pain affects 12 to 80 percent of dialysis patients and is a substantial contributor to reduced quality of life.[67] [68] The applicant further stated that cannulation pain is associated with fear of the cannulation process, the decision to undergo hemodialysis and sometimes the hemodialysis itself.

The applicant described the steps for using Buzzy® Pro during dialysis: (1) thread the hands free strap or regular tourniquet through the ice pack and the device so that the ice pack is on the concave side of the device; (2) attach the device and the ice directly over the site; (3) activate the vibration toggle switch and leave in place 30 to 120 seconds; (4) during cannulation, move the device proximally so the dot on the side opposite the switch is 2 to 3 cm proximal to the cannulation site; (5) clean the site per cannulation protocol; and (6) remove the device after the painful part of procedure is completed.

a. Renal Dialysis Service Criterion (§ 413.236(b)(1))

Regarding the first TPNIES eligibility criterion in § 413.236(b)(1), that the item has been designated by CMS as a renal dialysis service under § 413.171, pain management associated with dialysis cannulation is a service that is furnished to individuals for the treatment of ESRD and is essential for the delivery of maintenance dialysis. We consider Buzzy® Pro a renal dialysis service under § 413.171.

b. Newness Criterion (§ 413.236(b)(2))

With respect to the second TPNIES eligibility criterion in § 413.236(b)(2), that the item is new, meaning within 3 years beginning on the date of the FDA marketing authorization, the applicant stated that it is seeking 510(k) marketing authorization from the FDA for a new utility and design of Buzzy® created for dialysis fistulae sites, patented in 2022 under the name Buzzy® Pro. To be eligible for the TPNIES, the applicant must apply within 3 years of the FDA marketing authorization date and receive FDA marketing authorization by the HCPCS Level II deadline of July 3, 2023.

The applicant submitted the indications for use portion of its FDA 510(k) application that identifies Buzzy® as all Buzzy® models: Mini Healthcare, XL Healthcare, Mini Personal, XL Personal and Pro to control pain associated with needle procedures including dialysis and the temporary relief of minor injuries. The applicant provided supplemental information in a document titled ''510(k) Summary'' that included a comparison table of the Predicate Device (K130631) to the Subject Device (K202993). The document indicated that only the Buzzy® Pro model is recommended for dialysis. The document also indicated that Buzzy® Pro is identical to the predicate device in terms of materials, vibration motor, circuitry, functionality, and intended use; differs only in shape but is comparable in size to the predicate device; and Buzzy® Pro is distinguished by its rectangular shape to offer users a more professional looking alternative to the bee-shape of the other device. In the CY 2024 ESRD PPS proposed rule, we stated that we would be interested in better understanding the way in which the Buzzy® Pro, that is the subject of this TPNIES application, differs from the other Buzzy® models and whether Buzzy® Pro is indicated for adult versus pediatric patients, or both. We noted that to satisfy the newness criterion, the FDA 510(k) marketing authorization must have been issued within 3 years covering the specific device and model that is the subject of the TPNIES application. We invited public comment on this issue in the proposed rule.

Comment: The applicant submitted a comment to demonstrate that the device meets the newness criterion. With respect to our question regarding the way in which the Buzzy® Pro, which is the subject of this TPNIES application, differs from the other Buzzy® models, the applicant provided a table comparing Buzzy® Pro and predicate Buzzy® devices and stated that Buzzy® Pro is identical to the predicate devices in terms of materials, vibration motor, circuitry, functionality, curvature to fit the angle of the arm, and the mnemonic design with a ''dot'' to put near the

[67] Kosmadakis G, Amara I, Costel G. Pain on arteriovenous fistula cannulation: A narrative review. Semin Dial 2021;34(4):275–84 doi: 10.1111/sdi.12979 [published Online First: 20210507].

[68] Kosmadakis G, Amara B, Costel G, Lescure C. Pain associated with arteriovenous fistula cannulation: Still a problem. Nephrol Ther 2022;18(1):59–62 doi: 10.1016/j.nephro.2021.05.002 [published Online First: 20210618].

''shot.'' The applicant stated that Buzzy® Pro is thinner, lighter, and has dual arms to attach to the cannulation site compared to the predicate device; and Buzzy® Pro offers users a more professional looking alternative to the bee-shape of the other device.

With respect to FDA marketing authorization, the applicant indicated that Buzzy® Pro received FDA 510(k) approval on May 15, 2023, to control pain associated with needle procedures (for example, injections, vascular access, cannulation, lab draws, blood donation, dialysis, cosmetic and dental injections).

Response: We appreciate the applicant's clarification regarding Buzzy® Pro's similarity to its predicate devices and confirmation of FDA marketing authorization. Based on the information provided by the applicant, we agree that Buzzy® Pro meets the newness criterion.

c. Commercial Availability Criterion (§ 413.236(b)(3))

Regarding the third TPNIES eligibility criterion in § 413.236(b)(3), that the item is commercially available by January 1 of the particular CY, meaning the year in which the payment adjustment would take effect, the applicant stated that it expects Buzzy® Pro would be commercially available immediately after receiving FDA marketing authorization.

Comment: The applicant submitted a comment indicating that as of May 15, 2023, Buzzy® Pro is commercially available.

Response: Based on the information provided by the applicant, Buzzy® Pro meets the commercial availability criterion.

d. HCPCS Level II Application Criterion (§ 413.236(b)(4))

Regarding the fourth TPNIES eligibility criterion in § 413.236(b)(4) requiring that the applicant submit a complete HCPCS Level II code application by the HCPCS Level II application deadline of July 3, 2023, the applicant stated that it intends to apply by the deadline.

Comment: The applicant submitted a comment indicating that the HCPCS Level II code application was submitted to CMS on July 1, 2023.

Response: We appreciate the applicant's confirmation of having submitted the HCPCS Level II code application and confirm that CMS received the application by the deadline. Therefore, we agree the applicant has met the HCPCS Level II application criterion.

e. Innovation Criteria (§§ 413.236(b)(5) and 412.87(b)(1))

(1) Substantial Clinical Improvement Claims and Sources

With regard to the fifth TPNIES eligibility criterion under § 413.236(b)(5), that the item is innovative, meaning it meets the substantial clinical improvement criteria specified in § 412.87(b)(1), the applicant presented two substantial clinical improvement claims. First, the applicant stated that Buzzy® Pro controls needle pain for dialysis. Specifically, per the applicant, Buzzy® Pro makes cannulation pain relief available to dialysis patients, which significantly improves clinical outcomes related to depression and discontinuation of dialysis due to needle pain. Second, the applicant stated that Buzzy® Pro reduces needle fear.

With respect to the claim that Buzzy® Pro controls needle pain for dialysis, the applicant stated that currently, the most effective options for dialysis cannulation pain are the topical anesthetic, EMLA® and vapocoolant spray.[69] Per the applicant, systematic reviews recommend against vapocoolant use due to lack of efficacy[70] and EMLA® incurs $15 cost per use and takes 1 hour to become effective. The applicant asserted that the Buzzy® device has been shown to be superior to vapocoolant spray[71] and equivalent to topical anesthetics EMLA® and LMX® at a fraction of the cost and time.[72] [73] The applicant stated that while ice is effective for reducing dialysis pain for both adults and children, it is messy and inferior. The applicant further stated that a Buzzy® device cannulation study in adults found that ice is only 10 percent of the effect, with the mechanical gate control neuromodulation (vibration) providing 90 percent of the pain relief.[74]

With respect to the claim that Buzzy® Pro reduces needle fear, the applicant stated that 25 to 47 percent of chronic kidney patients have needle fear.[75] The applicant further stated that CDC recommends vibrating cold devices for needle fear in children, and cold devices with a buzzer for adults.[76] The applicant also stated that meta-analyses demonstrate significant fear reduction with Buzzy® device,[77] and a New Zealand study demonstrated improved adherence to Bicillin injections with fear reduced 50 percent after three uses of Buzzy® device.[78] The applicant also stated that Buzzy® device is indicated by Health Canada to ''control pain and fear from needles'' and is used for fearful dialysis patients in the Netherlands.

The applicant submitted 33 unique sources of evidence with its application in support of its claims of substantial clinical improvement. Thirty of the sources that were submitted examined the effect of external cold and vibration devices, including the Buzzy® device, though not Buzzy® Pro, during needle procedures other than dialysis cannulation. One article examined the effect of cryotherapy on pediatric pain management at the arteriovenous fistula site during hemodialysis.[79] Because the

[69] Çelik G, Özbek O, Yılmaz M, Duman I, Özbek S, Apiliogullari S. Vapocoolant spray vs lidocaine/prilocaine cream for reducing the pain of venipuncture in hemodialysis patients: a randomized, placebo-controlled, crossover study. Int J Med Sci 2011;8(7):623–7 doi: 10.7150/ijms.8.623 [published Online First: 20111012].

[70] Hogan ME, Smart S, Shah V, Taddio A. A systematic review of vapocoolants for reducing pain from venipuncture and venous cannulation in children and adults. J Emerg Med 2014;47(6):736–49 doi: 10.1016/j.jemermed.2014.06.028 [published Online First: 20140829].

[71] Baxter AL, Leong T, Mathew B. External thermomechanical stimulation versus vapocoolant for adult venipuncture pain: pilot data on a novel device. Clin J Pain 2009;25(8):705–10 doi: 10.1097/AJP.0b013e3181af1236 [published Online First: 2009/11/19].

[72] Lescop K, Joret I, Delbos P, et al. The effectiveness of the Buzzy® device to reduce or prevent pain in children undergoing needle-related procedures: The results from a prospective, open-label, randomised, non-inferiority study. Int J Nurs Stud 2021;113:103803 doi: 10.1016/j.ijnurstu.2020.103803 [published Online First: 20201019].

[73] Potts DA, Davis KF, Elci OU, Fein JA. A Vibrating Cold Device to Reduce Pain in the Pediatric Emergency Department: A Randomized Clinical Trial. Pediatr Emerg Care 2017 doi: 10.1097/pec.0000000000001041 [published Online First: 2017/01/26].

[74] Abidin NH. Assessing The Effectiveness Of A Thermomechanical Device (Buzzy®) In Reducing Venous Cannulation Pain In Adult Patients. Middle East Journal of Anesthesiology 2018;25(1):61–67.

[75] Duncanson E, Le Leu RK, Shanahan L, et al. The prevalence and evidence-based management of needle fear in adults with chronic disease: A scoping review. PLoS One 2021;16(6):e0253048 doi: 10.1371/journal.pone.0253048 [published Online First: 20210610].

[76] Easy to Read: Needle Phobia. Available at: *https://www.cdc.gov/ncbddd/humandevelopment/covid-19/needle-phobia/index.html.* Accessed March 9, 2023.

[77] Ballard A, Khadra C, Adler S, Trottier ED, Le May S. Efficacy of the Buzzy® Device for Pain Management during Needle-Related Procedures: A Systematic Review and Meta-analysis. Clin J Pain 2019 doi: 10.1097/ajp.0000000000000690 [published Online First: 2019/03/05].

[78] Russell K, Nicholson R, Naidu R. Reducing the pain of intramuscular benzathine penicillin injections in the rheumatic fever population of Counties Manukau District Health Board. J Paediatr Child Health 2014;50(2):112–7 doi: 10.1111/jpc.12400 [published Online First: 2013/10/19].

[79] Attia, A., Hassan, A. Effect of cryotherapy on pain management at the puncture site of arteriovenous fistula among children undergoing hemodialysis. International Journal of Nursing Sciences 2017; (4) 46–51.

study did not examine the effect of external cold and vibration devices such as the Buzzy® device or more specifically the device that is the subject of this TPNIES application, Buzzy® Pro, in managing dialysis related pain or fear, it was not directly applicable to the applicant's substantial clinical improvement claims. One article evaluated the effectiveness of distraction cards, in pediatrics in reducing pain and anxiety during intramuscular injection.[80] Because the study did not examine the effect of external cold and vibration devices such as the Buzzy® device or the Buzzy® Pro device in managing dialysis-related pain or fear, it was not directly applicable to the applicant's substantial clinical improvement claims. One document labeled as Dutch guidelines was submitted in non-English text and thus, was not readily accessible to our review team.

The applicant also submitted a list of references, referred to as a literature review, that pertained to the applicant's products, among which, the Buzzy® device was listed as relieving or reducing needle pain and fear and for needle procedures and for musculoskeletal pain.

In a document titled ''Summary of Clinical Evidence—relief of needle pain and fear,'' the applicant presented the study objectives and key features of 29[81] of the 30 submitted sources that examined the effect of external cold and vibration devices, including the Buzzy® device, though not Buzzy® Pro, during needle procedures other than dialysis cannulation. The document identified several additional sources that were not submitted by the applicant. Finally, the applicant submitted a document titled ''Buzzy Fear reduction rationale and table'' that duplicated information already captured in the ''Summary of Clinical Evidence—relief of needle pain and fear'' document. Table 10 lists the 29 sources that were both identified by the applicant in the ''Summary of Clinical Evidence—relief of needle pain and fear'' document and that were submitted. We have not included sources that were mentioned by the applicant, but not submitted to us.

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[80] Sahiner, N., Turkmen, A. The Effect of Distraction Cards on Reducing Pain and Anxiety During Intramuscular Injection in Children. Worldviews on Evidence-Based Nursing 2019; 1–6.

[81] The following source was not included in the summary table: Redfern RE, Chen JT, Sibrel S, Effects of Thermomechanical Stimulation during Vaccination on Anxiety, Pain, and Satisfaction in Pediatric Patients: A Randomized Controlled Trial. J Pediatr Nurs.2018.38: 1–7.

TABLE 10: Applicant's Substantial Clinical Improvement Sources

O: Study objective; F: Study format; N: Number of participants; P: Study population			
Study Description	**Test Article**	**Results**	**Reference Title**
(1) O: Pain relief and anxiety reduction for pediatric needle procedures F: Systematic review and meta-analysis N=1138 P: 3 – 18 y/o (2) O: Anxiety reduction F: Systematic Review and Meta-analysis N=1138 P: 2-17y	Buzzy	(1) Self-Reported pain reduction -1.11; 95% [CI]: -1.52 to -0.70; P<0.0001) Of 4 studies only assessing lab draws, IV catheter/venipuncture procedures (SMD: −1.30; 95% CI: −1.84 to −0.76 P<0.00001) (2) (Pain reduction -1.11; 95% confidence interval [CI]: -1.52 to -0.70; P<0.0001), anxiety reduction (SMD -1.37; 95% CI: -1.77 to -0.96; P<0.00001)	Ballard A Khadra C, Adler S, Doyon- Trottier E, Le May S. *Efficacy of the Buzzy Device for Pain Management during Needle-Related Procedures: A Systematic Review and Meta-analysis*. Clin J Pain. 2019 June; 35(6):532-543.
O: Pain relief and anxiety reduction for pediatric needle procedures F: Systematic review and meta-analysis N=1479 P: 2 – 18 y/o	Multiple devices	Meta-regression demonstrated a significant negative correlation of pain score with age. For children at 8.5 years, cold vibration reduced the pain score by 0.13 averagely for every increment in year compared with controls (MD -0.13; 95% CI: -0.25, -0.01)	Su HC, Hsieh CW, Lai NM, Chou PY, Lin PH, Chen KH. *Using vibrating and cold device for pain relievers in children: a systematic review and meta-analysis of randomized controlled trials*. J Pediatr Nurs. 2021 Mar 15; 61:23-33.
O: Pain relief for cannulation in pediatrics F: RCT: Buzzy compared to LMX topical anesthetic N=173 P: 18 months – 17 y/o	Buzzy M-stim only	There were no statistically significant differences among treatment groups based on the observational measures of pain or the self-report measures of pain. Findings support the use of both mechanical vibration and topical anesthetic as effective in children regardless of age group or sex.	Bahorski JS, Hauber RP, Hanks C, Johnson M, Mundy K, Ranner D, Stoutamire B, Gordon G. *Mitigating procedural pain during venipuncture in a pediatric population: A randomized factorial study*. Int J Nurs Stud. 2015 Oct;52(10):1553-64.
O: Pain relief and first stick vascular access success in pediatric emergency F: RCT: Buzzy v. Vapocoolant N=81 P: 4 – 18 y/o	Buzzy	Vascular access success more likely w/ Buzzy: (odds ratio, 3.05; 95% CI, 1.03- 9.02), p=.040); Self-reported pain scores lower with Buzzy: (-2; 95% CI, -4 to 0) than with vapocoolant (p=.029). Parent reported pain scores lower with Buzzy (-2; 95% CI -4 to -2) than vapocoolant (p=.005).	Baxter AL, Cohen LL, McElvery HL, Lawson ML, von Baeyer CL. *An integration of vibration and cold relieves venipuncture pain in a pediatric emergency department.* Pediatr Emerg Care. 2011 Dec;27(12):1151-6.

O: Study objective; F: Study format; N: Number of participants; P: Study population			
Study Description	**Test Article**	**Results**	**Reference Title**
(1) O: Pain relief in adult vascular access F: RCT: Buzzy v. Vapocoolant N=31 P: 18+ Years Hospital employees (2) O: Pain relief with cannulation on the dorsum of hand F: Crossover trial rated with VAS N=31 P: Adult healthcare workers	Buzzy	(1) In a crossover trial, Buzzy reduced angiocath placement pain (mean 9.9 mm, 95% [CI] 0.82-19, P=0.035, SD 16) compared to vapocoolant (mean 7.9 mm, 95% [CI]-1.8-17.7, P=0.1, SD 16.9) (2) Each 20mm of pre-procedural fear increased the likelihood of a successful intervention pain relief (odds ratio 2, P=0.043).	Baxter AL, Leong T, Mathew B. *External thermomechanical stimulation versus vapocoolant for adult venipuncture pain: pilot data on a novel device.* Clin J Pain. 2009 Oct;25(8):705-10.
(1) O: Pain and anxiety relief in vascular access procedures in children F: RCT: Buzzy, Buzzy + Cartoons, Cartoons alone, Control/nothing. N=150 P: Mean age 9.4 years (2) O: Fear reduction using Buzzy v. Cartoons v. Nothing v. Buzzy + Cartoons F: RCT N=150 P: Pediatric 5-12 years	Buzzy	(1) Pain: "Buzzy was highly effective in children younger than 9 (p=0.04). Also, a significant efficacy was recorded in the Buzzy and Cartoon group (p=0.04) for the nurse's perception of the child's pain, and in the Buzzy group for the mother's perception of the child's pain (p=0.002)." Anxiety: "Particularly, the difference was statistically significant in the Buzzy (p=0.03) and the Buzzy and animated Cartoon groups (p=0.02) for nurses' perception of the child's anxiety, and in the Buzzy group for mothers' perception of anxiety (p=0.03)." (2) (Children's Emotional Manifestation Scale for anxiety: per nursing and mother evaluation) Nothing -0.26 v. Buzzy -0.86 P=.03. Nothing -0.26 v. Buzzy + Cartoons -0.89 P=.02 Nothing -0.26 v. Cartoons alone -.073 P=.09).	Bergomi P, Scudeller L, Pintaldi S, Dal Molin A. *Efficacy of Non-pharmacological methods of pain management in children undergoing venipuncture in a pediatric outpatient clinic: A randomized controlled trial of audio-visual distraction and External Cold and Vibration.* J Pediatr Nurs. 2018 Sep-Oct; 42: e66-e72.
O: Pain reduction comparison in children during vascular access F: RCT: Buzzy, Bubbles, and Control N=96 P: 3 – 6 y/o	Buzzy	Pain scores were lower in the groups of Buzzy and blowing soap bubbles than the control group. There was no statistical difference between Self Report, Parent Report, Nurse Report, or Researcher Report between Buzzy and Bubbles. The differences between Buzzy or Bubbles and Control was significant for all P=.0000.	Binay Ş, Bilsin E, Gerçeker GÖ, Kahraman A, Bal-Yılmaz H. *Comparison of the Effectiveness of Two Different Methods of Decreasing Pain During Phlebotomy in Children: A Randomized Controlled Trial.* J Perianesth Nurs. 2019 Feb 20 S1089-9472(18)30414-3.

O: Study objective; F: Study format; N: Number of participants; P: Study population			
Study Description	**Test Article**	**Results**	**Reference Title**
O: Superiority trial of pain relief during vascular access F: RCT: Buzzy, Handheld computer distraction N=200 P: 4-12 y/o	Buzzy	No significant difference between a handheld computer distraction and Buzzy, median (IQR) = 3.0 (1.0–4.8) and 2.0 (1.0–4.8), respectively, P = 0.72.	Cozzi G, Crevatin F, Dri V, Bertossa G, Rizzitelli P, Matassi D, Minute M, Ronfani L, Barbi E. *Distraction Using Buzzy or Handheld Computers During Venipuncture*. Pediatr Emerg Care. 2018 Dec 27.
O: Pain relief during pediatric vascular access F: RCT: Virtual Reality (VR) versus Buzzy N=121 P: 7 - 12 y/o	Buzzy	Buzzy resulted in lower pain than VR and significantly better than control, P = 000). Buzzy n=40; 1.5 +/- .2SD versus VR n=41; 2 +/- .2SD, p<.0001).	Gerçeker GÖ, Binay Ş, Bilsin E, Kahraman A, Yılmaz HB. *Effects of Virtual Reality and External Cold and Vibration on Pain in 7- to 12-year- old Children During Phlebotomy: A Randomized Controlled trial*. J Perianesth Nurs. 2018 Mar 17.
O: Pain Relief for vascular access with Buzzy, Buzzy + Distraction, Distraction, and Control F: RCT: 4 arm trial N=218 P: 6 - 12 y/o	Buzzy	All groups using Buzzy had significantly reduced pain (P < 0.001) compared to the control group. Lowest pain measured w/Buzzy in combination w/DistrAction Cards.	Inal S., Kelleci M. *The Effect of External Thermomechanical Stimulation and Distraction on Reducing Pain Experienced by Children During Blood Drawing*. Pediatr Emerg Care. 2020 Feb;36(2):66-69.
(1) O: Pain relief during vascular access in pediatric patients F: RCT: [Buzzy v. control] N=120 P: 6 - 12 y/o (2) O: Pain and anxiety relief with lab draws F: RCT using Child Pain Scale N=120 P: 6-12y/o	Buzzy	(1) Lower pain (p < .001) and anxiety (p < .001 w/ Buzzy) compared to the control group. (2) (Lower pain (p < .001) and anxiety with Buzzy. CAPS Parent reported 1.61(Buzzy) v. 3.36 (Control) (p < .001))	Inal S, Kelleci M. *Relief of pain during blood specimen collection in pediatric patients*. MCN Am J Matern Child Nurs. 2012 Sep;37(5):339-45. PMID: 22895207.
(1) O: Pain, stress cortisol level, and fear relief during vascular access comparing Buzzy, Jet Lidocaine, Bubbles and aromatherapy F: RCT N=195, 39 x 5 groups P: 5 – 10 y/o (2) O: Pain, stress cortisol level, and fear relief during vascular access comparing Buzzy, Jet Lidocaine, Bubbles and aromatherapy F: RCT N=195, 39 x 5 groups P: 5 – 10 y/o	Buzzy	"A significant difference was found between the intervention and control groups in terms of levels of pain during and after phlebotomy in favor of the Buzzy group (p<0.05)." (2) ("children in the Buzzy group were less frightened during phlebotomy (CFS 1.33 v. 2.66 p < 0.05)." "There was a significant difference between intervention and control groups fear levels in favor of the Buzzy group during phlebotomy (p< 0.05)."	Küçük Alemdar D, Yaman Aktaş Y. *The use of the Buzzy, Jet lidocaine, bubble-blowing and aromatherapy for reducing pediatric pain, stress and fear associated with phlebotomy*. J Pediatr Nurs. 2019 Jan 30 S0882-5963(18)30352- X.

O: Study objective; F: Study format; N: Number of participants; P: Study population			
Study Description	**Test Article**	**Results**	**Reference Title**
O: Pain and anxiety in adults during cannulation using Buzzy or control. F: RCT N=100 P: Mean age: 49.6 +/- 13.8y	Buzzy	Pain was less than expected in 44/50 Buzzy patients and 0/50 control, and more than expected in no Buzzy patients and 6/50 control (P<.000), with overall less pain (1.04 v 5.32) and greater satisfaction. (95.3 v 2.12) P<.001. There was no difference in pulse, state, or trait anxiety before or after cannulation.	Pakiş Çetin S, Çevik K. *Effects of Vibration and Cold Application on Pain and Anxiety During Intravenous Catheterization*. J Perianesth Nurs. 2019 Aug:34(4):701-709.
O: Pain relief during vascular access in children with cognitive impairment F: RCT: Buzzy v. Control N=70 P: Median age – 9 y/o	Buzzy	"Reported no or mild procedural pain in 32 cases (91.4%) in the Buzzy group and in 22 cases (61.1%) in the no-intervention group (p = 0.003)."	Schreiber S, Cozzi G, Rutigliano R, Assandro P, Tubaro M, Cortellazzo Wiel L, Ronfani L, Barbi E. *Analgesia by cooling vibration during venipuncture in children with cognitive difficulties*. Acta Paediatr. 2016 Jan;105(1): e12-6.
O: Efficacy of Buzzy for pain reduction in children F: RCT N=72 P: 3 – 10 y/o	Buzzy	Buzzy pain 3.65 vs Magic Glove 4.67 (p=.039).	Susam V. Friedel M, Basile P, Ferri P, Bonetti L. *Efficacy of the Buzzy System for pain relief during venipuncture in children: a randomized controlled trial*. Acta Biomed. 2018 Jul 18;89(6-S):6-16.
(1) O: Effect of Buzzy, distraction cards, and balloons in reducing pain and anxiety in children receiving procedure requiring vascular access F: RCT N=180 P: 7 – 12 y/o (2) O: Fear reduction with venipuncture F: RCT with CFS N=180 P: pediatrics 9.3 +/- 1.9 years	Buzzy	(1) Lowest pain scores with Buzzy (1.90±1.34) vs Distracting cards (3.17±2.13) vs Balloon inflating (2.83±1.41) vs control (4.15±1.29), (p=0.012) (2) (Fear with Children's Fear Scale lowest with Buzzy (0.61) versus control (3.17), one way ANOVA with 4 arms p=.13 "clinically significant rather than statistically significant." – p <.0001 if Buzzy compared to control, p=.003 if compared to Balloon inflating (CFS 1.19).	Tork HM *Comparison of the Effectiveness of Buzzy, Distracting Cards and Balloon Inflating on Mitigating Pain and Anxiety During Venipuncture in a Pediatric Emergency Department*. Am J Nursing Science 2017 Feb;6(2):26- 32.
O: Effect of vibration on outpatient vascular access in children F: Retrospective review N=64 P: 4 – 18 y/o	Buzzy	"21 of the 26 [phlebotomists'] (80.8%) responses provided indicated that the device made the procedure easier; the other 5 claimed that it had no effect."	Whelan HM, Kunselman AR, Thomas NJ, Moore J, Tamburro RF. *The impact of a locally applied vibrating device on outpatient venipuncture in children*. Clin Pediatr (Phila). 2014Oct;53(12):1189-95.

O: Study objective; F: Study format; N: Number of participants; P: Study population			
Study Description	**Test Article**	**Results**	**Reference Title**
(1) O: Effect of vibration in reducing needle pain in children F: Systematic review N= 264 P: 0 - 18 y/o (2) O: Identify, evaluate and synthesize evidence of the effectiveness of vibratory stimulation to reduce needle-related procedural pain in children aged 18 years and younger. F: Systematic Review N=n/a P: 0 – 18 y/o	Buzzy	(1) "The effect size for the Buzzy tended to be higher than that for the other devices." "Buzzy self-rated pain (n=): -0.94, [95% CI]: -1.54, -0.35) p<.00001. [With Buzzy] the effect on the child's anxiety (SMD: -1.03, 95% CI: -1.85 to - 0.20 p<.00001) was significant." (2) Comparison devices DentalVibe and Vibrational Anesthesia Device used primarily or exclusively for Dental procedures. "The effect size for the Buzzy tended to be higher than that for the other devices. Overall, vibratory stimulation was significantly effective: self-rated pain: -0.55, 95% confidence interval [95% CI]: -0.92 to -0.18) observer-rated pain outcomes (SMD: -0.47, 95% CI: -0.76 to -0.18)."	Ueki S, Yamagami Y, Makimoto K. *Effectiveness of vibratory stimulation on needle-related procedural pain in children: a systematic review*. JBI Database System Rev Implement Rep. 2019 Jul;17(7):1428-1463.
O: Effect of the Use of Buzzy during Phlebotomy on Pain and Individual Satisfaction in Blood Donors F: Abstract N=90 P: Adult men	Buzzy	"Results indicate that the use of the Buzzy device was an effective method of reducing the pain of phlebotomy and increasing phlebotomy satisfaction in healthy adult male blood donors." [N=90, Pain 20.93 +/- 15.1 versus 35.23 +/- 19.3, p=.004, satisfaction Buzzy 76.0 +/- 23.7 v. 55.26 +/- 34.8 control, (p =.031)].	Yilmaz D., Heper Y., Gözler. *Effect of the Use of Buzzy during Phlebotomy on Pain and Individual Satisfaction in Blood Donors. Pain Management Nursing*. 2017 Aug;18(4):260-267. PMID: 28601479.
(1) O: Pain relief during intraoral injections using FLACC F: RCT N=50 P: 5-10 y/o (2) O: Oral dental injections F: RCT FLACC N=50 P: 5-10 years	Buzzy	(1) Conclusion: "Buzzy® can reduce pain and anxiety during local anesthetic delivery for various dental procedures". 1.4 Buzzy, 3.96 Conventional using FLACC, p<.05 (2) "Buzzy® can reduce pain and anxiety during local anesthetic delivery for various dental procedures." FLACC 1.4 Buzzy, 3.96 Conventional, p<.05	Suohu T, Sharma S, Marwah N, et al. A Comparative Evaluation of Pain Perception and Comfort of a Patient Using Conventional Syringe and Buzzy System. Int J Clin Pediatr Dent 2020;13(1):27-30.
O: Pain and anxiety relief for cannulation F: RCT VAS anxiety VAS pain N=176 P: 7-12 y/o	Buzzy	(WBFS pain Buzzy 2.75, Control 5.7 p=0.000, VAS pain Buzzy 1.66, Control 4.09 p=.000; VAS anxiety Buzzy 0.94, Control 2.09 p=.000; VAS observer anxiety Buzzy 0.92, Control 2.14 p=.000.).	Canbulat N, Ayhan F, Inal S. *Effectiveness of external cold and vibration for procedural pain relief during peripheral intravenous cannulation in pediatric patients*. Pain Manag Nurs. 2015 Feb;16(1):33-9.

O: Study objective; F: Study format; N: Number of participants; P: Study population			
Study Description	**Test Article**	**Results**	**Reference Title**
O: Pain and anxiety relief for vascular access with Child Fear Score F: RCT Virtual Reality v. Distraction cards v. Buzzy v control N=142 P: 7-12 y/o	Buzzy	"According to all raters, the Buzzy® group had the lowest mean CFS score, followed by the VR, DC, and control groups ($p < 0.05$)."	Erdogan B, Ozdemir AA. *The Effect of Three Different Methods on Venipuncture Pain and Anxiety in Children: Distraction Cards, Virtual Reality and Buzzy (Randomized Controlled Trial)*. J Pediatr Nurs. May-Jun 2021;58:e54-e62.
O: Pain, fear and anxiety from vaccination F: Systematic Review 27 articles N=n/a P: 4 – 15 years	Buzzy	"This review found consistent evidence for reduction in pain, distress and/or fear with interventions that combined cooling and vibrating together…" [pooled data not reported].	Lee VY, Caillaud C, Fong J, Edwards KM. *Improving vaccine-related pain, distress or fear in healthy children and adolescents-a systematic search of patient-focused interventions*. Hum Vaccin Immunother. 2018;14(11):2737-2747.
O: Anxiety and pain reduction with cannulation F: RCT Buzzy v control N=105 P: Elective Surgical Adults	Buzzy	(In subjects who reported higher pre procedure anxiety, the experimental [Buzzy] group reported lower pain (0.84 ± 0.50) than the control group (3.92± 0.58).	Redfern RE, Micham J, Sievert D, Chen JT. *Effects of Thermomechanical Stimulation During Intravenous Catheter Insertion in Adults: A Prospective Randomized Study*. J Infus Nurs. 2018 Sept/Oct;41(5):294-300.
O: Pain relief with flu vaccination F: RCT VAS, 10-point satisfaction scale N=497 P: Adult employees influenza vaccine clinic	Buzzy	(pain 0.87 v 1.12 p=.035, better than previous experiences 62% Buzzy 23.9% control p<.0001.) "Buzzy can be used in adult patients to reduce pain during immunization and is especially effective in those with high levels of anxiety."	Redfern RE, Micham J, Seegert S, Chen JT. Influencing Vaccinations: A Buzzy *Approach to Ease the Discomfort of a Needle Stick – a prospective, Randomized Controlled Trial*. Pain Management Nursing, 2019 Apr;20(2):164-169.
O: Reduction in fear and pain with Bicillin injections F: Observational prospective interventional trial N=118 P: Teens and Adults	Buzzy	(Nonadherent group offered Buzzy, LA bicillin, or both; overall pain and fear reduced 50%, Special needle phobia clinic able to be disbanded.)	Russell K, Nicholson R, Naidu R. *Reducing the pain of intramuscular benzathine penicillin injections in the rheumatic fever population of Counties Manukau District Health Board*. J Paediatr Child Health. 2014 Feb;50(2):112-7.
O: To investigate the effect of the Buzzy application on pain and satisfaction during injections. F: RCT N=65 P: Average age 52	Buzzy	(Pain 74% reduced, satisfaction 95 v. 84. P<.001 both favor Buzzy).	Sahin M. *Effect of Buzzy® application on pain and injection satisfaction in adult patients receiving intramuscular injections*. Pain Management Nurs2018 Dec:19(6):645.

O: Study objective; F: Study format; N: Number of participants; P: Study population			
Study Description	**Test Article**	**Results**	**Reference Title**
O: Immunization pain and fear reduction Buzzy v. control with TdAP F: RCT Children Fear Scale N=104 P: 7-year-olds	Buzzy	Buzzy: 0.58 +/- 0.63 v. 1.96 +/- 1.13 p=.001 Finding: The experimental group showed significantly lower pain and anxiety levels than the control group during immunization. Conclusions/implications for practice: The combined stimulation of skin with external cold and vibration can be used to reduce pain and anxiety during pediatric immunization.	Sahiner NC, Inal S, Akbay AS. *The effect of combined stimulation of external cold and vibration during immunization on pain and anxiety levels in children.* J Perianesth Nurs. 2015 Jun;30(3):228-35.
O: Buzzy Bubbles Shotblocker or nothing for IM injections F: RCT 4 arm N=160 P: 5-10 years	Buzzy	Results: A significant difference was found between the intervention and control groups in terms of levels of pain and fear during IM injection. Pain and fear were notably less in the group of children receiving the Buzzy intervention. Discussion: The Buzzy intervention should be used when children are undergoing IM injections to reduce their levels of pain and fear.	Yilmaz G, Almdar DK. *Using Buzzy, Shotblocker, and Bubble Blowing in a Pediatric Emergency Department to Reduce the Pain and Fear Caused by Intramuscular Injection: A Randomized Controlled Trial.* J Emerg Nurs. 2019 Sep;45(5):502-511.

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(2) CMS Assessment of Substantial Clinical Improvement Claims and Sources

As discussed in the CY 2024 ESRD PPS proposed rule (88 FR 42484 through 42485), we summarized our specific concerns regarding application of the substantial clinical improvement criteria under §§ 413.236(b)(5) and 412.87(b)(1) in connection with the submission.

As stated previously, the applicant must demonstrate that the equipment or supply meets at least one of the following three substantial clinical improvement criteria in order to be eligible for the TPNIES: (1) the item offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatment; (2) the item offers the ability to diagnose a medical condition in the patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods; or (3) the item significantly improves clinical outcomes relative to services or technologies previously available. The applicant stated that Buzzy® Pro makes dialysis cannulation pain relief available to dialysis patients, which significantly improves clinical outcomes related to depression and discontinuation of dialysis due to needle pain. Therefore, in the proposed rule, we noted our belief that the applicant was targeting the clinical outcomes criterion (previously noted number (3)). The applicant also stated that Buzzy® Pro reduces needle fear. In the proposed rule, we also noted that we did not identify evidence within the application or the submitted materials documenting improved clinical outcomes related to depression or dialysis adherence but would be interested in reviewing such evidence.

With respect to the submitted evidence, we noted that it did not appear that the studies reflected the use of (1) Buzzy® Pro, the device that is the subject of the TPNIES application, nor (2) Buzzy® Pro in the context of dialysis cannulation. Specifically, the applicant submitted an application for Buzzy® Pro, indicating that Buzzy® Pro is a new design created for dialysis fistulae sites, patented in 2022. However, the sources submitted were dated prior to the 2022 new design patent date for dialysis fistulae sites. As such, we stated that it appeared that the sources submitted reflected the use of a predecessor Buzzy® device. In addition, while the applicant's ''Summary of Clinical Evidence'' document presented sources as evaluating Buzzy® Pro's efficacy in managing vascular access pain or fear, we noted that none of these sources appear to evaluate vascular access in the context of dialysis cannulation. The studies evaluated pain and fear in the context of other types of needle procedures, including vaccine or medication injections, blood specimen collection, and intravenous catheter insertion.

We noted that it was unclear whether findings of pain or fear reduction from the use of the Buzzy® device in non-dialysis needle procedures could be extrapolated to dialysis cannulation pain or fear. There are several unique features to dialysis cannulation that may limit generalizability. These include the need for regular punctures several times per week, the maintenance of cannulation for several hours during dialysis treatments, the use of substantially larger needle sizes in dialysis, and complications that are associated with frequent vascular access cannulation, such as infections and thrombosis. As such, we questioned whether outcomes could reasonably be extrapolated as applicable to patients undergoing dialysis cannulation.

As identified in the table, most of the studies provided in support of the applicant's claims reflect pediatric patient experiences. We noted that pediatric patients comprise a small proportion, just 0.14 percent, of the total Medicare ESRD patient population (87 FR 67222). As such, we noted that the data that was heavily weighted towards the pediatric population may have limited generalizability to the non-pediatric majority of the ESRD patient population.

While the applicant stated that the Buzzy® devices are less expensive than topical anesthetic, we noted that cost is not an eligibility criterion for the TPNIES.

We also noted that it was unclear whether a single Buzzy® Pro device and its components (for example, tourniquet and ice pack) are intended for single versus multiple patient use in the ESRD facility setting. To the extent that the device or its components are intended for use among multiple patients, we noted that we would be interested in data that examines the risk of infection associated with the use of Buzzy® Pro in the dialysis patient population. Additionally, we noted that we were not aware of any data that examines the risk of harm to the dialysis access site or any other adverse events associated with use of the Buzzy® Pro in the dialysis patient population, including access and bloodstream infections and thromboses but would be interested in the results of such data.

In addition, the applicant stated that currently, the most effective options for dialysis cannulation pain are topical anesthetics and vapocoolant spray. We noted that we would be interested in studies comparing the use of Buzzy® Pro to topical anesthetics or vapocoolant and that demonstrate that Buzzy® Pro significantly improves clinical outcomes of dialysis patients relative to existing available treatments.

We invited public comments on whether the Buzzy® Pro meets the substantial clinical improvement criteria for the TPNIES.

Comment: We received a comment from the applicant in support of a TPNIES approval for Buzzy® Pro. The applicant stated that there are seven literature-supported parameters by which Buzzy® Pro meets the substantial clinical improvement criteria, any one of which independently would satisfy the standard. The applicant presented the following table highlighting the ways in which Buzzy® significantly improves clinical outcomes relative to renal dialysis services previously available.

[82] Russell K, Nicholson R, Naidu R. Reducing the pain of intramuscular Benzathine penicillin injections in the rheumatic fever populations of Counties Manukau District Health Board. J Paediatr Child Health 2014;50(2):112–7 doi: 10.1111/jpc.12400 [published Online First: 2013/10/19].

Buzzy® Pro Areas of Substantial Clinical Improvement	
Criterion + Source	**Specific Improvement**
Peer-reviewed publications of Buzzy	
1. A more rapid beneficial resolution of the disease process treatment (412.87(b)(1)(ii)(C)(4))	5 minutes for pain management compared to 1h 10 minutes with EMLA saves 169 hours/year
2. Improved quality of life (412.87(b)(1)(ii)(C)(6))	a. Decreased pain compared to vapocoolant spray b. Faster equivalent pain relief with EMLA c. Decreased fear compared to other interventions d. Pain relief access for patients with buttonholes
3. Reduction in at least one clinically significant adverse event (412.87(b)(1)(ii)(C)(1))	a. 25% reduction in severe vasovagal symptoms b. Vasodilation with potential reduction of vessel wall trauma.
Publications of impact of pain and depression addressed by improved availability + pain control	
4. Decrease in the number of future hospitalizations (412.87(b)(1)(ii)(C)(3))	Adherence to regular cannulation reduces hospitalization – Buzzy improves adherence.[82]
5. Improved quality of life (412.87(b)(1)(ii)(C)(6))	Increased feelings of control are correlated with reduced depression.

With respect to the more rapid beneficial resolution of the disease process treatment, the applicant stated that chronic patients consider a reduction in their procedural time a clinically significant improvement.

With respect to improved quality of life, the applicant stated that Buzzy® devices have been shown to be clinically superior to vapocoolant spray for pain relief in adults and children,[83] [84] and that vapocoolant spray lacks efficacy and is associated with potential risks of frostbite or triggering a sickle cell crisis. The applicant stated that EMLA is effective for cannulation pain but requires 60 minutes to become effective and is associated with potential risks, including petechiae and skin breakdown from the occlusive dressing used after applying the cream. The applicant stated that Buzzy® is equivalent to the topical anesthetics EMLA and LMX by patient and parent report and at a fraction of the time.[85] [86] [87] [88]

The applicant stated that Buzzy® decreases fear as compared to other interventions, citing multiple meta-analyses indicating that Buzzy® reduces fear and anxiety in pediatric venipuncture [89] [90] and that Buzzy® was also effective in adult venipuncture patients with needle fear or anxiety.[91] [92] The applicant referred to a generic recommendation for ''buzzing devices'' for adult needle fear on the CDC website.[93]

The applicant stated that 43 percent of dialysis patients experienced pain despite EMLA use [94] and that Buzzy® patients like the sense of control of being able to hold the device in the right spot for the best pain relief.

In support of the claim that Buzzy® reduces at least one clinically significant adverse event, the applicant stated that vibration over 150Hz results in vasodilation, which can reduce the likelihood of a needle side-walling a vein, causing pain or vasovagal stimulation.[95] The applicant referred to a recent study presented in 2023, which found that in 360 teenagers who received vaccination,[96] Buzzy® reduced severe vasovagal symptoms 25 percent and improved vasodilation, potentially reducing vessel wall trauma.

The applicant also provided responses to CMS's concerns identified in the CY 2024 proposed rule. In response to the CMS concern regarding a lack of evidence documenting improved clinical outcomes related to depression or dialysis adherence, the applicant stated that increased feelings of control are correlated with reduced depression. The applicant specified that

[83] Baxter AL, Cohen LL, McElvery HL, Lawson ML, von Baeyer CL. An integration of vibration and cold relieves venipuncture pain in a pediatric emergency department. Pediatr Emerg Care 2011;27(12):1151–6 doi: 10.1097/PEC.0b013e318237ace4.

[84] Baxter AL, Leong T, Mathew B. External thermomechanical stimulation versus vapocoolant for adult venipuncture pain: pilot data on a novel device. Clin J Pain 2009;25(8):705–10 doi: 10.1097/AJP.0b013e3181af1236 [published Online First: 2009/11/19].

[85] Bahorski JS, Hauber RP, Hanks C, et al. Mitigating procedural pain during venipuncture in a pediatric population: A randomized factorial study. Int J Nurs Stud 2015;52(10):1553–64 doi: 10.1016/j.ijnurstu.2015.05.014 [published Online First: 20150610].

[86] Lescop K, Joret I, Delbos P, et al. The effectiveness of the Buzzy(®) device to reduce or prevent pain in children undergoing needle-related procedures: The results from a prospective, open-label, randomised, non-inferiority study. Int J Nurs Stud 2021;113:103803 doi: 10.1016/j.ijnurstu.2020.103803 [published Online First: 20201019].

[87] Potts DA, Davis KF, Elci OU, Fein JA. A Vibrating Cold Device to Reduce Pain in the Pediatric Emergency Department: A Randomized Clinical Trial. Pediatr Emerg Care 2019;35(6):419–25 doi: 10.1097/pec.0000000000001041 [published Online First: 2017/01/26].

[88] Baxter AL, Cohen LL, Tsze D. Buzzy versus EMLA: Abstract omits clinical noninferiority and time and cost savings: A commentary on Lescop et al. (2021). Int J Nurs Stud 2021;121:104011 doi: 10.1016/j.ijnurstu.2021.104011 [published Online First: 20210626].

[89] Ballard A, Khadra C, Adler S, Trottier ED, Le May S. Efficacy of the Buzzy Device for Pain Management during Needle-Related Procedures: A Systematic Review and Meta-analysis. Clin J Pain 2019 doi: 10.1097/ajp.0000000000000690 [published Online First: 2019/03/05].

[90] Su HC, Hsieh CW, Lai NM, Chou PY, Lin PH, Chen KH. Using Vibrating and Cold Device for Pain Relieves in Children: A Systematic Review and Meta-analysis of Randomized Controlled Trials. J Pediatr Nurs 2021;61:23–33 doi: 10.1016/j.pedn.2021.02.027 [published Online First: 20210316].

[91] Baxter AL, Leong T, Mathew B. External thermomechanical stimulation versus vapocoolant for adult venipuncture pain: pilot data on a novel device. Clin J Pain 2009;25(8):705–10 doi: 10.1097/AJP.0b013e3181af1236 [published Online First: 2009/11/19].

[92] Redfern RE, Micham J, Sievert D, Chen JT. Effects of Thermomechanical Stimulation During Intravenous Catheter Insertion in Adults: A Prospective Randomized Study. J Infus Nurs 2018;41(5):294–300 doi: 10.1097/nan.0000000000000294.

[93] *https://www.cdc.gov/ncbddd/humandevelopment/covid-19/needle-phobia/healthcare-providers.html* Accessed September 8, 2023.

[94] *https://www.youtube.com/watch?v=1moJgluvS7c&t=350s* Accessed September 8, 2023.

[95] Skoglund CR. Vasodilatation in human skin induced by low-amplitude high-frequency vibration. Clin Physiol 1989;9(4):361–72.

[96] Smith MJ, Broder KR, Chung RJ, et al. Preventing Post-Vaccination Presyncope and Syncope in Adolescents Using Simple Clinic-Based Interventions: a Randomized-Controlled Trial. Pediatric Academic Societies Meeting. Washington, DC, 2023.

because studies of patients with chronic pain with or without depression have identified self-efficacy as a primary component of effective interventions [97] and because chronic pain and depression are common in dialysis patients,[98] [99] a fast intervention that allows self-adjustment and relief optimization should be more appropriate and effective among patients receiving dialysis than among patients undergoing single, small gauge, and less risky cannulations. The applicant stated that adherence to regular cannulation reduces hospitalization.[100] The applicant also stated that needle fatigue can lead to nonadherence to a treatment plan and that nonadherence increases healthcare costs, emergency department visits, disease complications, and in extreme cases, the likelihood of death.[101]

In response to the CMS concern that the sources submitted reflected the use of a predecessor Buzzy® device, the applicant stated that because Buzzy® Pro received FDA 510(k) approval on May 15, 2023, there are no studies specific to Buzzy® Pro.

In response to the CMS concern that it is unclear whether findings of pain or fear reduction from the use of the Buzzy® device in non-dialysis needle procedures could be extrapolated to dialysis cannulation pain or fear, the applicant asserted that because emergency department venipuncture studies typically involve anxiety, they are appropriate comparators for dialysis, where anxiety is common. The applicant further noted that many dialysis studies do not find a benefit the first time an intervention is attempted. The applicant also stated that adult dialysis cannulation studies that use vapocoolant and topical anesthetic do not evaluate anxiety, and the only studies evaluating anxiety and dialysis cannulation used lavender oil as a comparator.

In response to the CMS interest in studies comparing the use of Buzzy® Pro to topical anesthetics or vapocoolant and that demonstrate that Buzzy® Pro significantly improves clinical outcomes of dialysis patients relative to existing available treatments, the applicant provided the following two summary tables and stated that the numbers given in the tables allow relative comparison between interventions and the pain reported with dialysis cannulation and adult emergency department trials of Buzzy®. The first table summarizes studies of pain or anxiety relief specific to dialysis cannulation and identifies the significant differences in bold text. The second table summarizes Buzzy® outcomes including pain, anxiety, and vasovagal symptom relief in various types of cannulations and identifies the significant differences in bold text.

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Cannulation Studies in Dialysis (significant differences in bold)			
Study Description	**Test Article**	**Results**	**Reference Title**
O: Dialysis pain Randomized crossover trial N= 41 Scale: NRS (0-10)	Vapocoolant or Lidocaine spray or Placebo	**Vapocoolant** -2.29 (95%CI -4.17 to -0.43) Lidocaine Spray NS	Khosravi BMC Anesthesiol 2023(1):69[14]
O: Dialysis: Randomized crossover trial N= 41 Scale: VAS (0-100)	Vapocoolant or EMLA or Placebo	**EMLA -18.1** (10.7 +/- 10.6 VC -14.4 14+/-12.4 Control 28.8+/17.9	Çelik G. Int J Med Sci 2011;8(7):623-7[15]
O: Dialysis: Open crossover design N=38	Vapocoolant Or Placebo Or no treatment	**Vapocoolant** 2.98+/-1.53 Placebo 4.04+/-1.82 No treatment 4.45+/-1.31	Lee 2023 Appl Nurs Res June;71:151674[16]
O: Dialysis: Randomized controlled N=90 NRS (0-10)	EMLA or Valsalva or Control	**EMLA -4.13**(-5.44 – (-2.82)) VM -2.9(-4.2 – (-1.59))	Babamohamadi H, Ev Based Complem med 2022:8383021 e.[17]
O: Dialysis: Prospective crossover N=32	EMLA or Ice Cubes x 5 minutes	"Significant reduction in pain in favor of **[ice cubes]**."	Kortobi L. Saudi J Kidney Dis Trans 202;31(3):597-603[18]
O: Dialysis: Open Crossover Trial N=34 NRS	Lavender Oil or Placebo or Control	**Lavender** 2.91+/-1.69 No intervention 4.59 Placebo 4.18+/-1.66	Ghods A. Comp Ther Med 2015;23(3):325-330[19]
O: Dialysis Randomized Crossover trial N= 74 NRS STAI (anxiety)	Lavender Oil or Placebo	No difference first time **Lavender -2.68 (p=.002)** Anxiety correlated w/ pain	Sahin s. Pain Mgmt Nursing 2021;22(4):519-515[20]

[97] Borsbo B, Gerdle B, Peolsson M. Impact of the interaction between self-efficacy, symptoms and catastrophising on disability, quality of life and health in with chronic pain patients. Disability and rehabilitation 2010;32(17):1387–96 doi: 10.3109/09638280903419269 [published Online First: 2010/06/02].

[98] Davison SN, Jhangri GS. The impact of chronic pain on depression, sleep, and the desire to withdraw from dialysis in hemodialysis patients. J Pain Symptom Manage 2005;30(5):465–73 doi: 10.1016/j.jpainsymman.2005.05.013.

[99] Masià-Plana A, Juvinyà-Canal D, Suñer-Soler R, Sitjar-Suñer M, Casals-Alonso C, Mantas-Jiménez S. Pain, Anxiety, and Depression in Patients Undergoing Chronic Hemodialysis Treatment: A Multicentre Cohort Study. Pain Manag Nurs 2022;23(5):632–39 doi: 10.1016/j.pmn.2022.03.005 [published Online First: 20220422].

[100] Russell K, Nicholson R, Naidu R. Reducing the pain of intramuscular benzathine penicillin injections in the rheumatic fever population of Counties Manukau District Health Board. J Paediatr Child Health 2014;50(2):112–7 doi: 10.1111/jpc.12400 [published Online First: 2013/10/19].

[101] Lee K, Kim D, Lee H, Lee E. The effect of using vapocoolant spray for pain reduction in arteriovenous fistula cannulation among patients undergoing hemodialysis: A randomized control trial. Appl Nurs Res 2023;71:151674 doi: 10.1016/j.apnr.2023.151674 [published Online First: 20230317].

Cannulation Studies using Buzzy® (significant differences in bold)			
Study Description	**Test Article**	**Results**	**Reference Title**
O: Pain relief for cannulation *F: Vibration v cold v sham v both* *N: 184 18-65 years of age*	**4-arm Buzzy trial pain relief vibration v. cold v. combination**	**Buzzy v. + cold:** 33.92 **Buzzy alone**: 34.18 Sham + cold: 39.16 Sham no cold: 43.21 **P=.016 overall v. sham**	Abadin N. M East J Anesthesiology 2018 25(1)
O: Pain relief for cannulation F: RCT: Buzzy compared to **LMX topical anesthetic** N=173 18 months – 17 y/o	**Buzzy M-stim only NO ICE** v. LMX4	Findings support the use of **both mechanical vibration and topical anesthetic as effective**	Bahorski JS, Hauber RP, et al. Int J Nurs Stud. 2015 Oct;52(10):1553-64[21]
O: Pain relief and first stick vascular access success in pediatric emergency F: RCT: Buzzy v. Vapocoolant N=81 4 – 18 y/o	Buzzy v. Vapocoolant	Self-report (-2; 95% CI, -4 to 0) (p=.029) Parent report (-2; 95% CI -4 to -2 (p=.005) **Favor BUZZY** **Vascular access success more likely w/ Buzzy**: (odds ratio, 3.05; 95% CI, 1.03- 9.02), p=.040)	Baxter AL, Cohen LL, McElvery HL, Lawson ML, von Baeyer CL. Pediatr Emerg Care. 2011 Dec;27(12):1151-6[22]
O: Pain relief and cannulation success in vascular access F: Crossover trial N=30 P: adults	Buzzy Vapocoolant	**Buzzy** -9.9 mm, 95% [CI] 0.82-19, P=0.035, SD 16) 100% first stick success Vapocoolant: NS pain reduction, 95% [CI]-1.8-17.7, P=0.1, SD 16.9) 7.14% cannulation failure (vapocoolant)	Baxter AL, Leong T, Mathew B. Clin J Pain. 2009 Oct;25(8):705-10[23]
O: Pain relief during vascular access in pediatric patients F: RCT: [Buzzy v. control] N=120 P: 6 – 12 y/o	Buzzy Control	**Lower pain (p < .001) and anxiety (p < .001 w/ Buzzy) compared to the control group.**	Inal S, Kelleci M. MCN Am J Matern Child Nurs. 2012 Sep;37(5):339-45.[24]
O: Pain and anxiety in adults during cannulation using Buzzy or control. F: RCT N=100 P: Mean age: 49.6 +/- 13.8y	Buzzy Control	Pain: **BUZZY 1.04** c:5.32 Pain **less than** expected: **BUZZY** 44/50 C 0/50 Pain **more than** expected: BUZZY 0/50 **C 6/50** (P<.000) Satisfaction **BUZZY** (95.3 v 2.12) P<.001.	Pakiş Çetin S, Çevik K. J Perianesth Nurs. 2019 Aug:34(4):701-709[25 26]
O: Venipuncture pain with **anxious adults** F: RCT N=105 P: adults mean 63Y	Buzzy v Control	**Pain with high needle anxiety:** Buzzy: 0.84+/- .5 Control: 3.92+/- 0.58	Redfern RE J infusion nursing 2018 41(5):295[26]
O: Pain and Individual Satisfaction in **Blood Donation phlebotomy** F: Abstract N=90 P: Adult men	Buzzy Control	**BUZZY** 20.93 +/- 15.1 Control 35.23 +/- 19.3, p=.004 Satisfaction (p =.031)] Buzzy 76.0 +/- 23.7 Control 55.26 +/- 34.8	Yilmaz D., Heper Y., Gözler. Pain Management Nursing. 2017 Aug;18(4):260- 267.[27]
Vasovagal symptoms with vaccination F: RCT N=340 10-14y	Buzzy + Video v. Standard care	BUZZY 36% presyncope Control 48% presyncope **25% reduction (p=.02)**	Smith M. PAS 2023 (A) NCT04772755[28]

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In response to the CMS concern that the data heavily weighted towards the pediatric population may have limited generalizability to the non-pediatric majority of the ESRD patient population, the applicant referred to materials submitted with its application and asserted that these demonstrate significant pain and fear reduction with the Buzzy® device, superiority to vapocoolant, and equivalency to topical anesthetics but in a shorter period of time. The applicant stated that five independent peer reviewed studies on adult venipuncture using Buzzy®

demonstrate the following: vibration is the primary active ingredient; improved efficacy in patients with needle fear; superiority to vapocoolant spray; and pain reduction and improved satisfaction.

In response to our clarification that cost is not a TPNIES eligibility criterion, the applicant acknowledged our clarification but stated that cost is a barrier to the use of EMLA. The applicant compared the cost of EMLA at $6.48 per cannulation to the cost of Buzzy® at $0.375 per cannulation. The applicant concluded that increased access to pain relief is a substantial clinical benefit that is not currently available due to cost.

In response to the CMS question as to whether a single Buzzy® Pro device and its components (for example, tourniquet and ice pack) are intended for single versus multiple patient use in the ESRD facility setting, the applicant stated that Buzzy® and Buzzy® Pro are made of medical grade plastic in accordance with ISO–13485 and MDSAP standards and can be disinfected with chlorhexidine, alcohol swabs, or any hospital grade cleanser in accordance with the requirements applied to a stethoscope or blood pressure cuff. The applicant further noted that the ice packs are medical grade, intended for a single patient, but can be reused hundreds of times. Per the applicant, the straps are also intended for single-patient use but can be used multiple times in a home setting.

The applicant stated that infection control varies widely based on regional idiosyncrasies and may involve the use of an infection control bag around the ice pack; not using the ice pack; using an infection control bag around both the device and the ice pack; having patients bring their own ice pack; giving the ice pack to the patient following the procedure; or discarding the ice pack.

In response to the CMS interest in data that examines the risk of infection associated with the use of Buzzy® Pro in the dialysis patient population and the CMS interest in data that examines the risk of harm to the dialysis access site or any other adverse events associated with use of the Buzzy® Pro in the dialysis patient population, including access and bloodstream infections and thromboses, the applicant stated that to date, with conservatively over 114,000,000 needle procedures, there are no reported instances of Buzzy® being associated with a vascular access mishap. Per the applicant, the standard risks of vascular damage may be reduced because of the vasodilation. The applicant also stated that because the device goes proximal to the cannulation site when it is being cleaned and accessed, there is never a time when Buzzy® is placed on the area of recent cannulation. The applicant also stated that Buzzy® has been used for dialysis in the Netherlands for four years with only positive reports of efficacy, efficiency, and safety.

The applicant also provided additional information explaining the pain transmission process and its belief that that Buzzy® Pro's mechanical stimulation is an innovative approach in pain management. Specifically, the applicant stated that pain is transmitted to the spine on fast pain nerves and that local mechanisms to reduce pain transmission from skin to spine include lidocaine, cold spray or ice. Per the applicant, as cold travels to the brain on slow C-fibers it activates pain inhibition, which is most effective when applied at temperatures ranging from 0–4C, for a duration of 30 seconds or more, and when applied proximal or distant to the area of pain. The applicant also identified the mechanical stimulation of the fibers which transmit touch sensations as a mechanism for reducing pain, noting that optimal stimulation occurs between 180 and 250Hz. Per the applicant, Buzzy® units provide mechanical stimulation using a 200 Hz vibration motor.

The applicant also presented a new substantial clinical improvement claim, asserting that Buzzy® Pro offers a treatment option for a patient population unresponsive to, or ineligible for currently available treatment options. Specifically, the applicant stated that cost and time are barriers to patients accessing the currently available treatment options for dialysis cannulation pain control and asserted that Buzzy® Pro addresses these barriers. As stated previously, the applicant compared the cost of EMLA at $6.48 per cannulation to the cost of Buzzy® at $0.375 per cannulation and concluded that Buzzy® addresses the cost barrier to patients accessing dialysis cannulation pain relief. The applicant also asserted that the time requirement for using EMLA reduces the likelihood of its use in busy dialysis clinics or if the patient comes in late. The applicant stated that because patients prescribed EMLA for home application prior to treatment at the dialysis clinic often misuse the product, they are unresponsive to EMLA. Per the applicant, Buzzy® works on contact and can easily be applied by the patient. The applicant stated that given the short, 30 to 60 second duration of pain relief obtained from vapocoolant spray, needle pain is a barrier to receiving treatment in the home setting. The applicant also stated that the pain from the mechanical pressure of the dialysis needle inside the vessel cannot be treated with EMLA or vapocoolant spray. The applicant stated that because Buzzy® Pro works proximally to the pain, it is effective for patients who otherwise are unable to access pain control.

We also received several comments from patient advocates supporting the applicant's two substantial clinical improvement claims that Buzzy® Pro reduces pain and anxiety associated with dialysis. A few commenters offered anecdotal experience regarding the use of Buzzy® Pro in the context of dialysis cannulation and stated that Buzzy® Pro's benefits are supported by peer-reviewed scientific literature. Commenters stated that Buzzy® Pro would promote patient choice by providing fast onset dialysis cannulation pain relief without the hassles and expense of topical anesthetics. One commenter suggested that the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey should be updated to capture patient experience with dialysis cannulation pain.

Response: We appreciate the applicant and other commenters' input regarding whether Buzzy® Pro meets the TPNIES innovation criterion at § 413.236(b)(5) and substantial clinical improvement criteria at § 412.87(b)(1). While the applicant stated that there are seven literature-supported parameters by which Buzzy® Pro meets the substantial clinical improvement criteria, it was not clear to us to which parameters or sources of literature the applicant was referring.

In response to our request for evidence of improved clinical outcomes related to depression or dialysis adherence, the applicant stated that because increased feelings of control are correlated with reduced depression, an intervention that allows for self-adjustment and relief should be more effective among patients receiving dialysis than patients undergoing other types of needle cannulations. However, the applicant did not provide direct evidence that interventions to reduce pain in dialysis populations would subsequently reduce depression or that Buzzy® Pro specifically reduces depression. In addition, while the applicant stated that adherence to regular cannulation reduces hospitalization, the evidence cited by the applicant does not pertain to improved dialysis adherence or reductions in hospitalizations. We are not aware of evidence demonstrating

that the use of Buzzy® Pro is associated with the clinical outcome of improved dialysis adherence. Therefore, our request for evidence of improved clinical outcomes related to depression or dialysis adherence associated with the use of Buzzy® Pro in the dialysis patient population has not been sufficiently addressed.

We appreciate the applicant's confirmation that the evidence submitted pertained to studies of the predicate device, Buzzy® and that there are no studies specific to Buzzy® Pro. We also appreciate the applicant's responses to our concern about the absence of evidence that evaluates Buzzy® Pro's efficacy in managing pain or fear in the context of dialysis cannulation rather than in the context of non-dialysis needle procedures. The applicant asserted that emergency department venipuncture studies typically involve anxiety and are therefore appropriate comparators for dialysis, where anxiety is common. We do not believe that the presence of anxiety renders emergency department venipuncture a suitable proxy for dialysis cannulation. In addition, the applicant did not address the unique features of dialysis or the differences between venipuncture and dialysis cannulation that may limit generalizability, including the use of substantially larger needle sizes in dialysis, repeated cannulations thrice weekly, continued cannulation throughout a dialysis session, and complications associated with frequent vascular access cannulation such as infections and thrombosis. As such, we do not believe it is possible to extrapolate outcomes achieved with Buzzy® Pro in the context of non-dialysis needle procedures to dialysis cannulation.

We also appreciate the comments from patient advocates offering anecdotal experience with Buzzy® Pro in the context of dialysis cannulation but would be especially interested in additional detail, including the numbers of patients involved and the specific outcomes that they experienced from Buzzy® Pro. While some commenters asserted that Buzzy® Pro's benefits for the renal dialysis patient population are supported by peer-reviewed scientific literature, because such sources were not provided by the commenters, we were unable to verify these assertions.

While Buzzy® Pro may demonstrate similar results to that of its predicate devices, our primary concern regarding the lack of direct evidence that Buzzy® results in pain or fear reduction in the context of dialysis cannulation pain or fear has not been sufficiently addressed.

In response to our request for studies comparing Buzzy® Pro to topical anesthetics or vapocoolant spray and that demonstrate that Buzzy® Pro significantly improves clinical outcomes of dialysis patients relative to existing available treatments, the applicant's first summary table reflects outcomes specific to dialysis but does not reflect experiences with Buzzy® Pro. While the second table reflects outcomes specific to Buzzy®, it does not capture experience in the dialysis setting. Not all studies included in the summary tables shown previously in this rule were provided with the application or public comment. However, none of the studies appear to specifically examine Buzzy® Pro's efficacy in improving clinical outcomes of dialysis patients as compared to topical anesthetics or vapocoolant spray.

Regarding our concern that data in support of the applicant's claims may have limited generalizability to the non-pediatric majority of the ESRD patient population, the applicant reiterated references from its application to independent peer reviewed studies on adult venipuncture using Buzzy®. These studies compared Buzzy® to no intervention and Buzzy® to vapocoolant or cold interventions. We also note that the applicant referred to a source labeled ''Abedin et. al.,'' but we did not receive the study or the complete citation for this source. Because the studies did not compare Buzzy® to lidocaine and did not take place in the dialysis setting, the applicant has not sufficiently addressed our concern about the generalizability of these studies.

Regarding the applicant's additional evidence since the application submission, we acknowledge the reference to the 1989 study pertaining to vasodilation in human skin and the 2023 study pertaining to the prevention of post-vaccine syncope. While these studies were not submitted to us, similarly to the evidence previously submitted, it does not appear that they assessed the efficacy of Buzzy® Pro in the context of dialysis cannulation.

We appreciate the applicant's clarification regarding use among single vs. multiple patients in the ESRD facility setting and confirmation that to date, there are no reported instances of Buzzy® being associated with a vascular access mishap. However, because the applicant did not specify the percentage of the 114,000,000 needle procedures performed with Buzzy® that pertained to dialysis cannulation, our concern about the lack of data examining the risk of harm to the access site or any other adverse events associated with the use of Buzzy® Pro in the renal dialysis patient population has not been sufficiently addressed.

For the reasons noted previously, we do not believe that there is sufficient evidence to demonstrate that Buzzy® Pro significantly improves clinical outcomes relative to renal dialysis services previously available.

With respect to the applicant's new substantial clinical improvement claim that Buzzy® Pro offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, we acknowledge that patients may appreciate the option of a rapid acting form of dialysis cannulation pain relief. While the applicant stated that Buzzy® offers a more rapid beneficial resolution of the disease process treatment than currently available options, the applicant did not provide additional evidence demonstrating the clinical superiority of Buzzy® Pro over topical lidocaine in the context of dialysis cannulation. Although the applicant stated that lidocaine requires an hour to take full effect, it did not provide evidence that Buzzy® Pro is superior to lidocaine after shorter time frames in the dialysis setting, that shorter timeframes do not provide adequate pain control with topical lidocaine, or that patients are unable to apply lidocaine an hour before their scheduled dialysis treatment. With respect to the applicant's assertion that the higher cost of EMLA as compared to Buzzy® is a barrier to pain relief, we note that because topical lidocaine is included in the pain management category of drugs/biological products included in the ESRD PPS, dialysis facilities would be expected to provide it when determined necessary for the treatment of graft site pain. While cost may be a practical barrier to access for some patients, we do not equate this barrier with either unresponsiveness or ineligibility. In summary, based on the information provided, we are not able to conclude that there is sufficient evidence to demonstrate that Buzzy® Pro offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.

Finally, we note that the comment suggesting that the CAHPS Survey should be updated to capture patient experience with dialysis cannulation pain is beyond the scope of this proposed rule.

In accordance with TPNIES policy and § 412.87(b)(1)(i), we consider the totality of the circumstances when making a determination that a new renal dialysis equipment or supply represents

an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. In addition, per § 412.87(b)(1)(iii), CMS considers a range of evidence from published or unpublished information sources, including other appropriate information sources not otherwise listed under § 412.87(b)(1)(iii).

After carefully reviewing the application, the information submitted by the applicant addressing our concerns raised in the CY 2024 ESRD PPS proposed rule, and comments submitted by the public, we have determined that Buzzy® Pro has not shown that it represents an advance that substantially improves, relative to renal dialysis services previously available, the treatment of Medicare beneficiaries. For the reasons discussed previously, we conclude that Buzzy® Pro does not meet the TPNIES innovation criteria under § 413.236(b)(5) and § 412.87(b)(1).

f. Capital-Related Assets Criterion (§ 413.236(b)(6))

With respect to the sixth TPNIES eligibility criterion under § 413.236(b)(6), limiting capital-related assets from being eligible for the TPNIES, except those that are home dialysis machines, we note that Buzzy® Pro does not meet the definition of a capital-related asset under § 413.236(a)(2), because it is not an asset that the ESRD facility has an economic interest in through ownership that is subject to depreciation.[102]

Comment: The applicant submitted a comment indicating that Buzzy® Pro is not an asset that the ESRD facility has an economic interest in through ownership that is subject to depreciation.

Response: We agree that Buzzy® Pro does not meet the definition of a capital-related asset under § 413.236(a)(2).

Final Rule Action: After a consideration of all the public comments received, we have determined that the evidence and public comments submitted are not sufficient to demonstrate that Buzzy® Pro meets all eligibility criteria to qualify for the TPNIES for CY 2024. As a result, Buzzy® Pro will not be paid for using the TPNIES per § 413.236(d). We note that in the CY 2021 ESRD PPS final rule (85 FR 71412), CMS indicated that entities would have 3 years beginning on the date of FDA marketing authorization in which to submit their applications for the TPNIES. Based on the Buzzy® Pro FDA marketing authorization date of May 15, 2023, the applicant may be eligible to apply for the TPNIES for CYs 2025, 2026, or 2027, and CMS would review any new information provided for the applicable rulemaking cycle.

4. Other Public Comments on the TPNIES

We received several comments regarding the TPNIES policies, including the length of the TPNIES payment period and suggestions for new payment adjustments. Commenters urged CMS to extend the TPNIES payment period to at least three years to allow for two full years of data collection, and then increase the ESRD PPS base rate to account for the new technology. Commenters suggested that CMS issue an RFI seeking public feedback on a post-TPNIES add-on payment adjustment and adopt a post-TPNIES payment adjustment in future rulemaking.

Commenters suggested revisions to existing TPNIES policies, such as extending the TPNIES to all capital-related assets, expanding the TPNIES for home dialysis devices that are acquired through operating leases, removing the TPNIES offset amount, and developing further guidance explaining the way in which CMS evaluates TPNIES applicants' substantial clinical improvement data.

Commenters suggested that we clarify the way in which MACs determine and provide payment rates for items approved for the TPNIES. Commenters suggested that these rates should be provided no later than March 31 of the first year of TPNIES eligibility and that MACs should provide clear and timely TPNIES claims processing guidance to the dialysis facilities.

Finally, we received comments suggesting that CMS develop a Transitional Laboratory Add-on Payment Adjustment (TLAPA) to incentivize innovation in laboratory services for beneficiaries with ESRD.

While we are not providing detailed responses to these comments in this final rule because they are out of scope of the proposed rule, we thank the commenters for their input and will potentially consider the recommendations for future rulemaking.

D. Continuation of Approved Transitional Add-On Payment Adjustments for New and Innovative Equipment and Supplies for CY 2024

In this section of the final rule, we identify any items previously approved for the TPNIES and for which payment is continuing for CY 2024. As described in the CY 2023 ESRD PPS final rule, payment for the one item approved for the TPNIES, the Tablo® Hemodialysis System, as described by HCPCS code E1629, expires on December 31, 2023 (87 FR 67216). As such there are no items previously approved for the TPNIES for which payment is continuing in CY 2024.

Comment: Several commenters requested that CMS extend the TPNIES payment period for the Tablo® Hemodialysis System beyond the December 31, 2023, end date to December 31, 2024. Commenters stated that implementation difficulties with the first CMS-approved TPNIES application resulted in lower than anticipated uptake of the Tablo® System. Commenters stated that MACs demonstrated variable levels of understanding about the Capital Related Assets (CRA) for the TPNIES and that providers lacked clear guidance on what information ESRD facilities were to include on their claims. The commenters stated that these challenges contributed to claim denials and an administrative burden on ESRD facilities.

Response: CMS did not propose to extend the 2–CY TPNIES payment period as established in § 413.236(d)(1) in the CY 2024 ESRD PPS proposed rule, and we are not finalizing any such change in this final rule. However, we acknowledge the commenters' concerns pertaining to TPNIES claims processing related matters and have issued Change Request 12347 to the MACs outlining the way in which the CRA for the TPNIES is calculated for claims processing purposes.[103] In addition, in August 2022, CMS instructed MACs to adjust ESRD claims following CMS deployment of a corrected ESRD Pricer and to ensure that their systems were properly set up to suspend the claim for manual pricing. CMS provided a Medicare Learning Network (MLN) article instructing providers on how to submit Tablo® Systems claims.[104] This article was supplemented with an MLN Connects newsletter reminding

[102] See also CMS Provider Reimbursement Manual, Chapter 1, section 104.1. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929.*

[103] Change Request 12347. 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). *https://www.cms.gov/files/document/r11533otn.pdf.*

[104] MLN Matters Article. Implementation of the Capital Related Assets (CRA) Adjustment 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). *https://www.cms.gov/files/document/mm12347-implementation-capital-related-assets-cra-adjustment-transitional-add-payment-adjustment-new.pdf.*

providers to submit the invoice for the CRA for the TPNIES to their MAC and report the appropriate revenue code and HCPCS code with modifier on the claim for treatments in which the CRA for the TPNIES was used. Providers were also reminded to address any issues returned to them by their MAC and resubmit the effected claims.[105]

E. Continuation of Approved Transitional Drug Add-On Payment Adjustments for CY 2024

Under § 413.234(c)(1), a new renal dialysis drug or biological product that is considered included in the ESRD PPS base rate is paid the TDAPA for 2 years. In December 2021, CMS approved Korsuva® (difelikefalin) for the TDAPA under the ESRD PPS, effective April 1, 2022. Implementation instructions are specified in CMS Transmittal 11295,[106] dated March 15, 2022, and available at: *https://www.cms.gov/files/document/r11295CP.pdf*.

In July 2023, after the CY 2024 ESRD PPS proposed rule appeared in the **Federal Register** on June 30, 2023, CMS approved Jesduvroq (daprodustat) for the TDAPA under the ESRD PPS, effective October 1, 2023. Implementation instructions are specified in CMS Transmittal 12157, dated July 27, 2023, and available at: *https://www.cms.gov/files/document/r12157cp.pdf*.

Table 11 identifies the two new renal dialysis drugs for which the TDAPA payment period as specified in § 413.234(c)(1) will continue in CY 2024: Korsuva® (difelikefalin) that was approved for the TDAPA effective in CY 2022, and Jesduvroq (daprodustat) that was approved for the TDAPA effective in CY 2023. Table 11 also identifies the products' HCPCS coding information as well as the payment adjustment effective dates and end dates.

TABLE 11: Continuation of Approved Transitional Drug Add-On Payment Adjustments

HCPCS Code	Long Descriptor	Payment Adjustment Effective Date	Payment Adjustment End Date
J0879	Injection, difelikefalin, 0.1 microgram, (for ESRD on dialysis)	4/1/2022	3/31/2024
J0889	Daprodustat, oral, 1 mg, (for ESRD on dialysis)	10/1/2023	9/30/2025

III. Calendar Year (CY) 2024 Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

A. Background

The Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27) was enacted on June 29, 2015, and amended the Act to provide coverage and payment for dialysis furnished by an ESRD facility to an individual with AKI. Specifically, section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a subsection (r) to provide payment, beginning January 1, 2017, for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate, as adjusted by any applicable geographic adjustment applied under section 1881(b)(14)(D)(iv)(II) of the Act and adjusted (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under section 1881(b)(14)(D) of the Act that the Secretary elects.

In the CY 2017 ESRD PPS final rule, we finalized several coverage and payment policies to implement subsection (r) of section 1834 of the Act and the amendments to section 1861(s)(2)(F) of the Act, including the payment rate for AKI dialysis (81 FR 77866 through 77872 and 77965). We interpret section 1834(r)(1) of the Act as requiring the amount of payment for AKI dialysis services to be the base rate for renal dialysis services determined for a year under the ESRD PPS base rate as set forth in § 413.220, updated by the ESRD bundled market basket percentage increase factor minus a productivity adjustment as set forth in § 413.196(d)(1), adjusted for wages as set forth in § 413.231, and adjusted by any other amounts deemed appropriate by the Secretary under § 413.373. We codified this policy in § 413.372 (81 FR 77965).

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the CY 2024 Payment for Renal Dialysis Services Furnished to Individuals With AKI

The CY 2024 ESRD PPS proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model'' (88 FR 42430–42544), referred to as the ''CY 2024 ESRD PPS proposed rule,'' appeared in the June 30, 2023 version of the **Federal Register**, with a comment period that ended on August 25, 2023. In that proposed rule, we proposed to update the AKI dialysis payment rate for CY 2024. We received 10 public comments on our proposal. In this final rule, we provide a summary of each proposed provision, a summary of public comments received and our responses to them, and the policies we are finalizing for CY 2024 payment for renal dialysis services furnished to individuals with AKI.

[105] MLN Connects Newsletter. ESRD: Submitting Dialysis Claims the Include Capital Related Assets Eligible for the TPNIES *https://www.cms.gov/training-education/medicare-learning-network/newsletter/2023-09-14-mlnc#_Toc145581414*.

[106] CMS Transmittal 11295 rescinded and replaced CMS Transmittal 11278, dated February 24, 2022.

C. Annual Payment Rate Update for CY 2024

1. CY 2024 AKI Dialysis Payment Rate

The payment rate for AKI dialysis is the ESRD PPS base rate determined for a year under section 1881(b)(14) of the Act, which is the finalized ESRD PPS base rate, including the applicable annual market basket update, geographic wage adjustments, and any other discretionary adjustments, for such year. We note that ESRD facilities can bill Medicare for non-renal dialysis items and services and receive separate payment in addition to the payment rate for AKI dialysis.

As discussed in section II.B.1.d of this final rule, the ESRD PPS base rate is $271.02, which reflects the application of the CY 2024 wage index budget-neutrality adjustment factor of 0.999534 and the CY 2024 ESRDB market basket percentage increase of 2.4 percent reduced by the productivity adjustment of 0.3 percentage point, that is, 2.1 percent. Accordingly, we are finalizing a CY 2024 per treatment payment rate of $271.02 (($265.57 × 0.999534) × 1.021 = $271.02) for renal dialysis services furnished by ESRD facilities to individuals with AKI. This final payment rate is further adjusted by the wage index, as discussed in the next section of this final rule.

2. Geographic Adjustment Factor

Under section 1834(r)(1) of the Act and regulations at § 413.372, the amount of payment for AKI renal dialysis services is the base rate for renal dialysis services determined for a year under section 1881(b)(14) of the Act (updated by the ESRDB market basket percentage increase and reduced by the productivity adjustment), as adjusted by any applicable geographic adjustment factor applied under section 1881(b)(14)(D)(iv)(II) of the Act. Accordingly, we apply the same wage index under § 413.231 that is used under the ESRD PPS and discussed in section II.B.1.b of this final rule. The AKI dialysis payment rate is adjusted by the wage index for a particular ESRD facility in the same way that the ESRD PPS base rate is adjusted by the wage index for that ESRD facility (81 FR 77868). Specifically, we apply the wage index to the labor-related share of the ESRD PPS base rate that we utilize for AKI dialysis to compute the wage-adjusted, per-treatment-AKI dialysis payment rate. We also apply the wage index policies regarding the 0.600 wage index floor (87 FR 67161 through 67166) and the 5 percent cap on wage index decreases (87 FR 67159 through 67161) to AKI dialysis payments to ESRD facilities.

We received 10 public comments on our proposal to update the payment rate for renal dialysis services furnished to individuals with AKI. Commenters included a coalition of dialysis organizations, a non-profit dialysis organization, a trade association, a renal product development company, and multiple large dialysis organizations. The comments on our proposal and our responses are set forth below.

Comment: Some commenters expressed support for the CY 2024 proposed payment rate for individuals with AKI, which is to say the commenters supported increasing payments for AKI by the proposed productivity-adjusted ESRDB market basket update of 1.7 percent. Many commenters requested that CMS allow for AKI patients to select home dialysis modalities by eliminating the current prohibition. Some commenters also expressed concerns that the proposed market basket increase is insufficient to account for inflation. One commenter suggested that any forecast error adjustment applied to the ESRD PPS should also be applied to payments for AKI patients.

Response: We appreciate the commenters' support for the proposed CY 2024 productivity-adjusted ESRDB market basket update of 1.7 percent. We acknowledge the request for AKI patients to select home dialysis modalities, and we thank commenters for their input. We note that currently, CMS will only pay for renal dialysis services at an ESRD facility for patients with AKI, and we did not propose to change this policy in the CY 2024 ESRD PPS proposed rule. Current AKI dialysis payment policy was implemented under the CY 2017 ESRD PPS final rule (81 FR 77866 through 77872, and 77965). Over the years, we have received several comments regarding the site of renal dialysis services for Medicare beneficiaries with AKI. We have solicited comments in the recent past, including in the CY 2022 ESRD PPS proposed rule (86 FR 36322, 36408), when we requested information regarding potentially modifying the site of renal dialysis services for patients with AKI and payment for AKI in the home setting. CMS continues to believe that this population requires close medical supervision by qualified staff during their dialysis treatment. We recognize commenters' concerns that the proposed ESRDB market basket update is insufficient given inflation. As discussed in section II.B.1.a.(2)(c) of this final rule, we believe the final CY 2024 ESRDB market basket update using the 2020-based ESRDB adequately reflects the average change in the price of goods and services ESRD facilities purchase to provide renal dialysis services and is technically appropriate to use as the ESRD PPS payment update factor, which determines the payment rate for renal dialysis services furnished to patients with AKI at ESRD facilities. We appreciate the commenter's suggestion that any forecast error adjustment applied to payments under the ESRD PPS should also be applied to payments for AKI patients. As discussed in section II.B.1.a.(2)(e) of this final rule, we are not finalizing a forecast error adjustment for the ESRD PPS for several reasons, but we will consider this suggestion for potential future rulemaking.

Final Rule Action: We are finalizing our proposal to base the AKI payment rate on the finalized ESRD PPS base rate, adjusted by the ESRD facility's wage index. Specifically, the final CY 2024 ESRD PPS base rate is $271.02 as finalized in section II.B.1.d of this final rule. Accordingly, we are finalizing a CY 2024 per treatment payment rate of $271.02 for renal dialysis services furnished by ESRD facilities to individuals with AKI. Additionally, we are finalizing our proposal to apply the updated the ESRD PPS wage index for CY 2024 payments for renal dialysis services furnished by ESRD facilities to individuals with AKI as finalized in section II.B.1.b of this final rule.

IV. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

A. Background

For a detailed discussion of the ESRD QIP's background and history, including a description of the Program's authorizing statute and the policies that we have adopted in previous final rules, we refer readers to previous ESRD QIP rules at: 75 FR 49030; 76 FR 628; 76 FR 70228; 77 FR 67450; 78 FR 72156; 79 FR 66120; 80 FR 68968; 81 FR 77834; 82 FR 50738; 83 FR 56922; 84 FR 60648; 85 FR 71398; 86 FR 61874; and 87 FR 67136.

We have also codified many of our policies for the ESRD QIP at §§ 413.177 and 413.178.

B. Updates to the Regulation Text for the ESRD QIP

1. Revision to the Definition of ''Minimum Total Performance Score (mTPS)'' at § 413.178(a)(8)

In the CY 2019 ESRD PPS final rule, we codified a number of key terms used in the ESRD QIP at § 413.178(a) of our regulations (83 FR 56980 through 56982). One of these terms is ''minimum total performance score'' (mTPS), which we defined at § 413.178(a)(8) ''with

respect to a payment year'' [107] as ''the total performance score that an ESRD facility would receive if, during the baseline period, it performed at the 50th percentile of national ESRD facility performance on all clinical measures and the median of national ESRD facility performance on all reporting measures.''

In the CY 2024 ESRD PPS proposed rule, we stated that we have recently reevaluated this definition and determined that it should be revised to more accurately capture how we calculate the median of national ESRD facility performance on reporting measures (88 FR 42487). We noted that, although we use data prior to the performance period to calculate these medians, the data may not be from the same time period, or ''baseline period'' (see § 413.178(a)(2)) used to calculate the 50th percentile of national ESRD facility performance on the clinical measures. Instead, our policy has been to calculate the median of national ESRD facility performance on the ESRD QIP reporting measures using the most recently available data prior to the applicable performance period for the payment year. If there were no data available prior to the first performance period of a new reporting measure, as was the case for the Clinical Depression Screening and Follow-Up reporting measure, we would use a proxy median for purposes of including the reporting measure in our calculation of the mTPS. We stated that we selected the values for these proxy medians based on the availability of previous measure data, a facility's familiarity with similar measures or requirements, and considerations regarding a facility's ability to comply with new reporting measure requirements during the initial performance periods for a new reporting measure.

In the CY 2024 ESRD PPS proposed rule, we proposed to update the definition of ''minimum total performance score'' at § 413.178(a)(8) so that it accurately captures these policies (88 FR 42487). We also proposed that, with respect to the adoption of future reporting measures, including the reporting measures proposed in the CY 2024 ESRD PPS proposed rule, if there is an insufficient quantity of data available prior to the first performance period of a new reporting measure, we will set a proxy median of zero for the reporting measure until we have sufficient data to calculate the median. We stated our belief that this proposal will provide facilities with additional predictability and transparency regarding our calculation of the mTPS for a payment year. We noted that, although many facilities score much higher than zero during the initial performance periods of a new reporting measure, we believe that setting the proxy median at zero where we do not have sufficient data available will account for the possibility that new reporting measures may have different reporting requirements. For example, a new reporting measure may require a facility to report new or additional data in CMS's ESRD Quality Reporting System (EQRS) to be eligible for scoring on the reporting measure. Additionally, a new reporting measure may require that a facility reconsider its internal processes to comply with the reporting requirements and be eligible for scoring. In the proposed rule, we stated that we believe that using a median of zero for new reporting measures would ensure that the mTPS is calculated based on the worst-case scenario, rather than assuming a median higher than what may be observed once data are available. We noted that setting the proxy median at zero until we have sufficient data available to calculate the median would allow the timely inclusion of a new reporting measure in the ESRD QIP measure set, as well as our calculation of the mTPS, while also encouraging facilities to report the new or additional data that may be specified by that reporting measure so that they are able to receive credit for reporting.

We welcomed public comment on this proposal. The comments we received and our responses are set forth below.

Comment: A few commenters expressed support for the proposed update to the definition of mTPS, as it will allow for timely inclusion of new reporting measures and encourage facilities to report data.

Response: We thank commenters for their support.

Final Rule Action: After considering public comments, we are finalizing our proposal as proposed.

2. Codification of the ESRD QIP Measure Adoption, Retention, and Removal Policies

In the CY 2013 ESRD PPS final rule (77 FR 67475), we finalized a policy to retain measures from prior program years for each successive program year, unless otherwise proposed and finalized. In the CY 2019 ESRD PPS final rule (83 FR 56983 through 56985), we finalized eight measure removal factors for the ESRD QIP, and we refer readers to that final rule for details. We also finalized a policy to retain a measure for certain specified reasons, such as when a particular measure addresses a gap in quality so significant that removing the measure could result in poor quality or when a measure addresses a statutorily-required topic, even if one or more of the measure removal factors applies. In the CY 2013 ESRD PPS final rule (77 FR 67475), we also finalized that we would generally remove an ESRD QIP measure using notice and comment rulemaking unless we determined that the continued collection of data on the measure raised patient safety concerns. In that case, we stated that we would promptly remove the measure, immediately notify ESRD facilities and the public through the usual communication channels (including listening sessions, memos, email notification, and website postings), and publish the justification for the removal in the **Federal Register** during the next rulemaking cycle.

In the CY 2024 ESRD PPS proposed rule, we proposed to revise § 413.178(c) such that it incorporates these measure adoption, retention, and removal policies (88 FR 42487). We proposed that existing § 413.178(c)(1) through (5) would be consolidated and renumbered as § 413.178(c)(1)(i) through (v), and we would add a new § 413.178(c)(1)(vi), which would codify our policy to adopt measures for the ESRD QIP beyond those that address the topics described at § 413.178(c)(1)(i) through (v). We also proposed to codify at § 413.178(c)(2) our policies regarding the use of endorsed measures. We proposed to codify at § 413.178(c)(3) our policy regarding the updating of measure specifications. Additionally, we proposed to codify at § 413.178(c)(4) our policy regarding measure retention. Finally, we proposed to codify at § 413.178(c)(5) our policies regarding measure removal. We stated our belief that these proposals will make it easier for interested parties to find these policies and will further align the ESRD QIP regulations with the regulations we have codified for other quality reporting programs.

We welcomed public comment on these proposals. The comments we received and our responses are set forth below.

Comment: A few commenters expressed support for the proposals to codify existing measure adoption, retention, and removal policies, noting that these updates will provide transparency for evaluating measures.

Response: We thank the commenters for their support.

Final Rule Action: After considering public comments, we are finalizing our proposals as proposed.

[107] In the CY 2023 ESRD PPS final rule, we revised § 413.178(a)(8) to exempt PY 2023 (87 FR 67229).

C. Updates to Requirements Beginning With the PY 2026 ESRD QIP

1. PY 2026 ESRD QIP Measure Set

In the CY 2024 ESRD PPS proposed rule, we proposed to remove the Ultrafiltration Rate reporting measure and the Standardized Fistula Rate clinical measure beginning with PY 2026 (88 FR 42499 through 42500). We also proposed to add the Facility Commitment to Health Equity reporting measure to the ESRD QIP measure set beginning with PY 2026 (88 FR 42489 through 42494). The previously finalized and proposed new measures are summarized in Table 12 of the proposed rule (88 FR 42488). We describe the previously finalized measures and the measures we are finalizing in this final rule in Table 12. The technical specifications for each of these measures can be found in the CMS ESRD Measures Manual for the 2023 Performance Period.[108]

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[108] *https://www.cms.gov/files/document/esrd-measures-manual-v80.pdf*.

[109] In previous years, we referred to the consensus-based entity by corporate name. We have updated this language to refer to the consensus-based entity more generally.

TABLE 12: Previously Finalized and Newly Finalized Measures for the PY 2026 ESRD QIP Measure Set

Consensus-Based Entity[109] (CBE) #	Measure Title and Description
0258	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure Measure assesses patients' self-reported experience of care through percentage of patient responses to multiple survey questions.
2496	Standardized Readmission Ratio (SRR), a clinical measure Ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day readmissions.
Based on CBE #2979	Standardized Transfusion Ratio (STrR), a clinical measure Ratio of the number of observed eligible red blood cell transfusion events occurring in patients dialyzing at a facility to the number of eligible transfusions that would be expected.
N/A	(Kt/V) Dialysis Adequacy Comprehensive, a clinical measure A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume. Percentage of all patient months for patients whose delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.
2978	Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure Measures the use of a catheter continuously for 3 months or longer as of the last hemodialysis treatment session of the month.
1454	Hypercalcemia, a reporting measure Proportion of patient-months with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL.
1463	Standardized Hospitalization Ratio (SHR), a clinical measure Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.
Based on CBE #0418	Clinical Depression Screening and Follow-Up, a clinical measure* Facility reports in ESRD Quality Reporting System (EQRS) one of four conditions for each qualifying patient treated during performance period.
Based on CBE #1460	National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients, a clinical measure The Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.
N/A	NHSN Dialysis Event reporting measure Number of months for which facility reports NHSN Dialysis Event data to the CDC.
N/A	Percentage of Prevalent Patients Waitlisted (PPPW), a clinical measure Percentage of patients at each facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period.
2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec), a reporting measure Percentage of patient-months for which medication reconciliation was performed and documented by an eligible professional.
3636	COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP), a reporting measure** Percentage of HCP who are up to date on their COVID-19 vaccination course.
N/A	Facility Commitment to Health Equity, a reporting measure*** Facilities will receive two points each for attesting to five different domains of commitment to advancing health equity for a total of ten points.

*We are finalizing our proposal to update the Clinical Depression Screening and Follow-Up measure beginning with PY 2026, as discussed in section IV.C.4 of this final rule.

**We are finalizing our proposal to update the COVID-19 Vaccination Coverage Among HCP reporting measure beginning with PY 2026, as discussed in section IV.C.3 of this final rule.

*** We are finalizing our proposal to add the Facility Commitment to Health Equity reporting measure beginning with PY 2026, as discussed in section IV.C.2 of this final rule.

2. Adoption of the Facility Commitment to Health Equity Reporting Measure Beginning With the PY 2026 ESRD QIP

a. Background

In the CY 2024 ESRD PPS proposed rule, we stated that significant and persistent disparities in healthcare outcomes exist in the U.S. (88 FR 42489). For example, belonging to a racial or ethnic minority group, being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community, being a member of a religious minority, living in a rural area, being a person with a disability or disabilities, or being near or below the poverty level, is often associated with worse health outcomes.[110] [111] [112] [113] [114] [115] [116] [117] [118] [119] Numerous studies have shown that among Medicare beneficiaries, individuals who are racial and ethnic minorities often receive lower quality hospital care, report lower experiences of care, and experience more frequent hospital readmissions and procedural complications.[120] [121] [122] [123] [124] [125] Readmission rates in the Hospital Readmissions Reduction Program have shown to be higher among Black and Hispanic Medicare beneficiaries with common conditions, including congestive heart failure and acute myocardial infarction.[126] [127] [128] [129] [130] Data indicate that, even after accounting for factors such as socioeconomic conditions, members of racial and ethnic minority groups reported experiencing lower quality healthcare.[131] Evidence of differences in quality of care received by people from racial and ethnic minority groups show worse health outcomes, including a higher incidence of diabetes complications such as retinopathy.[132] Additionally, inequities in the drivers of health affecting these groups, such as poverty and healthcare access, are interrelated and influence a wide range of health and quality-of-life outcomes and risks.[133]

In the CY 2022 ESRD PPS proposed rule (86 FR 36362 through 36369), we requested information on our Equity Plan for Improving Quality in Medicare (also referred to as the CMS Framework for Health Equity),[134] which outlines our commitment to close health equity gaps through improved data collection, measurement, and analysis of disparities across programs and policies. The request for information requested public comment regarding the potential stratification of quality measure results by race and ethnicity and the potential creation of a hospital or facility equity score in CMS quality reporting and value-based purchasing programs, including the ESRD QIP. In the CY 2024 ESRD PPS proposed rule, we stated that we received many responses to that request for public comment (88 FR 42489), and we referred readers to the CY 2022 ESRD PPS final rule for summaries of those comments (86 FR 61934 through 61937). We noted in the CY 2022 ESRD PPS final rule the value of these comments in the continuing development of our health equity quality measurement efforts, and we stated that we would take the comments

[110] Joynt KE, Orav E, Jha AK. (2011). Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. *JAMA,* 305(7), 675–681. Available at: doi:10.1001/jama.2011.123.

[111] Lindenauer PK, Lagu T, Rothberg MB, et al. (2013). Income Inequality and thirty-Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. *BMJ,* 346. Available at: *https://doi.org/10.1136/bmj.f521.*

[112] Trivedi AN, Nsa W, Hausmann LRM, et al. (2014). Quality and Equity of Care in U.S. Hospitals. *N Engl J Med,* 371(24), 2298–2308. Available at: doi: 10.1056/NEJMsa1405003.

[113] Polyakova, M, Udalova V, Kocks, G, Genadek K, Finlay K, Finkelstein AN. (2021). Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. *Health Affairs,* 40(2), 307–316. Available at: *https://doi.org/10.1377/hlthaff.2020.02142.*

[114] Rural Health Research Gateway. (2018). Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. Available at: *https://www.ruralhealthresearch.org/assets/2200–8536/rural-communities-age-income-health-status-recap.pdf.*

[115] HHS Office of Minority Health. (2020). Progress Report to Congress, 2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities. Department of Health and Human Services. Available at: *https://minorityhealth.hhs.gov/report-congress-minority-health.*

[116] Heslin KC, Hall JE. (2021). Sexual Orientation Disparities in Risk Factors for Adverse COVID–19–Related Outcomes, by Race/Ethnicity—Behavioral Risk Factor Surveillance System, United States, 2017–2019. MMWR Morb Mortal Wkly Rep, 70(5), 149. doi: 10.15585/mmwr.mm7005a1.

[117] Poteat TC, Reisner SL, Miller M, Wirtz AL. (2020). COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. medRxiv. doi: 10.1101/2020.07.21.20159327.

[118] Vu M, Azmat A, Radejko T, Padela AI. (2016). Predictors of Delayed Healthcare Seeking Among American Muslim Women. *Journal of Women's Health,* 25(6), 586–593. doi: 10.1089/jwh.2015.5517.

[119] Nadimpalli SB, Cleland CM, Hutchinson MK, Islam N, Barnes LL, Van Devanter N. (2016). The Association Between Discrimination and the Health of Sikh Asian Indians. *Health Psychology,* 35(4), 351–355. *https://doi.org/10.1037/hea0000268.*

[120] CMS Office of Minority Health. (2020). Racial, Ethnic, and Gender Disparities in Healthcare in Medicare Advantage. Baltimore, MD: Centers for Medicare & Medicaid Services. Available at: .

[121] CMS Office of Minority Health. (Updated August 2018). Guide to Reducing Disparities in Readmissions. Baltimore, MD: Centers for Medicare & Medicaid Services. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[122] Singh JA, Lu X, Rosenthal GE, Ibrahim S, Cram P. (2014). Racial Disparities in Knee and Hip Total Joint Arthroplasty: An 18-year analysis of national Medicare data. Ann Rheum Dis., 73(12), 2107–15. Available at: doi:10.1136/annrheumdis-2013–203494.

[123] Rivera-Hernandez M, Rahman M, Mor V, Trivedi AN. (2019). Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. J Am Geriatr Soc., 67(8), 1672–1679. Available at: *https://doi.org/10.1111/jgs.15960.*

[124] Joynt KE, Orav E, Jha AK. (2011). Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA, 305(7), 675–681. Available at: doi:10.1001/jama.2011.123.

[125] Tsai TC, Orav EJ, Joynt KE. (2014). Disparities in Surgical 30-day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. Ann Surg., 259(6), 1086–1090. Available at: doi: 10.1097/SLA.0000000000000326.

[126] Rodriguez F, Joynt KE, Lopez L, Saldana F, Jha AK. (2011). Readmission Rates for Hispanic Medicare Beneficiaries with Heart Failure and Acute Myocardial Infarction. Am Heart J., 162(2), 254–261 e253. Available at: *https://doi.org/10.1016/j.ahj.2011.05.009.*

[127] Centers for Medicare & Medicaid Services. (2014). Medicare Hospital Quality Chartbook: Performance Report on Outcome Measures. Available at: *https://www.hhs.gov/guidance/document/medicare-hospital-quality-chartbook-performance-report-outcome-measures.*

[128] CMS Office of Minority Health. (Updated August 2018). Guide to Reducing Disparities in Readmissions. Baltimore, MD: Centers for Medicare & Medicaid Services. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[129] Prieto-Centurion V, Gussin HA, Rolle AJ, Krishnan JA. (2013). Chronic Obstructive Pulmonary Disease Readmissions at MinorityServing Institutions. Ann Am Thorac Soc., 10(6), 680–684. Available at: *https://doi.org/10.1513/AnnalsATS.201307-223OT.*

[130] Joynt KE, Orav E, Jha AK. (2011). Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA, 305(7), 675–681. Available at: doi:10.1001/jama.2011.123.

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[134] Centers for Medicare and Medicaid Services. (2022). CMS Framework for Health Equity 2022–2032. Available at: *https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf.* Centers for Medicare & Medicaid Services. (2021). Paving the Way to Equity: A Progress Report. Available at: *https://www.cms.gov/files/document/paving-way-equity-cms-omh-progress-report.pdf.* Accessed on February 20, 2023. See also, Centers for Medicare & Medicaid Services Office of Minority Health. (2021). The CMS Equity Plan for Improving Quality in Medicare. 2015–2021. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf#:~:text=The%20Centers%20for%20Medicare%20%26%20Medicaid%20Services%20%28CMS%29,evidence%20base%2C%20identifying%20opportunities%2C%20and%20gathering%20stakeholder%20input.* Accessed on February 20, 2023.

into account for future development and expansion of our health equity quality measurement efforts.

The Agency for Healthcare Research and Quality (AHRQ) and The Joint Commission have independently concluded that facility leadership plays an important role in promoting a culture of quality and safety.[135] [136] [137] AHRQ research shows that facility boards can influence quality and safety in a variety of ways; not only through strategic initiatives, but also through more direct interactions with frontline workers.[138] The Joint Commission found that a leader who is committed to prioritizing and making patient safety visible through every day actions is a critical part of creating a true culture of safety, which in turn fosters an organizational culture in which patients are treated with dignity and respect.[139] Because CMS is also working toward the goal of all patients receiving high-quality healthcare, regardless of individual characteristics, we are also committed to supporting healthcare organizations in building a culture of safety *and* equity that focuses on educating and empowering their workforce to recognize and eliminate health disparities. This includes patients receiving the right care, at the right time, in the right setting for their condition(s), regardless of those characteristics.

We believe that strong and committed leadership from dialysis facility executives and board members is essential and can play a role in shifting organizational culture and advancing equity goals for dialysis facilities. Studies demonstrate that hospital leadership can positively influence culture for better quality, patient outcomes, and experience of care.[140] [141] [142] A systematic review of 122 published studies showed that strong leadership that prioritized safety, quality, and the setting of clear guidance with measurable goals for improvement resulted in a high-performing hospital with better patient outcomes.[143] We believe this conclusion also applies to dialysis facilities, and that the commitment of dialysis facility leadership to health equity would result in a reduction of health disparities in the ESRD population.

Our belief that a leadership commitment to health equity can lead to a reduction of health disparities is also supported by research conducted by the Institute for Healthcare Improvement (IHI), which studied 23 health systems throughout the U.S. and Canada. The IHI's research showed that health equity must be a priority championed by leadership teams to improve both patient access to needed healthcare services and outcomes among populations that have been disadvantaged by the healthcare system.[144] This IHI study specifically identified concrete actions to make advancing health equity a core strategy, including establishing this goal as a leader-driven priority alongside organizational development structures and processes.[145] Based upon these findings, we believe that dialysis facility leadership can be instrumental in setting specific, measurable, attainable, realistic, and time-based (SMART) goals to assess progress towards achieving equity goals and ensuring high-quality care at dialysis facilities is accessible to all. Based on this well-developed body of evidence, in the proposed rule we proposed to adopt an attestation-based structural reporting measure, Facility Commitment to Health Equity, for the ESRD QIP beginning with PY 2026 (88 FR 42490).

The first pillar of our strategic priorities [146] reflects our deep commitment to improvements in health equity by addressing the health disparities that underly our health system. In line with this strategic pillar, we developed this structural measure to assess facility commitment to health equity across five domains (see Table 13) using a suite of organizational competencies aimed at achieving health equity for all patients, including but not limited to patients who belong to racial and ethnic minority groups, people with disabilities, members of the LGBTQ+ community, individuals with limited English proficiency, rural populations, religious minorities, and people facing socioeconomic challenges. We believe these elements are actionable focus areas, and assessment of dialysis facility leadership commitment to them is foundational.

We proposed to adopt the measure under section 1881(h)(2)(A)(iv) of the Act, which gives the Secretary broad authority to specify measures for the ESRD QIP (88 FR 42490). We noted that disparities in health equity are tied to worse patient outcomes in the ESRD community. For example, individuals from racial and ethnic minority groups and with lower incomes are less likely to receive recommended care for CKD risk factors and are also less likely to reduce CKD risk through recommended treatment goals.[147] [148] [149] [150]

[135] Agency for Healthcare Research and Quality. Leadership Role in Improving Patient Safety. Patient Safety Primer, September 2019. Available at: *https://psnet.ahrq.gov/primer/leadership-role-improving-safety.*

[136] Joint Commission on Accreditation of Healthcare Organizations, USA. The essential role of leadership in developing a safety culture. Sentinel Event Alert. 2017 (Revised June 2021). Available at: *https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/sea-57-safety-culture-and-leadership-final2.pdf.*

[137] See information on launch of new ''Health Care Equity Certification'' in July 2023 from Joint Commission on Accreditation of Healthcare Organizations, USA, available at: *https://www.jointcommission.org/our-priorities/health-care-equity/health-care-equity-prepublication/.*

[138] Agency for Healthcare Research and Quality. Leadership Role in Improving Patient Safety. Patient Safety Primer, September 2019: Available at: *https://psnet.ahrq.gov/primer/leadership-role-improving-safety.*

[139] Joint Commission on Accreditation of Healthcare Organizations, USA. The essential role of leadership in developing a safety culture. Sentinel Event Alert. 2017 (Revised June 2021). Available at: *https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/sea-57-safety-culture-and-leadership-final2.pdf.*

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[141] Smith SA, Yount N, Sorra J. (2017). Exploring Relationships Between Hospital Patient Safety Culture and Consumer Reports Safety Scores. BMC Health Services Research, 17(1), 143. doi:10.1186/s12913–017–2078–6.

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[143] Millar R, Mannion R, Freeman T, et al. (2013). Hospital Board Oversight of Quality and Patient Safety: A Narrative Review and Synthesis of Recent Empirical Research. The Milbank quarterly, 91(4), 738–70. doi:10.1111/1468–0009.12032.

[144] Mate KS and Wyatt R. (2017). Health Equity Must Be a Strategic Priority. NEJM Catalyst. Available at: *https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0556.*

[145] Mate KS and Wyatt R. (2017). Health Equity Must Be a Strategic Priority. NEJM Catalyst. Available at: *https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0556.*

[146] Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Centers for Medicare & Medicaid. Available at: *https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms.*

[147] United States Renal Data System. 2021 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States.* National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2021. We note that, following publication of the CY 2024 ESRD PPS proposed rule, the USRDS has published its 2022 annual report, which is available at: *https://usrds-adr.niddk.nih.gov/2022.*

[148] Benjamin O, Lappin SL. End-Stage Renal Disease. [Updated 2021 Sep 16]. In: Stat Pearls [internet]. Treasure Island (FL): StatPearls Publishing; 2022. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK499861/.*

[149] Norris, K.C., Williams, S.F., Rhee, C.M., Nicholas, S.B., Kovesdy, C.P., et al. (2017). Hemodialysis Disparities in African Americans: The Deeply Integrated Concept of Race in the Social Fabric of Our Society. Seminars in Dialysis 30(3):213–223. doi:10.1111/sdi.12589.

[150] CMS (2021). Chronic Kidney Disease Disparities: Educational Guide for Primary Care.

Consequently, some groups are more likely to progress from CKD to ESRD and less likely to be under the care of a nephrologist before starting dialysis.[151] Individuals from racial and ethnic minority groups with ESRD are more likely to have 30-day hospital readmissions when compared to non-Hispanic White patients.[152] We stated that we believe that this measure is an appropriate measure of ESRD quality of care because it would improve facilities' awareness of the tie between their structural practices and their patient outcomes by reporting these data, thus informing facility practices such that their patients attain better outcomes. We also stated our belief that the proposed measure would incentivize facilities to collect and utilize their data to identify their own critical equity gaps, implement plans to address said gaps, and ensure that they dedicate resources to addressing those gaps. Facilities could analyze data to understand, for example, whether there are any demographic factors (such as race, national origin, primary language, and ethnicity), or social drivers of health (such as housing status and food security) that may be affecting access to care or contributing to poor outcomes in their patient populations and, in turn, develop appropriate solutions to improve access and outcomes. Thus, the measure aims to support facilities in leveraging available data, pursuing focused quality improvement activities, and promoting efficient and effective use of their resources. While the measure does not require facilities to take specific actions, we expect that any solution a facility might develop to address a gap it identifies would comply with all applicable Federal non-discrimination laws. We also note that the measure is intended to promote health equity for all patients and is not intended to create a conflict between a CMS requirement and a State's civil rights laws.

The five questions of the structural measure are adapted from the CMS Office of Minority Health's Building an Organizational Response to Health Disparities framework, which focuses on data collection, data analysis, culture of equity, and quality improvement.[153] We have already adopted this measure for the Hospital Inpatient Quality Reporting (IQR) Program, and we refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49191 through 49201) for a discussion of the measure in that program. In the proposed rule, we stated that, other than replacing the term ''hospital'' with the term ''facility,'' the measure is identical to the Hospital IQR Program measure. The Facility Commitment to Health Equity measure is aligned with the Meaningful Measures Area of ''Equity of Care'' and the Meaningful Measures 2.0 goal to ''Leverage Quality Measures to Promote Equity and Close Gaps in Care'' because it seeks to assess structural health equity issues that could inform facility practices such that their patients attain better outcomes. This measure also supports the Meaningful Measures 2.0 objective to ''[c]ommit to a patient-centered approach in quality measure and value-based incentives programs to ensure that quality and safety measures address healthcare equity'' because the measure would incentivize facilities to identify their own healthcare equity gaps from a structural perspective.

b. Overview of Measure

The Facility Commitment to Health Equity reporting measure assesses dialysis facility commitment to health equity using a suite of equity-focused organizational competencies aimed at achieving health equity for all populations, including those that have been disadvantaged, marginalized, and underserved by the healthcare system. As previously noted, this includes, but is not limited to: racial and ethnic minority groups, people with disabilities, members of the LGBTQ+ community, individuals with limited English proficiency, rural populations, religious minorities, and people facing socioeconomic challenges. Table 13 includes the five attestation domains and the elements within each of those domains for which we had proposed a facility would report an affirmative attestation in order for the facility to receive points for that domain.

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Available at: *https://www.cms.gov/files/document/chronic-kidney-disease-disparities-educational-guide-primary-care.pdf*.

[151] Norton, J. M., Moxey-Mims, M. M., Eggers, P. W., Narva, A. S., Star, R. A., Kimmel, P. L., & Rodgers, G. P. (2016). Social Determinants of Racial Disparities in CKD. Journal of the American Society of Nephrology: JASN, 27(9), 2576–2595. *https://doi.org/10.1681/ASN.2016010027*.

[152] CMS (2014). Health Disparities Among Aged ESRD Beneficiaries, 2014. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/ESRD-Infographic.pdf*.

[153] Centers for Medicare & Medicaid Services. (2021). Building an Organizational Response to Health Disparities [Fact Sheet]. U.S. Department of Health and Human Services. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Health-Disparities-Guide.pdf*.

TABLE 13: Proposed Facility Commitment to Health Equity Measure's Five Attestations

Attestation	Elements: Select all that apply (Note: Affirmative attestation of all elements within a domain would be required for the facility to receive a point for the domain in the numerator)
Domain 1: Equity is a Strategic Priority	
Facility commitment to reducing healthcare disparities is strengthened when equity is a key organizational priority. Please attest that your facility has a strategic plan for advancing health equity and that it includes all the following elements.	(A) Our facility strategic plan identifies priority populations who currently experience health disparities. (B) Our facility strategic plan identifies health equity goals and discrete action steps to achieving these goals. (C) Our facility strategic plan outlines specific resources which have been dedicated to achieving our equity goals. (D) Our facility strategic plan describes our approach for engaging key stakeholders, such as community-based organizations.
Domain 2: Data Collection	
Collecting valid and reliable demographic and social determinant of health data on patients served in a facility is an important step in identifying and eliminating health disparities. Please attest that your facility engages in the following activities.	(A) Our facility collects demographic information (such as self-reported race, national origin, primary language, and ethnicity data) and/or social determinant of health information on the majority of our patients. (B) Our facility has training for staff in culturally sensitive collection of demographic and/or social determinant of health information. (C) Our facility inputs demographic and/or social determinant of health information collected from patients into structured, interoperable data elements using certified EHR technology.
Domain 3: Data Analysis	
Effective data analysis can provide insights into which factors contribute to health disparities and how to respond. Please attest that your facility engages in the following activities.	(A) Our facility stratifies key performance indicators by demographic and/or social determinants of health variables to identify equity gaps and includes this information on facility performance dashboards.
Domain 4: Quality Improvement	
Health disparities are evidence that high-quality care has not been delivered equitably to all patients.* Engagement in quality improvement activities can improve quality of care for all patients.	(A) Our facility participates in local, regional, or national quality improvement activities focused on reducing health disparities.
Domain 5: Leadership Engagement	
Leaders and staff can improve their capacity to address disparities by demonstrating routine and thorough attention to equity and setting an organizational culture of equity. Please attest that your facility engages in the following activities.	(A) Our facility senior leadership, including chief executives and the entire facility** board of trustees, annually reviews our strategic plan for achieving health equity. (B) Our facility senior leadership, including chief executives and the entire facility board of trustees, annually reviews key performance indicators stratified by demographic and/or social factors.

* After publication of the 2022 MUC List, we clarified the language in Domain 4: "Health disparities are evidence that high quality care has not been delivered *equitably* to all patients."

** After publication of the 2022 MUC List, we identified that Domain 5 incorrectly referred to the "hospital board of trustees" instead of the "facility board of trustees," and therefore updated the language in Domain 5 to be more applicable to the ESRD QIP.

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c. Measure Calculation

The Facility Commitment to Health Equity measure consists of five attestation-based questions, each representing a separate domain of commitment. For a facility to affirmatively attest ''yes'' to a domain, and receive points for that domain, the facility would need to determine that it engages in all of the activities that are included as elements under the domain. A facility that engages in all of the activities for a domain would report an affirmative attestation by answering ''yes'' to the attestation-based question for that domain. There is no option for a facility to answer ''yes'' in response to an attestation-based question for a domain if the facility engages in some, but not all, of the activities included as domain elements, and there is also no option for a facility to answer ''no'' in response to any attestation-based question for a domain. The measure would be expressed as a fraction, and a facility can score either 0, 2, 4, 6, 8, or 10 for the performance period, depending on the number of domains to which a facility positively attests. In the proposed rule, we proposed that the measure denominator would be ''ten,'' with each domain being represented as two points out of that total ten points, and that the numerator would be calculated as two points for each ''yes'' answer the facility reports which are then summed together (88 FR 42493). We stated that we chose to award facilities two points for each affirmative response to an attestation-based question so that the maximum number of points a facility could receive for the measure is ten, which is the same maximum number of points that a facility can receive on other ESRD QIP measures.

For example, for Domain 1 (''Facility commitment to reducing healthcare disparities is strengthened when equity is a key organizational priority''), a facility would evaluate and determine whether its strategic plan satisfies all of the elements described in (A) through (D) (see Table 13). If the facility's plan satisfies all four of these elements, the facility would respond ''yes'' to the attestation-based question for Domain 1 and receive two (2) points for that response. If the facility determined that its strategic plan satisfies elements (A) and (B) but not (C) and (D), the facility would not be able to respond ''yes'' to Domain 1 and would not receive any points for that domain.

The numerator is calculated as the sum of the points the facility earns for responding ''yes'' to the attestation-based questions. For example, a facility that responds ''yes'' to all five attestation-based questions would receive the maximum 10 points (two points for each of the five ''yes'' responses). A facility that responds ''yes'' to three of the attestation-based questions would receive six points.

We proposed that the Facility Commitment to Health Equity reporting measure would be added to the Reporting Measure Domain (88 FR 42493). We noted that technical specifications for the measure can be found in the ESRD QIP CY 2024 Technical Measure Specifications, which are available at: *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/esrdqip/061_technicalspecifications.* Consistent with case minimums we have adopted for our other ESRD QIP reporting measures, we proposed that facilities must have 11 qualifying patients and a CCN open date before September 1 of the performance period that applies to the program year in order to be eligible for scoring on the Facility Commitment to Health Equity reporting measure.

d. Data Submission and Reporting

In the proposed rule, we proposed to require facilities to submit data needed to calculate the Facility Commitment to Health Equity measure once on an annual basis using CMS's ESRD Quality Reporting System (EQRS) beginning with PY 2026 (88 FR 42494). We proposed that the deadline for submission would be the end of the EQRS December data reporting month for the applicable performance period, which is consistent with current reporting deadlines for other ESRD QIP measures. For example, for the PY 2026 ESRD QIP, facilities would need to report data on the measure by the end of the December data reporting month in CY 2024. As described in Table 17 of the proposed rule (88 FR 42504) and reproduced in Table 18 of this final rule, we proposed performance standards for the Facility Commitment to Health Equity reporting measure. We also proposed a 12-month performance period for the measure, and note that we did not receive any comments on this aspect of the measure proposal. We further proposed that facilities would be required to follow the submission and reporting requirements for web-based measures for the ESRD QIP posted on the QualityNet website: *https://qualitynet.cms.gov/esrd/esrdqip.*

e. Review by the Measure Applications Partnership

The Facility Commitment to Health Equity measure was included as a measure under consideration for the ESRD QIP on the publicly available ''List of Measures Under Consideration for December 1, 2022'' (MUC List), a list of measures under consideration for use in various Medicare quality programs.[154] The CBE-convened Measure Applications Partnership (MAP) Health Equity Advisory Group reviewed the MUC List and the Facility Commitment to Health Equity measure (MUC2022–027) in detail on December 6–7, 2022.[155] The Health Equity Advisory Group expressed concern that this is more of a ''checklist'' measure that may not directly address health inequities at a systemic level, but the advisory group generally agreed that a structural measure such as this one represents progress toward improving equitable care.[156] In addition, on December 8 through 9, 2022, the MAP Rural Health Advisory Group reviewed the 2022 MUC List, and the MAP Hospital Workgroup reviewed the 2022 MUC List on December 13 through 14, 2022.[157] The MAP Hospital Workgroup recognized that reducing health care disparities would represent a substantial benefit to overall quality of care, but expressed reservations about the measure's link to clinical outcomes; the MAP Hospital Workgroup members voted to conditionally support the measure for rulemaking pending: (1) endorsement by a consensus-based entity (CBE); (2) committing to look at outcomes in the future; (3) providing more clarity on the measure and supplementing interpretations with

[154] Centers for Medicare & Medicaid Services. 2022. List of Measures Under Consideration for December 1, 2022. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[155] Centers for Medicare & Medicaid Services. 2023. 2022–2023 MAP Final Recommendations. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[156] Centers for Medicare & Medicaid Services. 2023. 2022–2023 MAP Final Recommendations. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[157] Centers for Medicare & Medicaid Services. 2023. 2022–2023 MAP Final Recommendations. Rural Health Advisory Group. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

results; and (4) verifying attestation provided by the accountable entities.[158] Thereafter, the MAP Coordinating Committee deliberated on January 24 through 25, 2023 and ultimately voted to conditionally support the Facility Commitment to Health Equity measure for rulemaking with the same conditions.[159]

f. Consensus-Based Entity Endorsement

Although section 1881(h)(2)(B)(i) of the Act generally requires that measures specified by the Secretary for the ESRD QIP be endorsed by the entity with a contract under section 1890(a) of the Act, section 1881(h)(2)(B)(ii) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and therefore we believe the exception in section 1881(h)(2)(B)(ii) of the Act applies.

g. Public Display

In the proposed rule, we proposed to publicly display the facility-specific results for the Facility Commitment to Health Equity reporting measure on an annual basis through our *Care Compare* website at: *https://www.medicare.gov/care-compare/.* We stated that we anticipate making the first public report available in January 2026.

We invited public comment on this proposal. The comments we received and our responses are set forth below.

Comment: Several commenters expressed support for the Facility Commitment to Health Equity measure. A few of these commenters appreciated the Facility Commitment to Health Equity measure as a step towards requiring demonstration of equitable policies and practices. One commenter noted that the measure will help facilities assess commitment to health equity by focusing on relevant organizational competencies. One commenter, emphasizing the importance of strong, diverse, and committed leadership in advancing health equity goals at the facility level, stated that the measure would incentivize facilities to identify and address equity gaps. One commenter noted that the measure is a low burden first step to address inequity, supports Meaningful Measures 2.0, and focuses on SMART goals which are the basis for measuring improvement in health outcomes.

Response: We thank commenters for their support of our proposal to adopt the Facility Commitment to Health Equity reporting measure. We agree that the measure assesses a facility's commitment to health equity and is intended to encourage facilities to understand their own health equity gaps so they can improve patient outcomes.

Comment: A few commenters expressed support for public reporting of the measure.

Response: We thank the commenters for their support.

Comment: A few commenters who supported the adoption of the Facility Commitment to Health Equity measure also offered suggestions for possible expansion of the measure. A few commenters recommended expanding the scope of the measure to specifically ensure that facilities identify and address equity in access to home dialysis. One commenter recommended that the measure eventually be expanded to capture a greater depth of information that would provide more meaningful data to CMS and patients. The commenter also recommended that CMS include health equity requirements as part of the Conditions for Coverage for the Medicare program, which could potentially be used to require that facilities collect and stratify data on certain demographic elements. One commenter encouraged CMS take actions to further enable nurses to support health equity efforts, noting their critical role in patient engagement while balancing administrative burden.

Response: We thank commenters for their suggestions, which we will consider as we continue to develop potential future policies on this topic.

Comment: One commenter expressed support for the Facility Commitment to Health Equity measure but recommended that CMS ensure that there are no unintended consequences, such as disincentivizing facilities from operating in areas that may have greater health disparities.

Response: We appreciate the commenter's support and will monitor this measure, as we do all ESRD QIP measures, for any unintended or adverse outcomes associated with implementation.

Comment: Several commenters stated that it was unclear how the Facility Commitment to Health Equity measure would result in a reduction of social inequities. A few commenters expressed concern that the measure lacks follow-up and does not require facilities to take specific action upon identifying health equity gaps. A few commenters expressed concern that, without additional requirements for facilities to make changes based on identified health equity gaps, the Facility Commitment to Health Equity measure may only serve as a checklist measure rather than incentivizing change at the systemic level. One commenter expressed concern that the Facility Commitment to Health Equity measure is not relevant to the ESRD QIP because the measure was developed for the hospital setting. One commenter expressed concern that the measure would not promote meaningful action in patient care because it is not clinical.

Response: We believe this measure is an important foundational measure for improving health equity for the facility's entire patient population, which may include patients that have been underserved by the healthcare system. As we discussed in section IV.C.2.a. of the proposed rule, there is substantial research showing differences in care and experiences among underserved populations (88 FR 42489 through 42491). The measure is intended to encourage facilities to analyze their own data to understand whether there are demographic factors or other social drivers of health that may be contributing to the health outcomes experienced by their patients so they can develop solutions to improve those outcomes for all of their patients. We believe that adopting the measure for dialysis facilities will help improve access to care and outcomes for the ESRD population by making facilities more aware of certain potential opportunities for improvement. We also believe that a commitment to health equity by dialysis facility leadership can foster organizational competencies aimed at achieving health equity for the facility's patients. Although the Facility Commitment to Health Equity reporting measure is not a clinical measure, the measure could improve facility awareness of the tie between its structural practices and its patient outcomes, which we believe will lead to improved clinical outcomes for patients.

[158] Centers for Medicare & Medicaid Services. 2023. 2022–2023 MAP Final Recommendations. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[159] Centers for Medicare & Medicaid Services. 2023. 2022–2023 MAP Final Recommendations. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

Comment: Although commenters appreciated the importance of a commitment to health equity and expressed support for CMS's efforts to address health equity, a few commenters expressed concern that the Facility Commitment to Health Equity measure needs to be developed further prior to inclusion in the ESRD QIP so that it is more meaningful to the ESRD population and care setting. One commenter requested that CMS engage with stakeholders in the ESRD community to improve the measure so that it is more applicable to the dialysis facility setting.

Response: The Facility Commitment to Health Equity measure is a structural measure that is designed to apply across multiple healthcare settings. The five measure domains (that is, equity is a strategic priority, data collection, data analysis, quality improvement, and leadership engagement) apply to dialysis facilities. Specifically, dialysis facilities collect data and analyze data for quality improvement purposes. Facilities also establish organizational plans that define practices and policies that impact health equity. We believe strong and committed leadership from dialysis facility leadership is essential and can play a role in advancing equity goals for facilities. Although we appreciate commenters' desire that the measure be tailored further to the ESRD population and setting, we believe that the measure sufficiently addresses a facility's leadership and its commitment to health equity in a way that encompasses the needs of that population and setting. The measure is intended to provide information to facilities on the level of unmet need among their patients by encouraging facilities to identify and address potential health equity gaps. We believe this measure is an important step toward assessing facility leadership commitment and a fundamental step toward closing the gap in equitable care for the facility's patients. We will continue to monitor the measure as it is implemented to ensure that it is meaningful to the ESRD community.

Comment: A few commenters recommended that CMS submit the measure to the CBE for review and endorsement to ensure that it is useful and meaningful for the ESRD population and care setting.

Response: While we recognize the value of CBE endorsement review, and plan to submit this measure for CBE endorsement in the future, measures of health equity are a priority for CMS, and we believe it is important to implement this measure as soon as possible. We note that under section 1881(h)(2)(B)(ii) of the Act the Secretary may specify a measure that is not endorsed by a CBE as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and therefore, we believe the exception in section 1881(h)(2)(B)(ii) of the Act applies. We believe the Facility Commitment to Health Equity measure establishes an important foundation to prioritize the achievement of health equity among facilities.

Comment: A few commenters expressed concern regarding the reporting burden associated with the proposed measure requirements and recommended that CMS weigh the potential impact on patient health outcomes against this new administrative burden. A few commenters stated that certain types of facilities, such as rural and small facilities, may lack the resources to implement this measure and, as a result, could be unfairly penalized. One commenter stated that compliance with the new measure will require substantial training and additional staff support. One commenter expressed concern that the reporting requirements associated with the proposed measure would take resources away from patient care.

Response: We recognize the commenters' concerns about burden of new measure requirements in the ESRD QIP and believe that our data submission requirements pose minimal burden on facilities given that facilities will have 14 months to report the measure with respect to each performance period. We believe this measure reporting timeline will provide facilities with ample time to submit data in a timely manner. We also believe the benefits of this measure outweigh the burden of reporting it.

Comment: One commenter requested that facilities receive full credit for attestation, regardless of whether the facility negatively or positively attests to each given domain. The commenter noted that this would be consistent with other reporting measures in the ESRD QIP measure set, which award points for reporting the data, rather than the results of the reported data.

Response: We believe this measure is an important step towards assessing leadership commitment to health equity and a fundamental step towards identifying and closing gaps in quality outcomes. We also believe that a facility should not receive the maximum 10 points on the measure for a performance year if it cannot affirmatively attest to all five domains. We believe that the proposed scoring methodology is consistent with the scoring methodology we have adopted for the MedRec reporting measure, which requires that facilities report that medication reconciliation was performed and documented by an eligible professional during the reporting period in order to be awarded the maximum number of points for the measure (83 FR 57009 and 57011).

Comment: One commenter recommended removing the term ''priority'' from Domain 1 to avoid implying that there are populations who are not priorities.

Response: We agree with the commenter that a facility's entire patient population should have access to high quality ESRD care. However, we disagree with commenter that the term ''priority'' should be removed, as we believe the element focuses on populations that the facility may identify as having experienced health disparities at that particular facility. A facility has discretion to identify its own priority populations and develop its own solutions to support its equity goals. Therefore, we are finalizing the reference to ''priority populations'' in Domain 1 as proposed.

Comment: Several commenters recommended that CMS update the measure specifications in Domain 2 so that facilities without certified EHR technology are able to positively attest to all domains, noting that dialysis facilities are not required to use certified EHR technology and may not have it available. These commenters expressed concern that public reporting of measure results for facilities that do not positively attest to all domains because they are without access to certified EHR technology could lead the public to misinterpret the results as a lack of commitment to health equity. A few commenters recommended that CMS revise the language to remove the reference to certified EHR technology to provide flexibility regarding the type of data technology used while retaining the requirement to input the data into structured fields. One commenter requested clarification regarding whether it will accept Electronic Data Interchange (EDI) in the EQRS for this measure.

Response: We thank commenters for their feedback. Although the majority of dialysis facilities use some type of EHR technology, we acknowledge that dialysis facilities are not currently required to use EHR technology certified by the Office of the National Coordinator for Health Information

Technology (ONC) to comply with the requirements of the ESRD QIP. We agree with commenters that the proposed language in Domain 2 may prevent facilities from affirmatively attesting to Domain 2 if they can only affirmatively attest to the elements in (A) and (B). Therefore, we are finalizing a revision to the elements of Domain 2 so that facilities can affirmatively attest to that domain if they use EHR technology that is not certified by ONC. This updated language is provided in Table 14 below and states, ''(C) Our facility inputs demographic and/or social determinant of health information collected from patients into structured, interoperable data elements using EHR technology.'' Although we encourage facilities to use certified health IT to promote interoperability and health information exchange across the healthcare system, we are not requiring dialysis facilities to use certified EHR technology for purposes of reporting this measure. We note that EHR technology may include EDI, and therefore EDI may be accepted as part of the EHR technology requirements included under Domain 2.

Comment: One commenter noted the relatively short timeframe for implementation and potential for error in data collection and reporting due to the complexity of the new data collection and reporting requirements. One commenter expressed concern regarding the element under Domain 3 that the facility have facility performance dashboards to affirmatively attest to that domain beginning with PY 2024, noting that such dashboards require thoughtful development to ensure that they are appropriately designed for lower patient volumes and account for potential clinically-related factors.

Response: We believe that facilities should have sufficient time to implement any structural processes they need to report the measure. However, to the extent a facility may need to implement new data collections or update its systems to enable it to affirmatively attest to Domain 3 or any other domain, a facility will have until two months after the end of each 12-month performance period to submit its attestations for that performance period in EQRS. In addition, a facility can report an affirmative attestation for a domain as long as it satisfies the elements of the domain at any time during the applicable performance period.

Comment: One commenter stated that all facilities participating in the ESRD Network Program should meet the Domain 4 requirement that facilities engage in quality activities and recommended that all dialysis facilities receive automatic credit for this domain.

Response: We believe it is necessary for each dialysis facility to review its health equity practices under each domain and attest to each domain separately, including Domain 4. If a facility participates in quality improvement activities focused on reducing health disparities as part of a facility's participation in an ESRD Network, then a facility may affirmatively attest under Domain 4.

Comment: A few commenters observed that the language in Domain 5 does not apply to many individual dialysis facilities, as they are part of national groups and therefore do not have facility-level CEOs or boards of trustees. A few commenters also requested clarification as to whether the Facility Commitment to Health Equity measure requirements would apply to each individual dialysis facility separately, or whether they would apply to the larger organization which includes the individual dialysis facility. One commenter expressed concern regarding the potential burden imposed on small facilities if compliance with the Facility Commitment to Health Equity measure would be required at the facility level and recommended that small facilities be exempt from Facility Commitment to Health Equity reporting requirements, or that CMS allow such facilities that are part of a larger organization to use the organization's strategic plan to satisfy measure requirements. One commenter expressed concern that facility-level analysis of disparities may be insufficient to identify and address gaps in the dialysis setting as these facilities serve more geographically homogenous populations than other types of healthcare facilities, such as hospitals.

Response: We thank commenters for their feedback and are finalizing a modified version of the Domain 5 elements. Whereas the originally proposed language for Domain 5 required that facilities attest to leadership engagement at the facility level only, we agree that facilities should be able to attest to leadership engagement under Domain 5 if their senior leadership engages in the Domain 5 elements and that engagement applies to the facility, regardless of whether those senior leaders operate at only the facility or at a larger organization that includes the facility. Accordingly, we are finalizing that the referenced facility senior leadership could be, but are not required to be, the facility's own chief executives or its board of trustees.

Regarding commenters' requests for clarification as to whether the measure requirements would apply to each individual dialysis facility separately, or whether they would apply to the larger organization which includes the individual dialysis facility, we note that we proposed for the Facility Commitment to Health Equity reporting measure to apply to individual facilities. For all five measure domains, an individual facility may attest to both facility-level efforts as well as activities that are implemented by the individual facility as part of a larger organization's policies. For individual facilities that are part of larger organizations, we note that this may include leadership engagement at the larger organizational level as well as leadership engagement at the individual facility level. Specifically, the reporting measure would require facilities to review their own activities in relation to the five measure domains to identify ways to address disparities within the patient population they serve. We believe this revision will apply more broadly to accommodate the unique organization structures across facilities.

The elements of the Facility Commitment to Health Equity Measure, including the revised language for Domains 2 and 5, are provided in Table 14.

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TABLE 14: Facility Commitment to Health Equity Measure's Finalized Five Attestations

Attestation	Elements: Select all that apply (Note: Affirmative attestation of all elements within a domain would be required for the facility to receive a point for the domain in the numerator)
Domain 1: Equity is a Strategic Priority	
Facility commitment to reducing healthcare disparities is strengthened when equity is a key organizational priority. Please attest that your facility has a strategic plan for advancing health equity and that it includes all the following elements.	(A) Our facility strategic plan identifies priority populations who currently experience health disparities. (B) Our facility strategic plan identifies health equity goals and discrete action steps to achieving these goals. (C) Our facility strategic plan outlines specific resources which have been dedicated to achieving our equity goals. (D) Our facility strategic plan describes our approach for engaging key stakeholders, such as community-based organizations.
Domain 2: Data Collection	
Collecting valid and reliable demographic and social determinant of health data on patients served in a facility is an important step in identifying and eliminating health disparities. Please attest that your facility engages in the following activities.	(A) Our facility collects demographic information (such as self-reported race, national origin, primary language, and ethnicity data) and/or social determinant of health information on the majority of our patients. (B) Our facility has training for staff in culturally sensitive collection of demographic and/or social determinant of health information. (C) Our facility inputs demographic and/or social determinant of health information collected from patients into structured, interoperable data elements using EHR technology.*
Domain 3: Data Analysis	
Effective data analysis can provide insights into which factors contribute to health disparities and how to respond. Please attest that your facility engages in the following activities.	(A) Our facility stratifies key performance indicators by demographic and/or social determinants of health variables to identify equity gaps and includes this information on facility performance dashboards.
Domain 4: Quality Improvement	
Health disparities are evidence that high-quality care has not been delivered equitably to all patients. Engagement in quality improvement activities can improve quality of care for all patients.	(A) Our facility participates in local, regional, or national quality improvement activities focused on reducing health disparities.
Domain 5: Leadership Engagement	
Leaders and staff can improve their capacity to address disparities by demonstrating routine and thorough attention to equity and setting an organizational culture of equity. Please attest that your facility engages in the following activities.	(A) Our facility senior leadership, such as, but not limited to, chief executives and the entire facility board of trustees, annually reviews our strategic plan for achieving health equity.** (B) Our facility senior leadership, such as, but not limited to, chief executives and the entire facility board of trustees, annually reviews key performance indicators stratified by demographic and/or social factors.

* After consideration of public comments, we are refining the language in Domain 2 to remove the requirement that EHR technology must be "certified" to affirmatively attest to the elements of that domain.
** After consideration of public comments, we are refining the language in Domain 5 to provide flexibility regarding the type of leadership that may be engaged in these efforts.

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Comment: One commenter expressed concern regarding the Facility Commitment to Health Equity measure, stating that the measure essentially

served as a back-door mandate to require that facilities perform a specific activity and did not provide facilities with flexibility to achieve the ultimate goal of the measure.

Response: We disagree with the commenter. We believe this measure is an important foundation for improving health equity in the provision of ESRD care. We believe that each of the domains provides flexibility for facilities to affirmatively attest without imposing overly narrow or prescriptive requirements. Although facilities will be required to affirmatively attest to each of the elements for a domain to receive points for that domain, a facility has the discretion to determine what activities will satisfy each element. We encourage facilities to analyze their own data to improve their awareness of whether there is a tie between their structural practices and the outcomes experienced by their patients, with the goal of attaining better outcomes for all of their patients.

Final Rule Action: After considering public comments, we are finalizing the adoption of the Facility Commitment to Health Equity reporting measure with language refinements to the elements in Domains 2 and 5 as described in Table 14 of this final rule, beginning with PY 2026.

3. Modification of the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning With PY 2026

a. Background

On January 31, 2020, the Secretary of the Department of Health and Human Services declared a public health emergency (PHE) for the United States in response to the global outbreak of SARS–COV–2, a novel (new) coronavirus that causes a disease named ''coronavirus disease 2019'' (COVID–19).[160] Subsequently, the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure was adopted across multiple quality reporting programs including the ESRD QIP (87 FR 67244 through 67248), the Hospital IQR Program (86 FR 45374), the Inpatient Psychiatric Facility Quality Reporting Program (86 FR 42633 through 42640), the Hospital Outpatient Quality Reporting Program (86 FR 63824 through 63833), the PPS-Exempt Cancer Hospital Quality Reporting Program (86 FR 45428 through 45434), the Ambulatory Surgical Center Quality Reporting Program (86 FR 63875 through 63883), the Long-Term Care Hospital Quality Reporting Program (86 FR 45438 through 45446), the Skilled Nursing Facility Quality Reporting Program (86 FR 42480 through 42489), and the Inpatient Rehabilitation Facility Quality Reporting Program (86 FR 42385 through 42396). COVID–19 has continued to spread domestically and around the world with more than 103.9 million cases and 1.13 million deaths in the United States as of June 19, 2023.[161] In recognition of the ongoing significance and complexity of COVID–19, the Secretary renewed the PHE on April 21, 2020, July 23, 2020, October 2, 2020, January 7, 2021, April 15, 2021, July 19, 2021, October 15, 2021, January 14, 2022, April 12, 2022, July 15, 2022, October 13, 2022, January 11, 2023, and February 9, 2023.[162] While the PHE expired on May 11, 2023, HHS has stated that the public health response to COVID–19 remains a public health priority with a whole of government approach to combatting the virus, including through vaccination efforts.[163]

As we stated in the CY 2023 ESRD PPS final rule (87 FR 67244) and in our Revised Guidance for Staff Vaccination Requirements,[164] vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19. We continue to believe it is important to incentivize and track HCP vaccination through quality measurement across care settings, including dialysis facilities, to protect health care workers, patients, and caregivers, and to help sustain the ability of HCP in each of these care settings to continue serving their communities. Prior to the publication of the CY 2023 ESRD PPS final rule on November 7, 2022, the FDA had approved or issued emergency use authorizations (EUAs) for COVID–19 vaccines for adults manufactured by Pfizer-BioNTech,[165] Moderna,[166] and Janssen.[167] The populations for which all three vaccines were authorized at that time included individuals 18 years of age and older, and the Pfizer-BioNTech vaccine was authorized for ages 12 and older. The FDA issued an approval for the Pfizer-BioNTech vaccine, now marketed as Comirnaty, on August 23, 2021.[168] Additionally, the FDA issued approval for the Moderna vaccine, marketed as Spikevax, on January 31, 2022[169] and an EUA for the Novavax adjuvanted vaccine on July 13, 2022.[170] The FDA also issued EUAs for single booster doses of the then-authorized COVID–19 vaccines. As of November 19, 2021,[171] [172] [173] a single

[160] U.S. Dept of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2020). Determination that a Public Health Emergency Exists. Available at: *https://aspr.hhs.gov/legal/PHE/Pages/2019-nCoV.aspx.*

[161] CDC. COVID Data Tracker. Accessed June 19, 2023. Available at: *https://covid.cdc.gov/covid-data-tracker/#datatracker-home.* We note that we have updated in this final rule the number of cases and deaths provided in the proposed rule, which stated that ''COVID–19 has continued to spread domestically and around the world with more than 103.9 million cases and 1.1 million deaths in the United States as of March 27, 2023.'' (88 FR 42494).

[162] U.S. Dept. of Health and Human Services. Office of the Assistant Secretary for Preparedness and Response. (2023). Renewal of Determination that a Public Health Emergency Exists. Available at: *https://aspr.hhs.gov/legal/PHE/Pages/COVID19-9Feb2023.aspx.*

[163] U.S. Dept. of Health and Human Services. Fact Sheet: COVID–19 Public Health Emergency Transition Roadmap. February 9, 2023. Available at: *https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html.*

[164] Centers for Medicare & Medicaid Services. Revised Guidance for Staff Vaccination Requirements QSO–23–02–ALL. October 26, 2022. Available at: *https://www.cms.gov/files/document/qs0-23-02-all.pdf.*

[165] Food and Drug Administration. (December 2020). FDA Takes Key Action in Fight Against COVID–19 By Issuing Emergency Use Authorization for First COVID–19 Vaccine. Available at: *https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19.*

[166] Food and Drug Administration. (December 2020). FDA Takes Additional Action in Fight Against COVID–19 By Issuing Emergency Use Authorization for Second COVID–19 Vaccine. Available at: *https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid.*

[167] Food and Drug Administration. (February 2021). FDA Issues Emergency Use Authorization for Third COVID–19 Vaccine. Available at: *https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine.*

[168] Food and Drug Administration. (August 2021). FDA Approves First COVID–19 Vaccine. Available at: *https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.*

[169] Food and Drug Administration. (January 2022). Coronavirus (COVID–19) Update: FDA Takes Key Action by Approving Second COVID–19 Vaccine. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine.*

[170] Food and Drug Administration. (July 2022). Coronavirus (COVID–19) Update: FDA Authorizes Emergency Use of Novavax COVID–19 Vaccine, Adjuvanted. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-emergency-use-novavax-covid-19-vaccine-adjuvanted.*

[171] Food and Drug Administration. (September 2021). FDA Authorizes Booster Dose of Pfizer-BioNTech COVID–19 Vaccine for Certain Populations. Available at: *https://www.fda.gov/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations.*

[172] Food and Drug Administration. (October 2021). Coronavirus (COVID–19) Update: FDA Takes Additional Actions on the Use of a Booster Dose for COVID–19 Vaccines. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-actions-use-booster-dose-covid-19-vaccines.*

[173] Food and Drug Administration. (November 2021). Coronavirus (COVID–19) Update: FDA Expands Eligibility for COVID–19 Vaccine Boosters.

booster dose of each COVID–19 vaccine was authorized for all eligible individuals 18 years of age and older. EUAs were subsequently issued for a second booster dose of the Pfizer-BioNTech and Moderna vaccines in certain populations in in March 2022.[174] FDA first authorized the use of a booster dose of bivalent or ''updated'' COVID–19 vaccines from Pfizer-BioNTech and Moderna in August 2022.[175] Since the publication of the CY 2024 ESRD PPS proposed rule, the 2023–2024 updated Pfizer-BioNTech, Moderna, and Novavax COVID–19 vaccines were recommended by CDC for use in the United States.[176] The 2023–2024 updated COVID–19 vaccine more closely targets the XBB lineage of the Omicron variant and could restore protection against severe COVID–19 that may have decreased over time.

We stated in the CY 2023 ESRD PPS final rule that HCP are at risk of carrying COVID–19 infection to patients, experiencing illness or death themselves as a result of contracting COVID–19, and transmitting COVID–19 to their families, friends, and the general public (87 FR 67244). While the impact of COVID–19 vaccines on asymptomatic infection and transmission is not yet fully known, there is now robust data available on COVID–19 vaccine effectiveness across multiple populations against symptomatic infection, hospitalization, and death. Two-dose COVID–19 vaccines from Pfizer-BioNTech and Moderna were found to be 88 percent and 93 percent effective against hospitalization for COVID–19, respectively, over 6 months for adults over age 18 without immunocompromising conditions.[177] During a SARS–COV–2 surge in the spring and summer of 2021, 92 percent of COVID–19 hospitalizations and 91 percent of COVID–19-associated deaths were reported among persons not fully vaccinated.[178] Real-world studies of population-level vaccine effectiveness indicated similarly high rates of effectiveness in preventing SARS–COV–2 infection among frontline workers in multiple industries, with a 90 percent effectiveness in preventing symptomatic and asymptomatic infection from December 2020 through August 2021.[179] Vaccines have also been highly effective in real-world conditions preventing COVID–19 in HCP with up to 96 percent effectiveness for fully vaccinated HCP, including those at risk for severe infection and those in racial and ethnic groups disproportionately affected by COVID–19.[180] In the presence of high community prevalence of COVID–19, residents of nursing homes with low staff vaccination coverage had higher rates of COVID–19 cases and COVID–19 related deaths than those among residents of nursing homes with high staff vaccination coverage.[181] Overall, data demonstrate that COVID–19 vaccines are effective and prevent severe disease, including hospitalization and death.

As SARS–COV–2 persists and evolves, our COVID–19 vaccination strategy must remain responsive. When we finalized adoption of the COVID–19 Vaccination Coverage Among HCP measure in the CY 2023 ESRD PPS final rule, we stated that HCP should be counted as vaccinated if they received COVID–19 vaccination any time from when it first became available in December 2020 (87 FR 67247). We noted that a completed vaccination course, defined for purposes of the measure as the primary vaccination series, may require one or more doses depending on the specific vaccine used, and that the NHSN application automatically calculates the total value for ''Any completed COVID–19 vaccine series.'' We also stated that, as vaccination protocols continue to evolve, we would continue to work with the CDC to update relevant measure specifications as necessary. Since we finalized the COVID–19 Vaccination Coverage Among HCP measure in the CY 2023 ESRD PPS final rule, new variants of SARS–COV–2 have emerged around the world and within the United States. Specifically, the Omicron variant (and its related subvariants) is listed as a variant of concern by the CDC because it spreads more easily than earlier variants.[182] Vaccine manufacturers initially responded to the Omicron variant by developing bivalent COVID–19 vaccines, which included a component of the original virus strain to provide broad protection against COVID–19 and a component of the Omicron variant to provide better protection against COVID–19 caused by the Omicron variant.[183] These booster doses of the bivalent COVID–19 vaccines were shown to increase immune response to SARS–COV–2 variants, including Omicron, particularly in individuals who are more than 6 months removed from receipt of their primary series.[184] We noted in the proposed rule that the FDA issued EUAs for booster doses of two bivalent COVID–19 vaccines, one from Pfizer-BioNTech[185] and one from

Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-covid-19-vaccine-boosters*.

[174] Food and Drug Administration. (March 2022). Coronavirus (COVID–19) Update: FDA Authorizes Second Booster Dose of Two COVID–19 Vaccines for Older and Immunocompromised Individuals. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-second-booster-dose-two-covid-19-vaccines-older-and*.

[175] Food and Drug Administration. (August 2022). Coronavirus (COVID–19) Update: FDA Authorizes Moderna, Pfizer-BioNTech Bivalent COVID–19 Vaccines for Use as a Booster Dose. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use*. We note that, as of September 12, 2023, the bivalent COVID–19 vaccines are no longer FDA authorized. FDA. (September 11, 2023). FDA Takes Action on Updated mRNA COVID–19 Vaccines to Better Protect Against Currently Circulating Variants. Available at: *https://www.fda.gov/news-events/press-announcements/fda-takes-action-updated-mrna-covid-19-vaccines-better-protect-against-currently-circulating*. The bivalent COVID–19 vaccines have been replaced with the updated 2023–2024 (XBB-variant) COVID–19 vaccines.

[176] CDC. (October 4, 2023). Stay Up to Date with COVID–19 Vaccines. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html*.

[177] CDC. (September 24, 2021). Morbidity and Mortality Weekly Report (MMWR). Comparative Effectiveness of Moderna, Pfizer-BioNTech, and Janssen (Johnson & Johnson) Vaccines in Preventing COVID–19 Hospitalizations Among Adults Without Immunocompromising Conditions—United States, March–August 2021. Available at: *https://cdc.gov/mmwr/volumes/70/wr/mm7038e1.htm?s_cid=mm7038e1_w*.

[178] CDC. (September 10, 2021). Morbidity and Mortality Weekly Report (MMWR). Monitoring Incidence of COVID–19 Cases, Hospitalizations, and Deaths, by Vaccination Status—13 U.S. Jurisdictions, April 4–July 17, 2021. Available at: *https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e1.htm*.

[179] CDC. (August 27, 2021). Morbidity and Mortality Weekly Report (MMWR). Effectiveness of COVID–19 Vaccines in Preventing SARS–COV–2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance—Eight U.S. Locations, December 2020–August 2021. Available at: *https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e4.htm*.

[180] Pilishivi, T. et al. (December 2022). Effectiveness of mRNA Covid–19 Vaccine among U.S. Health Care Personnel. New England Journal of Medicine. 2021 Dec 16;385(25):e90. Available online at: *https://pubmed.ncbi.nlm.nih.gov/34551224/*.

[181] McGarry BE et al. (January 2022). Nursing Home Staff Vaccination and Covid-19 Outcomes. New England Journal of Medicine. 2022 Jan 27;386(4):397–398. Available online at: *https://pubmed.ncbi.nlm.nih.gov/34879189/*.

[182] Food and Drug Administration. (August 2021). Variants of the Virus. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/variants/index.html*.

[183] Food and Drug Administration. (November 2022). COVID–19 Bivalent Vaccine Boosters.

[184] Oster Y et al. (May 2022). The effect of a third BNT162b2 vaccine on breakthrough infections in health care workers: a cohort analysis. Clin Microbiol Infect. 2022 May;28(5):735.e1–735.e3. Available online at: *https://pubmed.ncbi.nlm.nih.gov/35143997/*.

[185] Food and Drug Administration. (November 2022). Pfizer-BioNTech COVID–19 Vaccines. Available at: *https://www.fda.gov/emergency-*

Continued

Moderna,[186] and strongly encouraged anyone who is eligible to consider receiving a booster dose with a bivalent COVID–19 vaccine to provide better protection against currently circulating variants.[187] Since the publication of the CY 2024 ESRD PPS proposed rule, an updated 2023–2024 formulation of COVID–19 vaccine has been approved that more closely targets the XBB lineage of the Omicron variant and could restore protection against severe COVID–19 that may have decreased over time.[188] Updated COVID–19 vaccine doses are associated with a greater reduction in infections among HCP and their patients relative to those who only received primary series vaccination,[189] [190] with a rate of breakthrough infections among HCP who received only a two-dose regimen of 21.4 percent compared to a rate of 0.7 percent among boosted HCP.[191] Data from the existing COVID–19 Vaccination Coverage Among HCP measure demonstrate clinically significant variation in booster dose vaccination rates across facilities.

We believe that vaccination remains the most effective means to prevent the worst consequences of COVID–19, including severe illness, hospitalization, and death. Given the availability of vaccine efficacy data, EUAs and Biologics License Application approvals issued by the FDA for updated 2023–2024 formulations of the vaccine, the continued presence of SARS–COV–2 in the United States, and variance among rates of updated vaccinations, it is important to modify the COVID–19 Vaccination Coverage Among HCP measure to reflect recent updates that explicitly specify for HCP to receive primary series and updated vaccine doses in a timely manner. As the COVID–19 pandemic persists, we continue to believe that monitoring and surveillance is important and provides patients, beneficiaries, and their caregivers with information to support informed decision making. In the CY 2024 ESRD PPS proposed rule, we proposed to modify the COVID–19 Vaccination Coverage Among HCP measure to replace the term ''complete vaccination course'' with the term ''up to date'' in the HCP vaccination definition (88 FR 42496). We also proposed to update the numerator to specify the time frames within which an HCP is considered up to date with recommended COVID–19 vaccines, including updated vaccine doses, beginning with PY 2026. As we stated in the CY 2023 ESRD PPS final rule (87 FR 67245), the COVID–19 Vaccination Coverage Among HCP measure is a process measure that assesses HCP vaccination coverage rates. Unlike outcome measures, process measures do not assess a particular outcome.

b. Overview of Updated Measure

The COVID–19 Vaccination Coverage Among HCP measure is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCP in settings such as dialysis facilities, and the measure is reported via the CDC's NHSN.

We refer readers to the CY 2023 ESRD PPS final rule (87 FR 67245 through 67246) for more information on the initial review of the measure by the Measure Applications Partnership (MAP). We included an updated version of the measure on the Measures Under Consideration (MUC) list for the 2022–2023 pre-rulemaking cycle for consideration by the MAP. In December 2022, the MAP's Hospital Workgroup discussed the modified measure. The Hospital Workgroup stated that the revision of the current measure captures up-to-date vaccination information in accordance with CDC recommendations updated since its initial development. Additionally, the Hospital Workgroup appreciated that the respecified proposed measure of the target population is broader and simplified from seven categories of HCP to four.[192] During review, the Health Equity Advisory Group highlighted the importance of COVID–19 measures and questioned whether the measure excludes individuals with contraindications to FDA authorized or approved COVID–19 vaccines, and whether the measure will be stratified by demographic factors. The measure developer confirmed that HCP with contraindications to the vaccines are excluded from the measure denominator, but the measure would not be stratified since the data are submitted at an aggregate rather than an individual level. The Rural Health Advisory Group expressed concerns about data collection burden, citing that collection is performed manually and that small rural facilities may not have employee health software.[193] The measure developer acknowledged the challenge of getting adequate documentation and emphasized the goal to ensure the measure does not present a burden on the provider. The developer also noted that the model used for this measure is based on the Influenza Vaccination Coverage Among HCP measure (CBE #0431), and it intends to utilize a similar approach to the modified COVID–19 Vaccination Coverage Among HCP measure if the COVID–19 vaccination strategy becomes seasonal. The revised measure received conditional support for rulemaking from both the MAP workgroups pending testing indicating the measure is reliable and valid, and endorsement by the consensus-based entity (CBE).[194] The MAP noted that the previous version of the measure received endorsement from the CBE (CBE #3636) [195] and that the CDC intends to submit the updated measure for endorsement.

(1) Measure Specifications

This reporting measure includes at least one week of data collection a month for each of the three months in

preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccines.

[186] Food and Drug Administration. (November 2022). Moderna COVID–19 Vaccines. Available at: *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccines*.

[187] Food and Drug Administration. (August 2022). Coronavirus (COVID–19) Update: FDA Authorizes Moderna, Pfizer-BioNTech Bivalent COVID–19 Vaccines for Use as a Booster Dose. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use*.

[188] CDC. (October 4, 2023). Stay Up to Date with COVID–19 Vaccines. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html*.

[189] Prasad N et al. (May 2022). Effectiveness of a COVID–19 Additional Primary or Booster Vaccine Dose in Preventing SARS-CoV–2 Infection Among Nursing Home Residents During Widespread Circulation of the Omicron Variant—United States, February 14–March 27, 2022. Morbidity and Mortality Weekly Report (MMWR). 2022 May 6;71(18):633–637. Available online at: *https://pubmed.ncbi.nlm.nih.gov/35511708/*.

[190] Oster Y et al. (May 2022). The effect of a third BNT162b2 vaccine on breakthrough infections in health care workers: a cohort analysis. Clin Microbiol Infect. 2022 May;28(5):735.e1–735.e3. Available online at: *https://pubmed.ncbi.nlm.nih.gov/35143997/*.

[191] Ibid.

[192] Centers for Medicare & Medicaid Services. MAP 2022–2023 Preliminary Analysis Worksheet. 2022. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: *https://mmshub.cms.gov/sites/default/files/map-preliminary-recommendations-2022-2023.xlsx*.

[193] Centers for Medicare & Medicaid Services. MAP 2022–2023 Final Recommendations. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports*.

[194] In previous years, we referred to the consensus-based entity by corporate name. We have updated this language to refer to the consensus-based entity more generally.

[195] We note that the reference provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now as follows: Centers for Medicare & Medicaid Services. Measure Specifications for Hospital Workgroup for the 2022 MUC List. Available at: *https://mmshub.cms.gov/sites/default/files/map-hospital-measure-specifications-manual-2022.pdf*.

a quarter. The denominator is the number of HCP eligible to work in the facility for at least one day during the reporting period, excluding persons with contraindications to COVID–19 vaccination that are described by the CDC. Facilities report the following four categories of HCP to NHSN:

1. Employees: includes all persons who receive a direct paycheck from the reporting facility (that is, on the facility's payroll), regardless of clinical responsibility or patient contact.

2. Licensed independent practitioners (LIPs): This includes physicians (MD, DO), advanced practice nurses, and physician assistants only who are affiliated with the reporting facility but are not directly employed by it (that is, they do not receive a direct paycheck from the reporting facility), regardless of clinical responsibility or patient contact. Post-residency fellows are also included in this category if they are not on the facility's payroll.

3. Adult students/trainees and volunteers: This includes all medical, nursing, or other health professional students, interns, medical residents, and volunteers aged 18 or over who are affiliated with the healthcare facility, but are not directly employed by it (that is, they do not receive a direct paycheck from the facility), regardless of clinical responsibility or patient contact.

4. Other contract personnel: Contract personnel are defined as persons providing care, treatment, or services at the facility through a contract who do not fall into any of the previously discussed denominator categories. This also includes vendors providing care, treatment, or services at the facility who may or may not be paid through a contract. Facilities are required to enter data on other contract personnel for submission in the NHSN application, but data for this category are not included in the COVID–19 Vaccination Coverage Among HCP measure.[196] The denominator excludes denominator-eligible individuals with contraindications as defined by the CDC.[197] There are no changes to the denominator exclusions.

The numerator of the modified measure is the cumulative number of HCP in the denominator population who are considered up to date with recommended COVID–19 vaccines. Facilities would refer to the definition of up to date as of the first day of the applicable reporting quarter, which can be found at *https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-508.pdf*. In the proposed rule, we provided the example that HCP would be considered up to date during the applicable performance period for the ESRD QIP if they met one of the following criteria:

1. Individuals who received an updated bivalent[198] booster dose, or

2a. Individuals who received their last booster dose less than 2 months ago, or

2b. Individuals who completed their primary series[199] less than 2 months ago.

We note that since publication of the proposed rule, the CDC's definition for up to date vaccination has evolved. HCP would be considered up to date during the applicable performance period for the ESRD QIP if they met the following criteria:

1. Individuals who received an updated[200] vaccine dose.

We refer readers to *https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-508.pdf* for more details on the measure specifications.

We noted in the proposed rule that the updated COVID–19 Vaccination Coverage Among HCP measure would remain a reporting measure. The updates to measure weighting for PY 2026 and PY 2027 are discussed further in sections IV.C.6 and IV.D.7 of this final rule.

(2) Consensus-Based Entity Endorsement

The current version of the measure in the ESRD QIP received CBE endorsement (CBE #3636, ''Quarterly Reporting of COVID–19 Vaccination Coverage among Healthcare Personnel'') on July 26, 2022. Although section 1881(h)(2)(B)(i) of the Act generally requires that measures specified by the Secretary for the ESRD QIP be endorsed by the entity with a contract under section 1890(a) of the Act, section 1881(h)(2)(B)(ii) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. In developing the CY 2024 ESRD PPS proposed rule, we reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic; therefore, we believe the exception for non-CBE-endorsed measures applies. The CDC, as the measure developer, is pursuing endorsement for the modified version of the measure.

c. Data Submission and Reporting

We refer readers to the CY 2023 ESRD PPS final rule (87 FR 67246) for information on data submission and reporting for the measure. We did not propose any changes to the existing data submission requirements.

We invited public comment on this proposal. The comments we received and our responses are set forth below.

Comment: Several commenters expressed support for the proposal to modify the COVID–19 Vaccination Coverage Among HCP reporting measure. Several of these commenters noted that vaccination is a critical tool to protect the health of HCP and patients. One commenter expressed support for the proposed modification, noting that continued tracking of up-to-date vaccination status is important to help facilities prepare for infectious

[196] For more details on the reporting of other contract personnel, we refer readers to the NHSN COVID–19 Vaccination Protocol, Weekly COVID–19 Vaccination Module for Healthcare Personnel available at: *https://www.cdc.gov/nhsn/pdfs/hps/covidvax/protocol-hcp-508.pdf.*

[197] CDC. (2022). Contraindications and precautions. Available at: *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#contraindications.*

[198] In the CY 2024 ESRD PPS proposed rule, we noted that the updated (bivalent) Moderna and Pfizer-BioNTech boosters targeted the most recent Omicron subvariants. The updated (bivalent) boosters were recommended by the CDC on September 2, 2022. As of the CY 2024 ESRD PPS proposed rule, we also noted that the original, monovalent mRNA vaccines are no longer authorized as a booster dose for people ages 12 years and older. Since the proposed rule was published, the bivalent COVID–19 vaccines are no longer FDA authorized. FDA. (September 11, 2023). FDA Takes Action on Updated mRNA COVID–19 Vaccines to Better Protect Against Currently Circulating Variants. Available at: *https://www.fda.gov/news-events/press-announcements/fda-takes-action-updated-mrna-covid-19-vaccines-better-protect-against-currently-circulating.* The bivalent COVID–19 vaccines have been replaced with the updated 2023–2024 (XBB-variant) COVID–19 vaccines.

[199] Although in the CY 2024 ESRD PPS proposed rule we indicated that completing a primary series means receiving a two-dose series of a COVID–19 vaccine or a single dose of Janssen/J&J COVID–19 vaccine (88 FR 42496), we note that the Janssen/J&J COVID–19 vaccine is no longer being used in the United States. For further information, please see CDC. (2023). Janssen (Johnson & Johnson) COVID–19 Vaccine. Available at: *https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html.*

[200] The 2023–2024 updated Pfizer-BioNTech, Moderna, and Novavax COVID–19 vaccines were recommended by CDC for use in the United States. The 2023–2024 updated COVID–19 vaccine more closely targets the XBB lineage of the Omicron variant and could restore protection against severe COVID–19 that may have decreased over time. Individuals are also considered up to date if they received a bivalent vaccine or a Novavax vaccine within the last 2 months, or if they received a Novavax vaccine after completing a primary series. For further details, please see: *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html.*

threats. One commenter expressed support for the proposed update because it will align the requirements between agencies.

Response: We thank the commenters for their support. We agree that vaccination plays a critical part of HHS's strategy to effectively counter the spread of COVID–19. We continue to believe it is important to incentivize and track rates of vaccination among HCP through quality measurement across care settings, including the dialysis facility setting, to protect healthcare workers, patients, and caregivers, and to help sustain the ability of HCP in each of these care settings to continue serving their communities.

Comment: Several commenters expressed concern regarding the reporting burden associated with the proposed changes, recommending that CMS weigh the potential impact on patient health outcomes against potential administrative burden for facilities. A few commenters recommended that the measure exclude staff who are not directly employed by the facility to reduce tracking burden. One commenter noted that the reporting burden associated with the measure was disproportionate to its weight as part of the ESRD QIP measure set.

Response: We acknowledge commenters' concerns regarding reporting burden associated with the specifications of this measure specifically around the definition of HCP. We note that given the highly infectious nature of the virus that causes COVID–19, we believe it is important to encourage all eligible personnel within the facility, regardless of patient contact, role, or employment type, to receive the COVID–19 vaccination to prevent outbreaks within the facility which may affect resource availability and have a negative impact on patient access to care. We note that the proposed updates to the COVID–19 Vaccination Coverage Among HCP reporting measure do not include a change to the definition of HCP, and that facilities have been reporting the COVID–19 Vaccination Coverage among HCP measure since January 1, 2022. With regard to the commenter's concern about the proportionality of the measure's reporting burden to its measure weight within the ESRD QIP, we note that the burden associated with a given measure is only one of several factors taken into consideration when determining the weight of the measure within the ESRD QIP. We take numerous factors into account when determining appropriate domain and measure weights, including clinical evidence, opportunity for improvement, clinical significance, and patient and provider burden (83 FR 56995 through 56996).

Comment: One commenter also supported aligning reporting with that for Influenza Vaccination Coverage Among HCP if the COVID–19 vaccination strategy becomes seasonal. One commenter recommended requiring annual reporting at the end of the respiratory season.

Response: We thank the commenter for this suggestion. As we stated in the CY 2024 ESRD PPS proposed rule (88 FR 42497), the model used for this measure is based on the Influenza Vaccination Coverage Among HCP measure (CBE #0431), and the measure developer intends to utilize a similar approach with respect to the modified version of the measure if the COVID–19 vaccination strategy becomes seasonal. For that reason, we may consider aligning reporting for the COVID–19 Vaccination Coverage Among HCP reporting measure with the Influenza Vaccination Coverage Among HCP measure in the future. We continue to monitor COVID–19 as part of our public health response and will consider information we collect to inform any potential action that may address seasonality in future rulemaking.

Comment: One commenter recommended that the measure get CBE review and endorsement prior to inclusion in the ESRD QIP.

Response: The current version of the measure received CBE endorsement (CBE #3636, ''Quarterly Reporting of COVID–19 Vaccination Coverage among Healthcare Personnel'') on July 26, 2022. As we stated in the CY 2024 ESRD PPS proposed rule (88 FR 42497 through 42498), in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. For this CY 2024 ESRD PPS rule cycle, we reviewed CBE-endorsed measures. While the current, CBE-endorsed version of the measure is available, the modified version of the measure more completely accounts for the availability of booster and bivalent doses which were not yet developed when the current version of the measure was adopted. Having given due consideration to CBE-endorsed measures, we believe the exception for non-CBE-endorsed measures under section 1881(h)(2)(B)(ii) of the Act applies. The measure steward, CDC, has submitted the modified measure to the CBE for endorsement and it is currently under review.

Comment: A few commenters expressed concern regarding the COVID–19 Vaccination Coverage Among HCP reporting measure, stating that facilities should not be held responsible for a HCP's decision to get vaccinated because those decisions are beyond the facility's control.

Response: We understand the commenters' concern that there are many factors outside of a facility's control that could affect vaccination coverage among a facility's HCP; however, we believe that all facilities face such concerns and that public reporting of these data can help patients and their caregivers identify which facilities have better vaccination coverage among their HCP. We wish to emphasize that the measure does not require that HCP actually receive the COVID–19 vaccine. The COVID–19 Vaccination Coverage Among HCP measure only requires reporting of vaccination rates.

Comment: A few commenters recommended removing the COVID–19 Vaccination Coverage Among HCP reporting measure from the ESRD QIP measure set. One commenter believed that the measure should be removed because the PHE has ended and CMS has also ended staff vaccination requirements related to COVID–19 vaccination. One commenter stated that the measure should be removed because it is outside the scope of the ESRD QIP.

Response: As commenters noted, the PHE for COVID–19 expired on May 11, 2023.[201] However, the expiration of the PHE for COVID–19 has no bearing on this measure because vaccination continues to be an essential tool in preventing COVID–19 transmission, and we believe that monitoring and surveillance of vaccination rates through measure performance is important and provides patients, beneficiaries, and their caregivers with information to support informed decision making.

Final Rule Action: After considering public comments, we are finalizing our proposal to modify the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure.

[201] U.S. Dept. of Health and Human Services. Fact Sheet: COVID–19 Public Health Emergency Transition Roadmap. February 9, 2023. Available at: *https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html.*

4. Conversion of the Clinical Depression Screening and Follow-Up Reporting Measure to a Clinical Measure Beginning With the PY 2026 ESRD QIP

In the CY 2015 ESRD PPS final rule, we finalized the adoption of the Clinical Depression Screening and Follow-Up reporting measure, beginning in PY 2018 (79 FR 66200 through 66203). As we noted in the CY 2015 ESRD PPS final rule, depression is a highly prevalent condition in patients with ESRD, which impacts many aspects of a patient's life and is associated with higher rates of mortality in the ESRD population. Adoption of a measure that assesses whether facilities screen patients for depression, and develop follow-up plans when appropriate, was and still is an opportunity to improve the health of patients with ESRD.

In the CY 2024 ESRD PPS proposed rule, we proposed to convert the Clinical Depression Screening and Follow-Up reporting measure to a clinical measure and to adopt a new methodology for scoring that measure as a clinical measure (88 FR 42498). We stated our belief that this proposed update would help to ensure that the measure is scored in a manner that more closely aligns with current clinical guidelines for depression screening and follow-up because it narrows the number of conditions on which a facility can earn points.

Clinical guidelines indicate that providers should both screen for depression and develop a follow-up plan for patients who test positive for depression.[202] Screening for depression is an important aspect of ESRD patient care, especially because ESRD and depression may present with similar symptoms, including but not limited to fatigue, poor appetite, headaches, and lack of focus.[203] Developing a follow-up plan for patients who screen positive for depression is equally important because ESRD patients may not be aware that they can seek treatment or that such treatment could be beneficial.[204] Under the specifications of the current Clinical Depression Screening and Follow-Up reporting measure, facilities are required to report one of six conditions with respect to each eligible patient, and we calculate the measure rate for the facility as the percentage of eligible patients for which the facility reports one of those six conditions. The six conditions are as follows:

- Screening for clinical depression is documented as being positive, and a follow-up plan is documented.
- Screening for clinical depression is documented as positive, and a follow-up plan is not documented, and the facility possesses documentation stating the patient is not eligible.
- Screening for clinical depression is documented as positive, the facility possesses no documentation of a follow-up plan, and no reason is given.
- Screening for clinical depression is documented as negative, and a follow-up plan is not required.
- Screening for clinical depression is not documented, but the facility possesses documentation stating the patient is not eligible.
- Screening for clinical depression is not documented, and no reason is given.

In the proposed rule, we did not propose to revise any of these conditions. However, we proposed that we would convert the measure to a clinical measure and award credit to facilities only if they report one of the following four of those six conditions:

- Screening for clinical depression is documented as being positive, and a follow-up plan is documented.
- Screening for clinical depression is documented as positive, and a follow-up plan is not documented, and the facility possesses documentation stating the patient is not eligible.
- Screening for clinical depression is documented as negative, and a follow-up plan is not required.
- Screening for clinical depression is not documented, but the facility possesses documentation stating the patient is not eligible.

In the proposed rule, we noted that if a facility selects one of the other two conditions (that is, ''Screening for clinical depression is documented as positive, the facility possesses no documentation of a follow-up plan, and no reason is given'' and ''Screening for clinical depression is not documented, and no reason is given''), the facility would not receive credit in the numerator (88 FR 42498). We stated that we believe this proposed update is important because it would assess facility performance on both the clinical depression screening and the follow-up plan, to the extent that one is needed, and would also incentivize facilities to report the reason for either not documenting that they screened for clinical depression, or why they do not possess documentation of a follow-up plan. We believe that the performance score calculation methodology changes we proposed to the Clinical Depression Screening and Follow-Up reporting measure would have a greater impact on fostering care coordination among providers and improving patient outcomes by incentivizing the documentation of depression screenings and follow-up plans, or alternatively requiring facilities to provide a reason why no screening or follow-up plan was documented. This measure update would also align with our efforts under the Meaningful Measures Framework, which identifies high-priority areas for quality measurement and improvement to assess core issues most critical to high-quality healthcare and improving patient outcomes.[205] In 2021, we launched Meaningful Measures 2.0 to promote innovation and modernization of all aspects of quality, and to address a wide variety of settings, stakeholders, and measure requirements.[206] We are addressing healthcare priorities and gaps with Meaningful Measures 2.0 by leveraging quality measures to increase efficiency, reduce burden, and close gaps in care. In the CY 2024 ESRD PPS proposed rule, we noted that the proposed updates to the Clinical Depression Screening and Follow-Up measure would support these efforts and would align with several Meaningful Measures Areas, including ''Seamless Care Coordination'' and ''Behavioral Health,'' as we believe that incentivizing the documentation of follow-up plans would encourage care coordination efforts to support the behavioral health outcomes of ESRD patients (88 FR 42499). We stated that the proposed modifications would also align with the Meaningful Measures 2.0 goal to ''Leverage measures to drive outcome improvement through public reporting and payment programs'' because we believe that converting the Clinical Depression Screening and Follow-Up reporting measure to a clinical measure would help to drive outcome improvement through the ESRD QIP. Additionally, in the

[202] KDOQI clinical practice guidelines for cardiovascular disease in dialysis patients√ Volume 45, SUPPLEMENT 3, 16–153, April 2005. *https://doi.org/10.1053/j.ajkd.2005.01.019*.

[203] PCORI Evidence Update. Treating Depression When You're on Dialysis (for Patients). July 2021. Available at: *https://www.pcori.org/sites/default/files/PCORI-Evidence-Update-for-Patients-Treating-Depression-When-Youre-on-Dialysis.pdf*.

[204] Michael J Fischer, Elani Streja, Jui-Ting Hsiung, Susan T Crowley, Csaba P Kovesdy, Kamyar Kalantar-Zadeh, Wissam M Kourany, Depression screening and clinical outcomes among adults initiating maintenance hemodialysis, Clinical Kidney Journal, Volume 14, Issue 12, December 2021, Pages 2548–2555, *https://doi.org/10.1093/ckj/sfab097*.

[205] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy*.

[206] Centers for Medicare & Medicaid Services. (2021). Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization*. We note that Meaningful Measures 2.0 is still under development.

proposed rule we stated that this proposed measure update would align with efforts to develop a Universal Foundation [207] that would help implement the vision outlined in our National Quality Strategy [208] and is fundamental to achieving several of the agency's quality and value-based care goals.[209] We noted that our proposal to update the Clinical Depression Screening and Follow-Up measure would help to align the measure that is used in the ESRD QIP with the measure identified for use across multiple programs as part of the Behavioral Health domain of the Universal Foundation measure set.[210]

We also proposed to convert the Clinical Depression Screening and Follow-Up measure from a reporting measure to a clinical measure beginning with PY 2026, and to move that measure to the Care Coordination Measure Domain beginning with that payment year (88 FR 42499). We proposed to convert the Clinical Depression Screening and Follow-Up measure from a reporting measure to a clinical measure because we believe that our proposed update to the performance score calculation aligned with that of a clinical measure. We proposed to move the Clinical Depression Screening and Follow-Up measure from the Reporting Measure Domain to the Care Coordination Measure Domain because the updated clinical measure would no longer be appropriate for inclusion under the Reporting Measure Domain. We note that we did not propose to change eligibility requirements for the measure. We discuss our updates to measure domains and weights for PY 2026 in section IV.C.6 of this final rule.

We welcomed public comment on our proposal. The comments we received and our responses are set forth below.

Comment: Several commenters expressed support for the proposal to convert the Clinical Screening and Follow-Up reporting measure to a clinical measure. A few of these commenters expressed support for the proposed update because it will help to better identify and treat clinical depression in ESRD patients. One commenter noted that the proposed change will better align the measure with current clinical guidelines for depression screening and follow-up.

Response: We thank commenters for their support.

Comment: Several commenters expressed concern regarding the reporting burden associated with the proposed changes, recommending that CMS weigh the potential impact on patient health outcomes against potential administrative burden.

Response: Although we would be converting the Clinical Depression Screening and Follow-Up measure from a reporting measure to a clinical measure and changing the methodology to score it as a clinical measure, we did not propose any changes that would change the reporting process or burden associated with the Clinical Depression Screening and Follow-Up measure. Although facilities would be scored differently and would be required to provide follow-up documentation or a reason no screening or follow-up has been documented to receive credit on the measure, they would continue to report data for this measure to EQRS in the same manner. We believe converting this measure to a clinical measure is important because it will assess facility performance on the measure in a way that is more meaningful to patient health outcomes, and that the potential beneficial impact on patient health outcomes outweighs the potential burden to facilities that may need to update their clinical depression screening and follow-up practices to receive credit for the measure. However, we will continue to monitor for potential unintended consequences.

Comment: Several commenters expressed concern regarding the ability of current facility staff to effectively support patients with clinical depression, noting that many facilities are under-resourced. A few commenters recommended establishing supports (such as allowing co-located mental health providers to bill Medicare) prior to converting the measure. A few commenters expressed concern regarding the meaningfulness of the Clinical Depression Screening and Follow-Up clinical measure, noting that many ESRD patients live in areas where there is a shortage of mental health care professionals and therefore would likely have difficulty accessing appropriate follow-up care following a positive depression screen.

Response: We thank the commenters for their feedback. We believe the updated scoring methodology has the potential to foster better care coordination and improve patient outcomes because it awards points facilities if they report that they documented follow-up plans for eligible patients who screened positive for clinical depression. As a documented outline of care for a positive depression screening, a follow-up plan may take into account a patient's ability to access follow-up care. However, we acknowledge that there might be circumstances, such as a lack of community resources, that may be beyond the facility's control, and the measure does not require the facility to ensure that the patient completed a follow-up plan.

Comment: A few commenters expressed concern about potential lack of patient privacy at facilities impacting the ability to engage effectively with the patient's care team to support mental health care needs. One commenter expressed concern that patients may feel pressured to participate in clinical depression screening surveys due to the proposed measure updates, and that a positive result on the screening may lead to patient stigma and impact future care.

Response: We appreciate commenters' concern and agree that protecting patient privacy is imperative. We note that the updated Clinical Depression Screening and Follow-Up clinical measure does not impose additional or new requirements on facilities that would interfere with a patient's right to privacy, and such information would be part of the patient's medical record and subject to same privacy protections as the patient's other medical information. The measure does not require patients to participate in a screening, and we have no reason to believe that facilities would pressure their patients into participating. Consistent with existing measure guidance, a patient would be considered ''not eligible'' for purposes of the measure if the patient's medical records document that the patient declined to participate in a clinical depression screening and would, therefore, be excluded from the measure cohort.[211] However, we will continue to monitor for potential unintended consequences.

[207] Jacobs D, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher, L. Aligning Quality Measures across CMS—The Universal Foundation. The New England Journal of Medicine, February 1, 2023. Available at: *https://www.nejm.org/doi/full/10.1056/NEJMp2215539*.

[208] Schreiber M, Richards AC, Moody-Williams J, Fleisher LA. The CMS National Quality Strategy: a person-centered approach to improving quality. Centers for Medicare and Medicaid Services, June 6, 2022 (*https://www.cms.gov/blog/cms-national-quality-strategy-person-centered-approach-improving-quality*).

[209] Jacobs D, Fowler E, Fleisher L, Seshamani M. The Medicare value-based care strategy: alignment, growth, and equity. Health Affairs, July 21, 2022 (*https://www.healthaffairs.org/content/forefront/medicare-value-based-care-strategy-alignment-growth-and-equity*).

[210] Jacobs D, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher, L. Aligning Quality Measures across CMS—The Universal Foundation. The New England Journal of Medicine, February 1, 2023. Available at: *https://www.nejm.org/doi/full/10.1056/NEJMp2215539*.

[211] *https://www.cms.gov/files/document/esrd-measures-manual-v81.pdf*.

Comment: One commenter expressed concerns regarding the timing of screening, stating that this would require screening all patients during the first quarter and stated that this is not clinically appropriate for some patients and not feasible for others due to fluctuating first dates of dialysis, hospitalizations, and other reasons. The commenter recommended including a denominator exclusion for ''patient stopped treatment at the facility prior to scheduled screening'' prior to adoption of this measure as a clinical measure.

Response: Facilities are required to report measure data before the close of the clinical month of December in EQRS each year, so patient screening may take place at any time during the 12-month period of performance. We note that, to be eligible for the measure, a patient must be treated at a facility for at least 90 days. However, a facility is not precluded from screening its patients during that initial 90-day period, and we would encourage facilities to do so as part of their overall patient health assessments. Therefore, we do not think the suggested denominator exclusion is necessary.

Comment: A few commenters recommended removing the Clinical Depression Screening and Follow-Up measure from the ESRD QIP altogether. A few commenters recommended moving the measure to Dialysis Facility Compare because it would more effectively provide beneficiaries with useful information about facility performance on the measure. A few commenters expressed the belief that the measure should be removed from the ESRD QIP because it is topped out.

Response: We believe that the Clinical Depression Screening and Follow-Up measure remains an important part of the ESRD QIP measure set and that the public reporting of facility performance scores on the measure provides patients and caregivers with helpful information. Including the Clinical Depression Screening and Follow-Up measure in the ESRD QIP also incentivizes facilities to improve their performance on the measure, which we believe will ultimately result in better patient outcomes. Although we acknowledge that the measure, in its current iteration as a reporting measure with six conditions, may be topped out, we proposed to update the conditions needed to receive credit and to convert the measure to a clinical measure. Under our previously adopted methodology (79 FR 66174), a clinical measure is considered to be topped out if national measure data show (1) statistically indistinguishable performance levels at the 75th and 90th percentiles; and (2) a truncated coefficient of variation (TCV) of less than or equal to 0.1. To determine whether a clinical measure is topped out, we initially focus on the top distribution of facility performance on each measure and note if their 75th and 90th percentiles are statistically indistinguishable. Then, to ensure that we properly account for the entire distribution of scores, we analyze the truncated coefficient of variation (TCV) for the measure. As PY 2026 would be the first year that the Clinical Depression Screening and Follow-Up clinical measure would be included in the ESRD QIP, we do not have the clinical national measure performance data necessary to perform a topped-out analysis at this time.

Final Rule Action: After considering public comments, we are finalizing our proposals to update the Clinical Depression Screening and Follow-Up measure and to convert it to a clinical measure beginning with PY 2026 as proposed.

5. Removal of Two Measures From the ESRD QIP Measure Set, Beginning With PY 2026

In the CY 2024 ESRD PPS proposed rule, we stated that we have undertaken efforts to review the existing ESRD QIP measure set to ensure continued clinical impact and effectiveness of the measures on facility performance (88 FR 42499). Based on that analysis and our evaluation of the Program's measures, we proposed to remove the Ultrafiltration Rate reporting measure and the Standardized Fistula Rate clinical measure beginning with PY 2026.

a. Removal of the Ultrafiltration Rate Reporting Measure From the ESRD QIP Measure Set Beginning With PY 2026

In the CY 2017 ESRD PPS final rule, we adopted the Ultrafiltration Rate reporting measure (81 FR 77912 through 77915). The measure assesses the number of months for which a facility reports all data elements required to calculate ultrafiltration rates (UFR) for each qualifying patient. The Ultrafiltration Rate reporting measure is intended to guard against risks associated with high ultrafiltration (that is, rapid fluid removal) rates for adult dialysis patients undergoing hemodialysis (HD), because of indications that high ultrafiltration is an independent predictor of mortality. Faster ultrafiltration may lead to a number of health risks resulting from large volumes of fluid removed rapidly during each dialysis session, with deleterious consequences for the patient both in the short and longer term. When we added this measure to the ESRD QIP, we believed the documentation of the ultrafiltration measurements would ultimately contribute to the quality of the patient's ESRD treatment (81 FR 77912 through 77915).

In the CY 2024 ESRD PPS proposed rule, we noted that more recent studies have indicated that the Ultrafiltration Rate reporting measure may not result in the intended patient outcomes (88 FR 42499). For example, a patient's body size may be a confounding, possibly explanatory factor for the relationship between higher UFR and increased mortality.[212] Additionally, although the Ultrafiltration Rate reporting measure captures a patient's UFR measurements reported monthly, the mortality risks associated with high UFR may be due to the frequency or number of HD sessions with high UFR.[213] We stated our belief that these findings show that the documentation of a patient's ultrafiltration measurements through the current Ultrafiltration Rate reporting measure may not necessarily indicate the quality of a patient's ESRD treatment and tracking the ultrafiltration rate as a quality indicator may influence decision-making regarding dialysis treatment. Therefore, a facility's performance on the measure may not accurately reflect the quality of care provided. Accordingly, in the proposed rule we proposed to remove this measure from the ESRD QIP measure set under measure removal factor 2 (performance or improvement on a measure does not result in better or the intended patient outcomes) beginning with the PY 2026 ESRD QIP (88 FR 42499).

We welcomed public comment on our proposal. The comments we received and our responses are set forth below.

Comment: Several commenters expressed support for our proposal to remove the Ultrafiltration Rate reporting measure from the ESRD QIP measure set. A few commenters agreed that the measure should be removed because UFR measurement may not necessarily reflect the quality of a patient's HD session. A few commenters expressed support for removing the measure because it would enable a more individualized approach to clinical

[212] John T. Daugirdas and Daniel Schneditz. Seminars in Dialysis: Hemodialysis Ultrafiltration Rate Targets Should Be Scaled to Body Surface Area Rather than to Body Weight. 2017.

[213] Jose E. Navarrete, Ajai Rajabalan, Jason Cobb, and Janice P. Lea. Proportion of Hemodialysis Treatments with High Ultrafiltration Rate and the Association with Mortality. Kidney360 3: 1359–1366, 2022. doi: *https://doi.org/10.34067/KID.0001322022.*

decision-making regarding fluid management and allow flexibility to provide care that is specific to a patient's individual case. A few commenters expressed support for removing the measure because they believe that the measure is topped out.

Response: We thank commenters for their support. Although we do not believe that the measure is topped out, we do agree with commenters that the Ultrafiltration Rate reporting measure is appropriate for removal because the measure may not reflect quality of care provided and removing the measure from the ESRD QIP measure set would support a more individualized approach to fluid management.

Comment: Several commenters noted the importance of fluid management and recommended ways to continue encouraging facilities to monitor patient-level UFR data. A few commenters recommended that CMS expand the Ultrafiltration Rate reporting measure to collect data on patient symptoms experienced during and between treatments as well to better understand the relationship between UFR and patient outcomes. One commenter recommended that CMS convert the Ultrafiltration Rate reporting measure to a clinical measure. One commenter recommended that the measure be modified to address the confounding factors associated with high UFR.

Response: We thank commenters for their recommendations. Given the importance of fluid management to ESRD treatment, we encourage facilities to continue monitoring patient UFR data to ensure patient safety and improve HD care for ESRD patients. Although we are removing the Ultrafiltration Rate reporting measure because we do not believe that performance or improvement on the measure itself results in better patient outcomes, we may consider alternative measures which address confounding factors associated with high UFR in future rulemaking.

Comment: Several commenters expressed concern regarding the proposed removal of the Ultrafiltration Rate reporting measure, stating that high UFR is associated with health complications and the measure incentivizes patient safety. One commenter posited that the decline in hospitalization events and ED visits for ESRD patients on hemodialysis between 2019 and 2020 could be attributed to the implementation of the Ultrafiltration Rate reporting measure in 2019. The commenter noted that most HD machines are designed to facilitate the tracking of patient UFR data, and that it is important for staff to review and analyze this patient data to address symptoms and/or medical complications. One commenter noted there was no clinical support for high UFR.

Response: We encourage facilities to continue monitoring patient UFR data to ensure patient safety and improve hemodialysis (HD) care for ESRD patients. Although we are removing the Ultrafiltration Rate reporting measure because we believe that performance or improvement on the measure itself does not result in better patient outcomes, we believe that facilities will continue to monitor patient UFR data as part of a patient's ESRD treatment.

Comment: A few commenters expressed concern regarding the reporting burden associated with the proposed changes, recommending that CMS weigh the potential impact on patient health outcomes against potential administrative burden. One commenter specifically expressed concern regarding the burden impact on rural facilities due to the lack of resources.

Response: We do not believe that removing a measure from the ESRD QIP will impose additional burden on facilities.

Final Rule Action: After considering public comments, we are finalizing our proposal to remove the Ultrafiltration Rate reporting measure from the ESRD QIP measure set beginning with PY 2026 as proposed.

b. Removal of the Standardized Fistula Rate Clinical Measure From the ESRD QIP Measure Set

In the CY 2018 ESRD PPS final rule, we adopted the Standardized Fistula Rate clinical measure (82 FR 50774 through 50777). Along with the Long-Term Catheter Rate clinical measure, we stated that the two vascular access measures, when used together, consider arteriovenous (AV) fistula use as a positive outcome and prolonged use of a tunneled catheter as a negative outcome. With the growing recognition that some patients may exhaust their options for an AV fistula, or have comorbidities that may limit the success of AV fistula creation, pairing the measures accounts for all vascular access options. The Standardized Fistula Rate measure adjusts for patient factors where fistula placement may be either more difficult or not appropriate and acknowledges that in certain circumstances an AV graft may be the best access option by accounting for that possibility in the current measure specifications. In the CY 2018 ESRD PPS final rule, we stated that this paired incentive structure that relies on both measures reflects consensus best practice and supports maintenance of the gains in vascular access success achieved via the Fistula First/Catheter Last Project over the last decade (82 FR 50777).

In the CY 2024 ESRD PPS proposed rule, we noted that since the CY 2018 ESRD PPS final rule, there have been several changes to what many experts consider to be best practices with respect to vascular access in ESRD patients due to improvements in the care of ESRD patients overall, changes in patient demographics, and increasing patient longevity (88 FR 42500). Guidance published in 2019 by the National Kidney Foundation's Kidney Disease Outcome Quality Initiative (KDOQI) reflects updated best practices.[214] The KDOQI's 2019 guidance notes that prior guidelines and initiatives have emphasized a ''fistula first'' approach to vascular access choice due to the AV fistula's associations with better short-term results compared with other vascular access types.[215] However, the 2019 guidance also notes that more recent data have challenged these associations because of the high complication rates of AV fistula maturation failure requiring intervention. The guidance also encourages a more holistic, long-term approach to dialysis access that strives to preserve patient vasculature and avoid unnecessary procedures and complications. Therefore, following re-evaluation of this Fistula First approach, the KDOQI's 2019 guidance concludes that the Fistula First approach should no longer be considered a clinical best practice. Instead, the KDOQI's 2019 guidance concludes that a patient-centered approach to hemodialysis vascular access that is based on a consideration of the patient's needs and dialysis access eligibility is preferred. Providers should consider what would be most appropriate for the individual patient, including that AV fistula may not always be most appropriate based on the individual patient's needs.

After considering these evolving best practices and the KDOQI's 2019 guidance, in the proposed rule we stated that we have determined that the Standardized Fistula Rate Clinical Measure does not provide patients and their healthcare providers the necessary

[214] Lok CE, Huber TS, Lee T, et al; KDOQI Vascular Access Guideline Work Group. KDOQI clinical practice guideline for vascular access: 2019 update. Am J Kidney Dis. 2020;75(4)(suppl 2):S1–S164.

[215] KDOQI clinical practice guidelines for vascular access. Am J Kidney Dis. 2006;48:S176–S247.

level of flexibility to choose the most suitable AV access (88 FR 42500). We noted our belief that patients, in consultation with their healthcare providers, should have the flexibility to choose AV access (either AV fistula or AV graft) where appropriate to their specific patient characteristics and treatment plans. This determination should be based on the healthcare provider's best clinical judgment that considers the vessel characteristics, patient comorbidities, health circumstances, and patient preference. Accordingly, we proposed to remove the Standardized Fistula Rate clinical measure from the ESRD QIP measure set beginning with PY 2026 under measure removal factor 3 (a measure no longer aligns with current clinical guidelines or practice).

We stated in the proposed rule that we continue to consider both AV fistula and AV graft as preferable forms of vascular access to a long-term catheter, and that evidence shows that long-term catheters should only be used when all other AV access options have been exhausted (88 FR 42500).[216] We also expressed our continued belief that it is important to track the use of long-term catheters, minimize their use where possible, and incentivize best practices for vascular access. For those reasons, we did not propose to remove the Long-Term Catheter Rate clinical measure.

In the proposed rule, we also proposed to remove the reference to the Vascular Access Type Measure Topic and to assign the total weight of that topic (12 percent) solely to the Long-Term Catheter Rate clinical measure (88 FR 42500), as described in Table 15 of the proposed rule. We proposed to assign the total weight to the Long-Term Catheter Rate clinical measure because we believe this continues to be an important measure of facility performance tied to improved patient outcomes. We noted our belief that our proposal to assign the total 12 percent weight to the Long-Term Catheter Rate clinical measure reflected our view that long-term catheter use is the least-favored vascular access treatment option and should be avoided where more clinically preferable vascular access treatment options would be appropriate.

We welcomed public comment on our proposal. The comments we received and our responses are set forth below.

Comment: Many commenters expressed support for the proposed removal of the Standardized Fistula Rate clinical measure from the ESRD QIP. Several of these commenters noted that removing the Standardized Fistula Rate clinical measure would enable clinicians to support the vascular access care treatment options that are most appropriate for their individual patients. Several commenters stated that the continued focus on long-term catheter rates through the Long-Term Catheter Rate clinical measure will sufficiently address reduction of catheters. One commenter stated that removing the measure will reduce costs by not incentivizing clinicians to perform procedures that may be unnecessary, painful, or have a low likelihood of success. One commenter expressed the belief that the measure should be removed because it is topped out.

Response: We thank commenters for their support. Although we do not believe that the measure is topped out, we do agree with commenters that the Standardized Fistula Rate clinical measure is appropriate for removal because the measure no longer aligns with current clinical guidelines or best practices and that removing the measure will support a more individualized approach to vascular access care.

Comment: Although a few commenters expressed support for the proposed removal, the commenters recommended that CMS continue to monitor AV fistula and AV graft rates.

Response: We thank the commenters for their support, and we will continue to monitor trends in ESRD patient data and quality of care.

Comment: One commenter did not support removal of the measure. The commenter stated that they believe there is strong evidence that AV fistula utilization is associated with better outcomes and is superior to AV grafts and tunneled catheters. This commenter recommended lowering the performance standard for the Standardized Fistula Rate clinical measure and stated that this would indirectly make the use of AV grafts less punitive without removing the measure while still allowing individualized care for each patient. This commenter expressed concern that removal of the measure will further incentivize the use of AV grafts instead of AV fistula due to higher costs associated with grafts because of more frequent procedures. This commenter expressed concern that these new incentives will cause significant reductions in fistula utilization with adverse consequences.

Response: We agree with the commenter that AV fistulas are the preferred vascular access treatment option in cases where it is appropriate based on the individual patient's needs, and we continue to consider both AV fistula and AV graft as preferable forms of vascular access to a long-term catheter. Although we will continue to monitor trends in AV fistula and AV graft utilization, we believe that removing the Standardized Fistula Rate clinical measure will provide flexibility to determine which vascular access treatment option is most appropriate based on the patient's specific characteristics and treatment plans.

Comment: A few commenters expressed concern regarding the increased weight of the Long-Term Catheter Rate clinical measure in the ESRD QIP. One commenter noted that, particularly among small or rural facilities, long-term catheter rates may be impacted by factors beyond a facility's control, such as physician availability, surgeon appointment openings, and operating room availability. One commenter recommended that CMS update the Long-Term Catheter Rate clinical measure to account for the increased prevalence of two-step fistula placements, which may impact long-term catheter rates. One commenter recommended several patient exclusions be added to the denominator of the Long-Term Catheter Rate clinical measure to account for different situations in which AV fistula or AV graft placement is not appropriate based on the patient's clinical case or individual preferences. The commenter stated that such exclusions would help to make the measure more patient-centered and meaningful, reflecting that the ''right'' vascular access is different for every patient.

Response: We appreciate commenters' concern. However, we believe the Long-Term Catheter Rate clinical measure continues to be an important measure of facility performance tied to improved patient outcomes. The increased weight of the Long-Term Catheter Rate clinical measure reflects our view that long-term catheter use is the least-favored vascular access treatment option and should be avoided where more clinically preferable vascular access treatment options would be appropriate. Although we acknowledge that long-term catheter usage may be appropriate in certain circumstances depending on a particular patient's clinical case, we believe the Long-Term Catheter Rate clinical measure continues to align with current clinical guidelines and incentivizes best practices in vascular access treatment for ESRD patients. However, we will also continue to monitor the impact of our updated policy, as well as trends in the use of two-step fistula placements.

[216] Lok CE, Huber TS, Lee T, et al; KDOQI Vascular Access Guideline Work Group. KDOQI clinical practice guideline for vascular access: 2019 update. Am J Kidney Dis. 2020;75(4)(suppl 2):S1–S164.

Comment: A few commenters expressed concern regarding the reporting burden associated with the proposed changes, recommending that CMS weigh the potential impact on patient health outcomes against potential administrative burden. One commenter specifically expressed concern with the burden impact on rural facilities due to the lack of resources.

Response: We do not believe that removing a measure from the ESRD QIP will impose additional burden on facilities.

Final Rule Action: After considering public comments, we are finalizing our proposal to remove the Standardized Fistula Rate clinical measure from the ESRD QIP measure set beginning with PY 2026 as proposed.

6. Revisions To Measure Domains and To Measure Weights Used To Calculate the Total Performance Score (TPS) Beginning With the PY 2026 ESRD QIP

In the CY 2023 ESRD PPS final rule (87 FR 67251 through 67254), we finalized revisions to the ESRD QIP measure domains beginning with PY 2025. Specifically, we added the Reporting Measure Domain and updated measure domains and measure weights across five measure domains: Patient & Family Engagement, Care Coordination, Clinical Care, Safety, and Reporting. The measure domains and weights we finalized in the CY 2023 ESRD PPS final rule were depicted in Table 14 of the CY 2024 ESRD PPS proposed rule (88 FR 42501) and are depicted in this final rule in Table 15.

TABLE 15: Previously Finalized PY 2026 ESRD QIP Measure Domains and Weights

Measure/Measure Topics by Subdomain	Measure Weight as Percent of TPS
Patient and Family Engagement Measure Domain	**15.00**
ICH CAHPS measure	15.00
Care Coordination Measure Domain	**30.00**
SHR clinical measure	12.00
SRR clinical measure	12.00
PPPW measure	6.00
Clinical Care Measure Domain	**35.00**
Kt/V Dialysis Adequacy Comprehensive Measure	11.00
Vascular Access Type Measure Topic	12.00
STrR clinical measure	12.00
Safety Measure Domain	**10.00**
NHSN BSI clinical measure	10.00
Reporting Measure Domain	**10.00**
Clinical Depression Screening and Follow-Up reporting measure	1.67
Hypercalcemia reporting measure	1.67
Ultrafiltration Rate reporting measure	1.67
MedRec reporting measure	1.67
NHSN Dialysis Event reporting measure	1.67
COVID-19 HCP Vaccination reporting measure	1.67

As discussed previously, we are finalizing our proposals that beginning with PY 2026, the Clinical Depression Screening and Follow-Up reporting measure will be converted to a clinical measure and included in the Care Coordination Measure Domain, the Standardized Fistula Rate clinical measure will be removed from the Clinical Care Measure Domain, the Ultrafiltration Rate reporting measure will be removed from the Reporting Measure Domain, and the Facility Commitment to Health Equity reporting measure will be added to the Reporting Measure Domain. To accommodate the new numbers of measures in the Care Coordination Measure Domain, Clinical Care Measure Domain, and Reporting Measure Domain, in the CY 2024 ESRD PPS proposed rule, we proposed to update the individual measure weights in each of these domains (88 FR 42501).

We stated our belief that these proposed updates to the individual measure weights would help to ensure that a facility's individual measure performance has an appropriately proportionate impact on a facility's TPS, while also further incentivizing improvement on clinical measures. For example, for the Care Coordination Measure Domain, we proposed to update the measure weights for the SHR clinical measure and the SRR clinical measure to accommodate the inclusion of the proposed Clinical Depression Screening and Follow-Up clinical measure. We stated that we believe these newly proposed measure weights would strike an appropriate balance between the importance of facility performance on the SHR clinical measure and the SRR clinical measure on measuring patient outcomes, while also reflecting the impact of the proposed Clinical Depression Screening and Follow-Up clinical measure on patient quality of care. Additionally, we noted in the proposed rule that the Vascular Access Type Measure Topic is currently weighted at 12 percent and includes both the Standardized Fistula Rate clinical measure and the Long-Term Catheter Rate clinical measure. We proposed to remove the Standardized Fistula Rate clinical measure and the Vascular Access Type Measure Topic, and we also proposed to weight the Long-Term Catheter Rate clinical measure at 12 percent. We noted our belief this proposal would incentivize improvement and reflect the impact of facility performance on the Long-Term Catheter Rate clinical measure (as the sole vascular access type measure) on patient outcomes. We also stated that we continue to believe that patient outcomes improve when

they receive the most clinically appropriate vascular access treatment option, and that long-term catheters should only be used when other vascular access treatment options are not feasible. Consistent with our approach in the CY 2023 ESRD PPS final rule (87 FR 67251 through 67253), we proposed to assign individual measure weights to reflect the proposed updated number of measures in the Reporting Measure Domain so that each measure is weighted equally (88 FR 42501 through 42502). In light of these proposed updates to measures within the Reporting Measure Domain, we stated that we would weight each measure equally at 2 percent, which is consistent with our previously finalized approach to weight each measure in the Reporting Measure Domain equally. We note that although we proposed to change the number of measures in three of the domains and the weights of certain individual measures in those domains, we did not propose to change the weights of the five domains themselves because we believe the updates to individual measures and measure weights do not significantly impact the measure domains themselves such that updating the weights of the measure domains would be required to accommodate the updated individual measure weights. In the CY 2024 ESRD PPS proposed rule, the previously finalized and newly proposed measures weights that would be included in each domain, along with the proposed new measure weights, for PY 2026 were depicted in Table 15 (88 FR 42502).

We welcomed public comment on these proposals. The comments we received and our responses are set forth below.

Comment: A few commenters expressed concern regarding the proposed updates to the individual measure weights within the Clinical Care Measure Domain. One commenter expressed concern regarding the proposed updates to the weight of the Long-Term Catheter Rate clinical measure, recommending that CMS re-weight the Long-Term Catheter Rate clinical measure at 9 percent and the STrR clinical measure at 10 percent within the Clinical Care Measure Domain. One commenter stated that because catheters are clinically appropriate for some patients, the measure weight for the Long-Term Catheter Rate clinical measure should not be updated and the remaining weight should be distributed among the other measure domains.

Response: We appreciate commenters' concerns. However, we believe that the Long-Term Catheter Rate clinical measure continues to be an important measure of facility performance tied to improved patient outcomes and that the increased weight would incentivize improvement and reflect the impact of facility performance on the Long-Term Catheter Rate clinical measure (as the sole vascular access type measure) on patient outcomes. The increased weight of the Long-Term Catheter Rate clinical measure reflects our view that long-term catheter use is the least-favored vascular access treatment option and should be avoided where more clinically preferable vascular access treatment options would be appropriate. We will also take commenters' recommendations regarding specific measure weights into consideration for future rulemaking, but believe that the proposed weights are appropriate at this time to incentivize quality improvement in clinical measures.

Comment: One commenter recommended that CMS increase the weight of the Reporting Measure Domain, noting the burden of complying with reporting measure requirements.

Response: We take numerous factors into account when determining appropriate domain and measure weights, including clinical evidence, opportunity for improvement, clinical significance, and patient and provider burden (83 FR 56995 through 56996). We also consider (1) the number of measures and measure topics in a domain; (2) how much experience facilities have had with the measures and measure topics in a domain; and (3) how well the measures align with CMS's highest priorities for quality improvement for patients with ESRD (79 FR 66214). We assign weights to the measure domains based on the clinical value and meaningfulness of the measures to patients, and the burden of complying with individual measure requirements. We believe that the Reporting Measure Domain weights are appropriate to incentivize the provision of high quality health care for all ESRD QIP measures.

Final Rule Action: After considering public comments, we are finalizing our proposals to update the measure domains and measure weights for the PY 2026 ESRD QIP as proposed, and therefore, provide the newly finalized ESRD QIP measure domains and measure weights in Table 16.

TABLE 16: Newly Finalized ESRD QIP Measure Domains and Weights for PY 2026

Measures by Domain	Measure Weight as Percent of TPS
Patient and Family Engagement Measure Domain	**15.00**
ICH CAHPS measure	15.00
Care Coordination Measure Domain	**30.00**
SHR clinical measure	9.00
SRR clinical measure	9.00
PPPW measure	6.00
Clinical Depression Screening and Follow-Up measure*	6.00
Clinical Care Measure Domain	**35.00**
Kt/V Dialysis Adequacy Comprehensive Measure	11.00
Long-Term Catheter Rate clinical measure	12.00
STrR clinical measure	12.00
Safety Measure Domain	**10.00**
NHSN BSI clinical measure	10.00
Reporting Measure Domain	**10.00**
Facility Commitment to Health Equity measure**	2.00
Hypercalcemia reporting measure	2.00
MedRec reporting measure	2.00
NHSN Dialysis Event reporting measure	2.00
COVID-19 HCP Vaccination reporting measure	2.00

*We are finalizing our proposal to convert the Clinical Depression Screening and Follow-Up measure from a reporting measure to a clinical measure beginning with PY 2026, as discussed in section IV.C.4 of this final rule.
**We are finalizing our proposal to add the Facility Commitment to Health Equity reporting measure beginning with PY 2026, as discussed in section IV.C.2 of this final rule.

7. Performance Standards for the PY 2026 ESRD QIP

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as determined appropriate by the Secretary, and must be established prior to the beginning of the performance period for the year involved, as required by section 1881(h)(4)(C) of the Act. We refer readers to the CY 2013 ESRD PPS final rule (76 FR 70277) for a discussion of the achievement and improvement standards that we have established for clinical measures used in the ESRD QIP. We define the terms ''achievement threshold,'' ''benchmark,'' ''improvement threshold,'' and ''performance standard'' in our regulations at § 413.178(a)(1), (3), (7), and (12), respectively. For reporting measures, performance standards are the levels of data submission and completion of other actions specified by CMS that are used to award points to an ESRD facility on the measure (§ 413.178(a)(12)).

In the CY 2023 ESRD PPS final rule (87 FR 67259 through 67260), we set the performance period for the PY 2026 ESRD QIP as CY 2024 and the baseline period as CY 2022. In the proposed rule, we estimated the performance standards for the PY 2026 clinical measures in Table 16 using data from CY 2021, which was the most recent data available (88 FR 42502). For certain measures previously suppressed for the PY 2023 performance period due to significant impacts on the measure related to the COVID–19 public health emergency (87 FR 67225 through 67237), we used CY 2019 data. We are updating these performance standards for all measures, using CY 2022 data, in this final rule, in Table 17.

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TABLE 17: Performance Standards for the ESRD QIP Clinical Measures for PY 2026

Measure	Achievement Threshold (15th Percentile of National Performance)	Median (50th Percentile of National Performance)	Benchmark (90th Percentile of National Performance)
Vascular Access Type (VAT)			
Long-Term Catheter Rate	18.35%*	11.04%*	4.69%*
Kt/V Comprehensive	94.33%*	97.61%*	99.42%*
Standardized Readmission Ratio[a]	34.27*	26.50	16.19
NHSN BSI	0.734	0.248	0
Standardized Hospitalization Ratio[b]	166.60	129.14	87.98
Standardized Transfusion Ratio[b]	48.29	26.19	8.86
PPPW	8.12%*	16.73%*	33.90%*
Clinical Depression**	87.10%	94.29%	100.00%
ICH CAHPS: Nephrologists' Communication and Caring	58.20%*	67.90%*	79.15%*
ICH CAHPS: Quality of Dialysis Center Care and Operations	54.87%	63.22%	72.83%
ICH CAHPS: Providing Information to Patients	74.49%*	81.09%*	87.80%*
ICH CAHPS: Overall Rating of Nephrologists	49.33%*	62.22%*	76.57%*
ICH CAHPS: Overall Rating of Dialysis Center Staff	51.01%	64.86%	78.86%
ICH CAHPS: Overall Rating of the Dialysis Facility	54.58%	69.42%	84.09%

*Values are the same final performance standards for those measures for PY 2025. In accordance with our longstanding policy, we are using those numerical values for those measures for PY 2026 because they are higher standards than the PY 2026 numerical values for those measures.
**We are finalizing our proposal to update the Clinical Depression Screening and Follow-Up measure beginning in PY 2026, as discussed in section IV.C.4 of this final rule.

[a]Rate calculated as a percentage of hospital discharges
[b]Rate per 100 patient-years
Data sources: VAT measure: 2022 EQRS; SRR, SHR: 2022 Medicare claims; STrR: 2022 Medicare claims; Kt/V: 2022 EQRS; Hypercalcemia: 2022 EQRS; NHSN: 2022 CDC; ICH CAHPS: CMS 2022; PPPW: 2022 EQRS and 2022 Organ Procurement and Transplantation Network (OPTN); Clinical Depression: 2022 EQRS.

In addition, we summarize in Table 18 our requirements for successful reporting on our previously finalized reporting measures for the PY 2026 ESRD QIP and our proposed requirements for successful reporting of the Facility Commitment to Health Equity reporting measure. We address comments regarding our proposed reporting requirements for the Facility Commitment to Health Equity reporting measure in section IV.C.2 of this final rule.

TABLE 18: Requirements for Successful Reporting of the Previously Finalized and Newly Proposed ESRD QIP Reporting Measures for PY 2026

Measure	Reporting Frequency	Data Elements
MedRec	Monthly	• Date of the medication reconciliation. • Type of eligible professional who completed the medication reconciliation: o physician, o nurse, o advanced registered nurse practitioner (ARNP), o physician assistant (PA), o pharmacist, or o pharmacy technician personnel • Name of eligible professional
NHSN Dialysis Event	Monthly	Three types of dialysis events reported: • IV antimicrobial start; • positive blood culture; and • pus, redness, or increased swelling at the vascular access site.
Hypercalcemia	Monthly	Total uncorrected serum or plasma calcium lab values
COVID-19 Vaccination Coverage Among HCP*	At least one week of data each month, submitted quarterly	Cumulative number of HCP eligible to work in the facility for at least one day during the reporting period and who received an up to date vaccination course against SARS-CoV-2.
Facility Commitment to Health Equity**	Annually	Domains to which facility must attest affirmatively: • Equity is a Strategic Priority • Data Collection • Data Analysis • Quality Improvement • Leadership Engagement

* We are finalizing our proposal to update the COVID-19 Coverage Among HCP reporting measure beginning with PY 2026, as discussed in section IV.C.3 of this final rule.

** We are finalizing our proposal to add the Facility Commitment to Health Equity reporting measure beginning with PY 2026, as discussed in section IV.C.2 of this final rule.

8. Eligibility Requirements for the PY 2026 ESRD QIP

Our previously finalized minimum eligibility requirements for scoring the ESRD QIP measures are described in Table 18a of the CY 2024 ESRD PPS proposed rule (88 FR 42505), and provided in Table 19a.

TABLE 19a: Previously Finalized Eligibility Requirements for Scoring on ESRD QIP Measures

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Kt/V Comprehensive (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
VAT: Long-term Catheter Rate (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
VAT: Standardized Fistula Rate (Clinical)*	11 qualifying patients	N/A	11-25 qualifying patients
Hypercalcemia (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
NHSN BSI (Clinical)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	11-25 qualifying patients
NHSN Dialysis Event (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
SRR (Clinical)	11 index discharges	N/A	11-41 index discharges
STrR (Clinical)	10 patient-years at risk	N/A	10-21 patient-years at risk
SHR (Clinical)	5 patient-years at risk	N/A	5-14 patient-years at risk
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities would not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period	Before October 1 prior to the performance period that applies to the program year.	N/A
Depression Screening and Follow-Up (Reporting)**	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
Ultrafiltration (Reporting)***	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
MedRec (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
PPPW (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
COVID-19 Vaccination Coverage Among HCP (Reporting)****	N/A	Before September 1 of the performance period that applies to the program year.	N/A

* We are finalizing our proposal to remove the Standardized Fistula Rate clinical measure beginning in PY 2026, as discussed in section IV.C.5 of this final rule, and removed from Table 19b.
** We are finalizing our proposal to update the Clinical Depression Screening and Follow-Up measure and convert it to a clinical measure beginning with PY 2026, as discussed in section IV.C.4 of this final rule.
*** We are finalizing our proposal to remove the Ultrafiltration Rate reporting measure beginning in PY 2026, as discussed in section IV.C.5 of this final rule, and removed from Table 19b.
**** We are finalizing our proposal to update the COVID-19 Vaccination Coverage Among HCP measure beginning with PY 2026, as discussed in section IV.C.3 of this final rule.

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In the CY 2024 ESRD PPS proposed rule, we proposed to add eligibility requirements for the new Facility Commitment to Health Equity reporting

measure, as well as other proposed updates to the ESRD QIP measure set beginning with the PY 2026 ESRD QIP, as reflected in Table 18b in the proposed rule (88 FR 42504 through 42506).

We welcomed public comment on these proposals. The comments we received and our responses are set forth below.

Comment: One commenter expressed continued concern regarding the potential to unfairly penalize small facilities due to eligibility requirements and encouraged CMS to engage with the community to better support small facilities.

Response: We acknowledge the commenter's concern and will continue to monitor the impact of all ESRD QIP measures on small facilities to ensure they are not unfairly penalized due to eligibility requirements associated with a given measure.

Final Rule Action: After considering public comments, we are finalizing our proposals as proposed. Since we are finalizing our proposal for the new measure as proposed, as well as finalizing other proposed updates to the ESRD QIP measure set beginning with the PY 2026 ESRD QIP, our newly finalized minimum eligibility requirements for scoring the ESRD QIP measures are described in Table 19b.

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TABLE 19b: Eligibility Requirements for Scoring on ESRD QIP Measures Beginning with PY 2026

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Kt/V Comprehensive (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
VAT: Long-term Catheter Rate (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
Hypercalcemia (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
NHSN BSI (Clinical)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	11-25 qualifying patients
NHSN Dialysis Event (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
SRR (Clinical)	11 index discharges	N/A	11-41 index discharges
STrR (Clinical)	10 patient-years at risk	N/A	10-21 patient-years at risk
SHR (Clinical)	5 patient-years at risk	N/A	5-14 patient-years at risk
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities would not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period	Before October 1 prior to the performance period that applies to the program year.	N/A
Depression Screening and Follow-Up (Clinical)*	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
MedRec (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
PPPW (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
COVID-19 Vaccination Coverage Among HCP (Reporting)**	N/A	Before September 1 of the performance period that applies to the program year.	N/A
Facility Commitment to Health Equity (Reporting)***	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	

* We are finalizing our proposal to update the Clinical Depression Screening and Follow-Up measure beginning with PY 2026, as discussed in section IV.C.4 of this final rule.
** We are finalizing our proposal to update the COVID-19 Vaccination Coverage Among HCP measure beginning with PY 2026, as discussed in section IV.C.3 of this final rule.
*** We are finalizing our proposal to add the Facility Commitment to Health Equity reporting measure beginning with PY 2026, as discussed in section IV.C.2 of this final rule.

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9. Payment Reduction Scale for the PY 2026 ESRD QIP

Under our current policy, a facility does not receive a payment reduction for a payment year in connection with its performance under the ESRD QIP if it achieves a TPS that is at or above the minimum TPS (mTPS) that we establish for the payment year. We have defined the mTPS in our regulations at § 413.178(a)(8) as, with respect to a payment year, the TPS that an ESRD facility would receive if, during the baseline period, it performed at the 50th percentile of national performance on all clinical measures and the median of

national ESRD facility performance on all reporting measures.

Under our current policy, which is codified at § 413.177 of our regulations, we implement the payment reductions on a sliding scale using ranges that reflect payment reduction differentials of 0.5 percent for each 10 points that the facility's TPS falls below the mTPS (76 FR 634 through 635).

In the proposed rule, we stated that for PY 2026, we estimated using available data that a facility must meet or exceed a mTPS of 52 to avoid a payment reduction (88 FR 42507). We noted that the mTPS estimated in the proposed rule is based on data from CY 2021 and CY 2019 instead of the PY 2026 baseline period (CY 2022) because CY 2022 data were not yet available. We presented the estimated payment reduction scale in Table 19 of the CY 2024 ESRD PPS proposed rule (88 FR 42507). We stated our intention to update the mTPS for PY 2026, as well as the payment reduction ranges for that payment year, in this CY 2024 ESRD PPS final rule. We have now finalized the payment reductions that will apply to the PY 2026 ESRD QIP using updated CY 2022 data. The mTPS for PY 2026 will be 53, and the finalized payment reduction scale is shown in Table 20.

TABLE 20: Updated Payment Reduction Scale for PY 2026 Based on the Most Recently Available Data

Total performance score	Reduction (%)
100-53	0%
52-43	0.5%
42-33	1.0%
32-23	1.5%
22-0	2.0%

D. Updates to Requirements Beginning With the PY 2027 ESRD QIP

1. PY 2027 ESRD QIP Measure Set

Under our current policy, we generally retain all measures once adopted for a payment year for subsequent payment years. In the proposed rule, we proposed to add the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure to the ESRD QIP measure set beginning with PY 2027. As discussed in sections IV.D.2 and IV.D.3 of this final rule, we are finalizing these measure proposals and provide the finalized PY 2027 ESRD QIP measure set in Table 21.

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TABLE 21: Newly Finalized PY 2027 ESRD QIP Measure Set

Consensus-Based Entity (CBE) #	Measure Title and Description
0258	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure Measure assesses patients' self-reported experience of care through percentage of patient responses to multiple survey questions.
2496	Standardized Readmission Ratio (SRR), a clinical measure Ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day readmissions.
Based on CBE #2979	Standardized Transfusion Ratio (STrR), a clinical measure Ratio of the number of observed eligible red blood cell transfusion events occurring in patients dialyzing at a facility to the number of eligible transfusions that would be expected.
N/A	(Kt/V) Dialysis Adequacy Comprehensive, a clinical measure A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume. Percentage of all patient months for patients whose delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.
2978	Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure Measures the use of a catheter continuously for 3 months or longer as of the last hemodialysis treatment session of the month.
1454	Hypercalcemia, a reporting measure Proportion of patient-months with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL.
1463	Standardized Hospitalization Ratio (SHR), a clinical measure Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.
Based on CBE #0418	Clinical Depression Screening and Follow-Up, a clinical measure Facility reports in End Stage Renal Disease Quality Reporting System (EQRS) one of four conditions for each qualifying patient treated during performance period.
Based on CBE #1460	NHSN Bloodstream Infection (BSI) in Hemodialysis Patients, a clinical measure The Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.
N/A	NHSN Dialysis Event reporting measure Number of months for which facility reports NHSN Dialysis Event data to the CDC.
N/A	Percentage of Prevalent Patients Waitlisted (PPPW), a clinical measure Percentage of patients at each facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period.
2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec), a reporting measure Percentage of patient-months for which medication reconciliation was performed and documented by an eligible professional.
3636	COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP), a reporting measure Percentage of HCP who are up to date on their COVID-19 vaccination course.
N/A	Facility Commitment to Health Equity, a reporting measure Facilities will receive two points each for attesting to five different domains of commitment to advancing health equity for a total of ten points.
N/A	Screening for Social Drivers of Health, a reporting measure* Percentage of patients at a dialysis facility who are 18 years or older screened for all five health-related social needs (HRSNs) (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety).
N/A	Screen Positive Rate for Social Drivers of Health, a reporting measure** Percentage of patients at a dialysis facility who are 18 years or older screened for all five HRSNs, and who screen positive for one or more of the following five HRSNs: Food insecurity, housing instability, transportation problems, utility difficulties, or interpersonal safety.

* We are finalizing our proposal to add the Screening for Social Drivers of Health reporting measure beginning with PY 2027, as discussed in section IV.D.2 of this final rule.

** We are finalizing our proposal to add the Screen Positive Rate for Social Drivers of Health reporting measure beginning with PY 2027, as discussed in section IV.D.3 of this final rule.

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2. Adoption of the Screening for Social Drivers of Health Reporting Measure Beginning With PY 2027

Our commitment to supporting facilities in building equity into their health care delivery practices is, in part, focused on empowering their workforce to recognize and eliminate health disparities that disproportionately impact their patients who have health-related social needs (HRSNs). HRSNs are significant risk factors associated with worse health outcomes as well as increased health care utilization.[217] We believe that the identification of HRSNs among facility patients has two significant benefits. First, research has shown that certain HRSNs disproportionately impact populations that have historically been underserved by the healthcare system and screening helps identify individuals who may have HRSNs.[218] Due to the association between chronic condition risk and HRSNs, screening for these needs could serve as evidence-based building blocks for supporting ESRD facilities in addressing persistent disparities and tracking progress towards closing the health equity gap in the ESRD population. Second, we believe HRSN screening by facilities could enable them to engage in meaningful collaboration with other healthcare providers and community-based organizations as part of a more holistic approach to addressing health equity gaps that negatively impact their ESRD patients, which may also eventually result in implementing and evaluating related innovations in health and social care delivery among these facilities, healthcare providers and community-based organizations.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49191 through 49220), we finalized the adoption of two evidence-based measures in the Hospital Inpatient Quality Reporting (IQR) Program, the Screening for Social Drivers of Health and the Screen Positive Rate for Social Drivers of Health measures. These two Social Drivers of Health measures support identification of specific risk factors for inadequate healthcare access and adverse health outcomes among patients. These measures also encourage hospitals to systematically collect HRSN data. We have also finalized a policy requiring that all Special Needs Plans (SNPs) include one or more questions on housing stability, food security, and access to transportation in their Health Risk Assessment (HRA) using questions from a list of screening instruments specified in sub-regulatory guidance (87 FR 27726 through 27740), as well as adopted the Screening for Social Drivers of Health measure in the Merit-based Incentive Payment System (87 FR 70054 and 70055).

In the CY 2024 ESRD PPS proposed rule, we stated that advancing health equity by addressing the health disparities that underlie the country's health system is one of our strategic pillars and a Biden-Harris Administration priority (88 FR 42509).[219] We noted our belief that the Screening for Social Drivers of Health reporting measure aligns with *The CMS Quality Strategy Goals* for effective care coordination and prevention and treatment of chronic conditions.[220] We stated that the Screening for Social Drivers of Health reporting measure would enable facilities to identify patients with HRSNs, who are known to experience the greatest risk of poor health outcomes. Improvement in risk identification has the potential to reduce healthcare access barriers, address the disproportionate expenditures attributed to populations with greatest risk, and improve the facility's quality of care through the facility taking steps to mitigate poor health outcomes by improving their care coordination efforts.[221] [222] [223] [224] These data could help facilities improve their care coordination efforts, including by understanding what HRSNs might be contributing to poor patient outcomes so that facilities can direct resources, as appropriate, toward referring their patients to resources that might be able to help them resolve their HRSNs.

a. Background

Health disparities manifest primarily as worse health outcomes in population groups where access to care is inequitable.[225] [226] [227] [228] [229] Such differences persist across geography and healthcare settings irrespective of improvements in quality of care over time.[230] [231] [232] Assessment of HRSNs is an essential mechanism for capturing the interaction between social, community, and environmental factors associated with health status and health

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[224] Jaffrey, J.B., Safran, G.B., Addressing Social Risk Factors in Value-Based Payment: Adjusting Payment Not Performance to Optimize Outcomes and Fairness. Health Affairs Blog, April 19, 2021. Available at: *https://www.healthaffairs.org/do/10.1377/forefront.20210414.379479/full/*.

[225] Seligman, H.K., & Berkowitz, S.A. (2019). Aligning Programs and Policies to Support Food Security and Public Health Goals in the United States. Annual Review of Public Health, 40(1), 319–337. Available at: *https://pubmed.ncbi.nlm.nih.gov/30444684/*.

[226] The Physicians Foundation. (2020). Survey of America's Patients, Part Three. Available at: *https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf*.

[227] Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress*.

[228] Trivedi AN, Nsa W, Hausmann LRM, et al. Quality and Equity of Care in U.S. Hospitals. New England Journal of Medicine. 2014; 371(24):2298–2308.

[229] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b*.

[230] Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress*.

[231] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https://pubmed.ncbi.nlm.nih.gov/33139407/*.

[232] Khullar, D., MD. (2020, September 8). Association Between Patient Social Risk and Physician Performance American academy of Family Physicians. Addressing Social Determinants of Health in Primary Care team-based approach for advancing health equity. Available at: *https://www.aafp.org/dam/AAFP/documents/patient_care/everyone_project/team-based-approach.pdf*.

outcomes.[233] [234] [235] Growing evidence demonstrates that specific social risk factors are directly associated with patient health outcomes as well as healthcare utilization, costs, and performance in quality reporting and payment programs.[236] [237]

Significant and persistent health disparities in the United States result in adverse health outcomes for people with ESRD.[238] [239] The COVID–19 pandemic has illuminated the detrimental interaction between HRSNs, adverse health outcomes, and health care utilization in the United States.[240] [241] Emerging evidence has shown that specific social risk factors are directly associated with health outcomes and health care utilization and costs.[242] [243] [244] [245] Of particular concern among people with ESRD are HRSNs that have an effect on treatment outcomes, including inadequate access to healthy foods, unstable housing, limited transportation, and community safety concerns.[246] [247]

We believe that improvement in care coordination between ESRD facilities, hospitals, and community-based organizations would yield better health outcomes for people with ESRD, and subsequently lead to improvements in quality performance for dialysis and other health care providers. We believe that the Screening for Social Drivers of Health reporting measure would help inform facilities of the impact of HRSNs in people with ESRD by assessing the proportion of adult patients who are screened for social drivers of health in five core domains: food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

In the CY 2023 ESRD PPS proposed rule, we sought public comment on the potential future inclusion of the Screening for Social Drivers of Health measure in the ESRD QIP (87 FR 38554 through 38556). For a summary of the comments we received, as well as our responses, we refer readers to the CY 2023 ESRD PPS final rule (87 FR 67265 through 67268). In the CY 2023 ESRD PPS final rule, we stated that we were considering whether to incorporate measures that assess screening for health-related social needs into the ESRD QIP measure set (87 FR 67264).

In the CY 2024 ESRD PPS proposed rule, we proposed to adopt the Screening for Social Drivers of Health reporting measure under section 1881(h)(2)(A)(iv) of the Act, which gives the Secretary broad authority to specify measures for the ESRD QIP (88 FR 42510). As discussed previously, disparities in health equity are tied to worse patient outcomes in the ESRD community. While widespread interest in addressing HRSNs exists, action is inconsistent, specifically in ESRD facilities. Therefore, we believe it is appropriate to require facilities to report data on this measure because the intent of the proposed measure is to incentivize facilities to collect and utilize their data to identify the impact of HRSNs in their ESRD patient population, including whether there is a relationship between those HRSNs and the outcomes experienced by their patients with those HRSNs. Screening data collected by the facility could inform their provision of care such that they improve the outcomes experienced by patients with HRSNs. Facilities could analyze their screening data to understand whether there are any HRSNs that may be affecting their patients' access to care or contributing to poor outcomes in their patient populations and, in turn, develop appropriate solutions to improve access and outcomes. While the measure does not require facilities to take specific actions following an HRSN screening, we expect that any solution a facility might develop to address a gap it identifies would comply with all applicable Federal non-discrimination laws. We also noted that the measure is intended to promote health equity for all patients and is not intended to create a conflict between a CMS requirement and a State's civil rights laws.

Under our Meaningful Measures Framework,[248] the Screening for Social Drivers of Health reporting measure, along with the Screen Positive Rate for Social Drivers of Health reporting measure discussed in section IV.D.3 of this final rule, addresses the quality priority of ''Work with Communities to Promote Best Practices of Healthy Living'' through the Meaningful Measures Area of ''Equity of Care.'' Additionally, consistent with Meaningful Measures 2.0, these measures address the ''healthcare equity'' priority area and align with our commitment to introduce plans to close health equity gaps and promote equity through quality measures, including to ''develop and implement measures that reflect social and economic determinants.'' [249] Development and proposal of these measures also aligns with our strategic pillar to advance

[233] Institute of Medicine. (2014). Capturing Social and Behavioral Domains and Measures in Electronic Health Records: Phase 2. Washington, DC: The National Academies Press. Available at: *https://doi.org/10.17226/18951*.

[234] Alley, D. E., C. N. Asomugha, P. H. Conway, and D. M. Sanghavi. (2016). Accountable Health Communities—Addressing Social Needs through Medicare and Medicaid. The New England Journal of Medicine 374(1):8–11. Available at: *https://doi.org/10.1056/NEJMp1512532*.

[235] CDC. CDC COVID–19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID–19 Disparities and Achieving Health Equity. July 2020. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html*. Accessed November 17, 2021.

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[237] Khullar, D., Schpero, W.L., Bond, A.M., Qian, Y., & Casalino, L.P. (2020). Association Between Patient Social Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System. JAMA, 324(10), 975–983. *https://doi.org/10.1001/jama.2020.13129*.

[238] United States Renal Data System. 2021 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States*. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2021. We note that, following publication of the CY 2024 ESRD PPS proposed rule, the USRDS has published its 2022 annual report, which is available at: *https://usrds-adr.niddk.nih.gov/2022*.

[239] Weinhandl, E.D., Wetmore, J.B., Peng, Y., Liu, J., Gilbertson, D.T., et al., (2021). Initial Effects of COVID–19 on Patient with ESKD. Journal of the American Society of Nephrology 32: 1444–1453. doi: *https://doi.org/10.1681/ASN.2021010009*.

[240] CDC. CDC COVID–19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID–19 Disparities and Achieving Health Equity. July 2020. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html*. Accessed November 17, 2021.

[241] Weinhandl, E.D., Wetmore, J.B., Peng, Y., Liu, J., Gilbertson, D.T., et al., (2021). Initial Effects of COVID–19 on Patient with ESKD. Journal of the American Society of Nephrology 32: 1444–1453. doi: *https://doi.org/10.1681/ASN.2021010009*.

[242] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https://care.diabetesjournals.org/lookup/doi/10.2337/dci20-0053*.

[243] Dean, E.B., French, M.T., Mortensen, K. (2020). Health Services Research 55 (Supplement 2): 883–893. doi: 10.1111/1475–6773.13283.

[244] Berkowitz, S.A., Kalkhoran, S., Edwards, S.T., Essien, U.R., Baggett, T.P. (2018). Unstable Housing and Diabetes-Related Emergency Department Visits and Hospitalization: A Nationally Representative Study of Safety-Net Clinic Patients. Diabetes Care 41: 933–939. *https://doi.org/10.2337/dc17-1812*.

[245] National Academies of Sciences, Engineering, and Medicine 2019. *Dialysis Transportation: The Intersection of Transportation and Healthcare*. Washington, DC: The National Academies Press. *https://doi.org/10.17226/25385*.

[246] *Ibid.*

[247] CMS (2021). Chronic Kidney Disease Disparities: Educational Guide for Primary Care. Available at: *https://www.cms.gov/files/document/chronic-kidney-disease-disparities-educational-guide-primary-care.pdf*.

[248] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy*.

[249] Centers for Medicare & Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization*. We note that Meaningful Measures 2.0 is still under development.

health equity by addressing the health disparities that underlie our health system.[250] We also believe these measures address the quality priority ''Promoting Effective Prevention and Treatment of Chronic Disease'' through the Meaningful Measures Area ''Management of Chronic Conditions,'' by improving a facility's ability to assess and implement effective care coordination for its patients. For example, data demonstrate that an overwhelming majority of people with ESRD travel outside their homes for dialysis three times per week, round trip, and that transportation challenges contribute to shortened treatment episodes and adverse health outcomes.[251] [252] Identification of patients with transportation difficulties could encourage facilities to provide information to these patients about available community-based transportation services that could help these patients with their transportation needs. We also believe that the measures would encourage facilities to incorporate HRSN screening into their routine care, which would in turn improve their ability to understand the full needs of their patients, including those who may need additional care coordination but might be reluctant to otherwise seek assistance due to concerns about personal stigmatization.

Growing evidence demonstrates that specific social risk factors are directly associated with patient health outcomes as well as healthcare utilization, costs, and performance in quality reporting and payment programs.[253] [254] In 2017, CMS's Center for Medicare and Medicaid Innovation (CMMI) launched the Accountable Health Communities (AHC) Model to test the impact of systematically identifying and addressing the HRSNs of community-dwelling Medicare and Medicaid beneficiaries (through screening, referral, and community navigation on their health outcomes and related healthcare utilization and costs).[255] [256] [257] [258] The CMS Innovation Center developed the AHC Model based on evidence that addressing HRSNs through enhanced linkages between health systems and community-based organizations can improve health outcomes and reduce costs.[259] HRSNs are significant risk factors associated with adverse health outcomes and increased health care utilization, including excessive emergency department (ED) visits and avoidable hospitalizations.[260] [261] Unmet HRSNs, such as food insecurity, inadequate or unstable housing, and inadequate transportation may increase risk for onset of chronic conditions, such as ESRD, and accelerate exacerbation of related adverse health outcomes.[262] [263] [264] The AHC Model had a 5-year period of performance that began in May 2017 and concluded in April 2022, with beneficiary screening beginning in the summer of 2018 following an implementation period.[265] [266] Evaluation of the AHC Model data is still underway, and the most recent evaluation was published in the second AHC Model evaluation report on May 18, 2023.[267]

While social risk factors may have a significant impact on health outcomes, the mechanisms by which this connection emerges are complex and multifaceted.[268] [269] [270] [271] The persistent interactions between individuals' HRSNs, medical providers' practices/behaviors, and community resources significantly impact healthcare access, quality, and ultimately costs, as described in the CMS Equity Plan for Improving Quality in Medicare.[272] [273] In

[250] Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Available at: *https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms.*

[251] *Ibid.*

[252] United States Renal Data System. 2021 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States.* National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2021. We note that, following publication of the CY 2024 ESRD PPS proposed rule, the USRDS has published its 2022 annual report, which is available at: *https://usrds-adr.niddk.nih.gov/2022.*

[253] Zhang Y, Li J, Yu J, Braun RT, Casalino LP. (2021). Social Determinants of Health and Geographic Variation in Medicare per Beneficiary Spending. JAMA Network Open. 2021;4(6):e2113212. doi:10.1001/jamanetworkopen.2021.13212.

[254] Khullar, D., Schpero, W. L., Bond, A. M., Qian, Y., & Casalino, L. P. (2020). Association Between Patient Social Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System. JAMA, 324(10), 975–983. *https://doi.org/10.1001/jama.2020.13129.*

[255] Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. June 2021. Accessed: November 23, 2021. Available at: *https://innovation.cms.gov/media/document/ahcm-screeningtool-companion.*

[256] Alley, D. E., C. N. Asomugha, P. H. Conway, and D. M. Sanghavi. 2016. Accountable Health Communities—Addressing Social Needs through Medicare and Medicaid. The New England Journal of Medicine 374(1):8–11. Available at: *https://doi.org/10.1056/NEJMp1512532.*

[257] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b.*

[258] Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Accessed November 23, 2021. Available at: *https://innovation.cms.gov/innovation-models/ahcm.*

[259] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt.*

[260] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b.*

[261] Alley, D. E., C. N. Asomugha, P. H. Conway, and D. M. Sanghavi. 2016. Accountable Health Communities—Addressing Social Needs through Medicare and Medicaid. The New England Journal of Medicine 374(1):8–11. Available at: *https://doi.org/10.1056/NEJMp1512532.*

[262] Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

[263] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https://care.diabetesjournals.org/lookup/doi/10.2337/dci20-0053.*

[264] Laraia, B.A. (2013). Food Insecurity and Chronic Disease. Advances in Nutrition, 4: 203–212, doi: 10.3945/an.112.003277.

[265] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt.*

[266] We note that the model officially concluded in April 2022 but many awardees are continuing with no-cost extensions to continue utilizing unspent cooperative agreement funding and all awardees will conclude by April 2023.

[267] RTI International. (2023). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2023/ahc-second-eval-rpt.*

[268] Kaiser Family Foundation. (2021). Racial and Ethnic Health Inequities and Medicare. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.* Accessed November 23, 2021.

[269] Khullar, D., MD. (2020, September 8). Association Between Patient Social Risk and Physician Performance American academy of Family Physicians. (2020). Addressing Social Determinants of Health in Primary Care team-based approach for advancing health equity.

[270] Hammond, G., Johnston, K., Huang, K., Joynt Maddox, K. (2020). Social Determinants of Health Improve Predictive Accuracy of Clinical Risk Models for Cardiovascular Hospitalization, Annual Cost, and Death. Circulation: Cardiovascular Quality and Outcomes, 13 (6) 290–299. Available at: *https://doi.org/10.1161/CIRCOUTCOMES.120.006752.*

[271] The Physicians Foundation. (2021). Viewpoints: Social Determinants of Health. Available at: *https://physiciansfoundation.org/wp-content/uploads/2019/08/The-Physicians-Foundation-SDOH-Viewpoints.pdf.* Accessed December 8, 2021.

[272] Centers for Medicare & Medicaid Services. (2021). Paving the Way to Equity: A Progress Report. Accessed January 18, 2022. Available at: *https://www.cms.gov/files/document/paving-way-equity-cms-omh-progress-report.pdf.*

[273] Centers for Medicare & Medicaid Services Office of Minority Health. (2021). The CMS Equity Plan for Improving Quality in Medicare. 2015–2021. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf#:~:text=The%20Centers%20for%20Medicare%20%26%20Medicaid%20Services%20%*

their 2018 survey of 8,500 physicians, The Physicians Foundation found almost 90 percent of physician respondents reported their patients had a serious health problem linked to poverty or other social conditions.[274] Additionally, associations between disproportionate health risk, hospitalization, and adverse health outcomes have been highlighted and magnified by the COVID–19 pandemic.[275] [276]

The following five core domains were selected to screen for HRSNs among Medicare and Medicaid beneficiaries under the AHC Model: (1) food insecurity; (2) housing instability; (3) transportation needs; (4) utility difficulties; and (5) interpersonal safety. These domains were chosen based upon literature review and expert consensus utilizing the following criteria: (1) availability of high-quality scientific evidence linking a given HRSN to adverse health outcomes and increased healthcare utilization, including hospitalizations and associated costs; (2) ability for a given HRSN to be screened and identified in the inpatient setting prior to hospital discharge, addressed by community-based services, and potentially improve healthcare outcomes, including reduced hospital re-admissions; and (3) evidence that a given HRSN is not systematically addressed by healthcare providers.[277] In addition to established evidence of their association with health status, risk, and outcomes, these five domains were also selected because they can be assessed across the broadest spectrum of individuals in a variety of settings.[278] [279] [280]

These five evidence-based HRSN domains informed our development of the Screening for Social Drivers of Health reporting measure, as well as a second measure, Screen Positive Rate for Social Drivers of Health reporting measure. These domains are described in Table 22.

TABLE 22: Five Core HRSN Domains Used in the Screening for Social Drivers of Health Reporting Measure and the Screen Positive Rate for Social Drivers of Health Reporting Measure

Domain	Description
Food Insecurity	Food insecurity is defined as limited or uncertain access to adequate quality and quantity of food at the household level. It is associated with diminished mental and physical health and increased risk for chronic conditions.[281,282] Individuals experiencing food insecurity often have inadequate access to healthier food options which can impede self-management of chronic diseases like diabetes and heart disease, and require individuals to make personal trade-offs between food purchases and medical needs, including prescription medication refills and preventive health services.[283,284] Food insecurity is associated with high-cost healthcare utilization including emergency department (ED) visits and hospitalizations.[285,286,287]
Housing Instability	Housing instability encompasses multiple conditions ranging from inability to pay rent or mortgage, frequent changes in residence including temporary stays with friends and relatives, living in crowded conditions, and actual lack of sheltered housing in which an individual does not have a personal residence.[288,289] Population surveys consistently show that people from some racial and ethnic minority groups constitute the largest proportion of the U.S. population experiencing unstable housing.[290] Housing

28CMS%29,evidence%20base%2C%20identifying%20opportunities%2C%20and%20gathering%20stakeholder%20input.

[274] The Physicians Foundation. (2019). Viewpoints: Social Determinants of Health. Available at: *https://physiciansfoundation.org/wp-content/uploads/2019/08/The-Physicians-Foundation-SDOH-Viewpoints.pdf.* Accessed December 8, 2021.

[275] CDC. (2020). CDC COVID–19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID–19 Disparities and Achieving Health Equity. July 2020. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html.* Accessed November 17, 2021.

[276] Kaiser Family Foundation. (2021). Racial and Ethnic Health Inequities and Medicare. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.* Accessed November 23, 2021.

[277] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b.*

[278] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b.*

[279] Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Accessed November 23, 2021. Available at: *https://innovation.cms.gov/innovation-models/ahcm.*

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[281] Berkowitz SA, Seligman HK, Meigs JB, Basu S. Food insecurity, healthcare utilization, and high cost: a longitudinal cohort study. Am J Managed Care. 2018 Sep;24(9):399–404. PMID: 30222918; PMCID: PMC6426124.

[282] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https://pubmed.ncbi.nlm.nih.gov/33139407/.*

[283] Seligman, H.K., Berkowitz, S.A. (2019). Aligning Programs and Policies to Support Food Security and Public Health Goals in the United States. Annual Review of Public Health, 40(1), 319–337. Available at: *https://pubmed.ncbi.nlm.nih.gov/30444684/.*

Domain	Description
	instability is associated with higher rates of chronic illnesses, injuries, and complications and more frequent utilization of high-cost healthcare services.[291,292]
Transportation Needs	Unmet transportation needs include limitations that impede transportation to destinations required for all aspects of daily living.[293] Groups disproportionately affected include older adults (aged >65 years), people with lower incomes, people with impaired mobility, residents of rural areas, and people from some racial and ethnic minority groups. Transportation needs contribute to postponement of routine medical care and preventive services which ultimately lead to chronic illness exacerbation and more frequent utilization of high-cost healthcare services including emergency medical services, EDs, and hospitalizations.[294,295,296,297]
Utility Difficulties	Inconsistent availability of electricity, water, oil, and gas services is directly associated with housing instability and food insecurity.[298] Specifically, interventions that increase or maintain access to such services have been associated with individual and population-level health improvements.[299]
Interpersonal Safety	Interpersonal safety affects individuals across the lifespan, from birth to old age, and is directly linked to mental and physical health. Assessment for this domain includes screening for exposure to intimate partner violence, child abuse, and elder abuse.[300] Exposure to violence and social isolation are reflective of individual-level social

Domain	Description
	relations and living conditions that are directly associated with injury, psychological distress, and death in all age groups.[301,302]

[284] National Academies of Sciences, Engineering, and Medicine 2006. Executive Summary: Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation. Washington, DC: The National Academies Press. Available at: *https://doi.org/10.17226/23285.*

[285] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https://pubmed.ncbi.nlm.nih.gov/33139407/.*

[286] Berkowitz SA, Seligman HK, Meigs JB, Basu S. Food insecurity, healthcare utilization, and high cost: a longitudinal cohort study. Am J Managed Care. 2018 Sep;24(9):399–404. PMID: 30222918; PMCID: PMC6426124.

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[288] Larimer, M. E. (2009). Health Care and Public Service Use and Costs Before and After Provision of Housing for Chronically Homeless Persons with Severe Alcohol Problems. JAMA, 301(13), 1349. Available at: *https://doi.org/10.1001/jama.2009.414.*

[289] Hill-Briggs, F. (2021). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https://pubmed.ncbi.nlm.nih.gov/33139407/.*

[290] Henry M., de Sousa, T., Roddey, C., Gayen, S., Bednar, T.; Abt Associates. The 2020 Annual Homeless Assessment Report (AHAR) to Congress; Part 1: Point-in-Time Estimates of Homelessness, January 2021. U.S. Department of Housing and Urban Development. Accessed November 24, 2021. Available at: *https://www.huduser.gov/portal/sites/default/files/pdf/2020-AHAR-Part-1.pdf.*

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[292] Baxter, A., Tweed, E., Katikireddi, S., Thomson, H. (2019). Effects of Housing First approaches on health and well-being of adults who are homeless or at risk of homelessness: systematic review and meta-analysis of randomized controlled trials. Journal of Epidemiology and Community Health, 73; 379–387. Available at: *https://jech.bmj.com/content/jech/73/5/379.full.pdf.*

[293] National Academies of Sciences, Engineering, and Medicine 2006. Executive Summary: Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation. Washington, DC: The National Academies Press. Available at: *https://doi.org/10.17226/23285.*

[294] National Academies of Sciences, Engineering, and Medicine 2006. Executive Summary: Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation. Washington, DC: The National Academies Press. Available at: *https://doi.org/10.17226/23285.*

[295] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https://pubmed.ncbi.nlm.nih.gov/33139407/.*

[296] Billioux, A., Verlander, K., Anthony, S., Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b.*

[297] Shier, G., Ginsburg, M., Howell, J., Volland, P., Golden, R. (2013). Strong Social Support Services, Such as Transportation And Help For Caregivers, Can Lead To Lower Health Care Use And Costs. Health Affairs, 32(3), 544–551. Available at: *https://doi.org/10.1377/hlthaff.2012.0170.*

[298] Baxter, A., Tweed, E., Katikireddi, S., Thomson, H. (2019). Effects of Housing First approaches on health and well-being of adults who are homeless or at risk of homelessness: systematic review and meta-analysis of randomized controlled trials. Journal of Epidemiology and Community Health, 73; 379–387. Available at: *https://jech.bmj.com/content/jech/73/5/379.full.pdf.*

[299] Wright, B. J., Vartanian, K. B., Li, H. F., Royal, N., Matson, J. K. (2016). Formerly Homeless People Had Lower Overall Health Care Expenditures After Moving into Supportive Housing. Health Affairs, 35(1), 20–27. Available at: *https://doi.org/10.1377/hlthaff.2015.0393.*

[300] Billioux, A., Verlander, K., Anthony, S., Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b.*

[301] Henry M., de Sousa, T., Roddey, C., Gayen, S., Bednar, T.; Abt Associates. The 2020 Annual Homeless Assessment Report (AHAR) to Congress; Part 1: Point-in-Time Estimates of Homelessness, January 2021. U.S. Department of Housing and Urban Development. Accessed November 24, 2021. Available at: *https://www.huduser.gov/portal/sites/default/files/pdf/2020-AHAR-Part-1.pdf.*

The Screening for Social Drivers of Health reporting measure assesses screening of the same HRSNs.

In the proposed rule, we proposed that facilities would be able to choose a screening tool for purposes of this measure or otherwise screen their patients using a method of their choosing in order to give facilities the flexibility to accommodate the population they serve and their individual needs (88 FR 42513).[303] [304] We noted that the 10-item AHC Health-Related Social Needs Screening Tool that AHC Model participants used to identify HRSNs in the five core domains (described in Table 22) among community-dwelling Medicare, Medicaid, and dually eligible beneficiaries was tested across varied care-delivery sites in diverse geographic locations across the U.S.[305] [306] Facilities may wish to consider using that tool because it has been found to be both reliable and valid, including high inter-rater reliability and concurrent and predictive validity.[307] Moreover, the screening tool can be implemented in a variety of places where patients seek healthcare, including dialysis facilities.[308] However, as stated previously, we did not propose to require facilities to use this tool, or any other specific tool, for purposes of the Screening for Social Drivers of Health reporting measure.

b. Overview of Measure

The Screening for Social Drivers of Health measure assesses the percentage of patients age 18 and older that a dialysis facility screens for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. To report on this measure, facilities would provide: (1) the number of patients admitted to the facility who are 18 years or older during the applicable performance period who are screened for all of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety; and (2) the total number of patients at the facility who are 18 years or older during the applicable performance period and who are not excluded from the measure. In the proposed rule, we proposed to add this measure to the Reporting Measure Domain beginning with PY 2027 (88 FR 42514). We discuss measure domains and weights for PY 2027 in section IV.D.7 of this final rule.

Measure specifications for this measure are currently available on the QualityNet website at: *https://qualitynet.cms.gov/esrd/esrdqip*.

(1) Cohort

The cohort for the Screening for Social Drivers of Health reporting measure is all patients, aged 18 years and older, who are treated at the facility during the applicable performance period and not eligible to be excluded from the measure.

(2) Numerator

The numerator is calculated as the number of patients who are 18 years or older who are treated at the facility during the applicable performance period and are not eligible to be excluded from the measure, and are screened during the performance period for all of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

(3) Denominator

The denominator is calculated as the number of patients at the dialysis facility and who are 18 years or older on the first day of the performance period. The following patients are excluded from the denominator: (1) Patients who opt-out of screening; and (2) patients who are unable to complete the screening and have no legal guardian or caregiver who is able to complete the screening on their behalf.

c. Measure Calculation

The Screening for Social Drivers of Health measure is calculated as the number of patients at a dialysis facility who are 18 years or older who are treated at the facility during the applicable performance period and are not eligible to be excluded from the measure, and are screened by the facility for all five HRSNs (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) divided by the total number of patients 18 years or older on the 1st day of the performance period (January 1st) at that dialysis facility. In the proposed rule, we proposed a 12-month period of performance for the measure, and facilities would be required to report annually (88 FR 42514). We proposed that a facility would be scored according to the following equation:

$$\left[\frac{\text{Number of Eligible Patients for Whom a Facility Screened for all Five HSRNs During the Performance Period}}{\text{Total Number of Eligible Patients During the Performance Period}}\right] \times 10$$

We believe that this scoring policy would encourage facilities to report the measure data appropriately without penalizing facilities for the results of such data, which may be based on circumstances beyond a facility's control.

d. Data Submission and Reporting

In the proposed rule, we proposed to require facilities to report this measure on an annual basis beginning with PY 2027 (88 FR 42514). In alignment with the policy we finalized for the Hospital IQR Program, we would allow facilities flexibility to select their own screening tool or method to screen patients for

[302] Larimer, M. E. (2009). Health Care and Public Service Use and Costs Before and After Provision of Housing for Chronically Homeless Persons with Severe Alcohol Problems. JAMA, 301(13), 1349. Available at: *https://doi.org/10.1001/jama.2009.414*.

[303] Social Interventions Research & Evaluation Network. (2019). Social Needs Screening Tool Comparison Table. Available at: *https://sirenetwork.ucsf.edu/tools-resources/resources/screening-tools-comparison*. Accessed January 18, 2021.

[304] Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights (June 2021). Available at: *https://innovation.cms.gov/media/document/ahcm-screeningtool-companion*. Accessed January 18, 2021.

[305] More information on the HRSN Screening Tool is available at: *https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf*.

[306] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt*.

[307] Lewis C., Wellman R., Jones S., Walsh-Bailey C., Thompson E., Derus A., Paolino A., Steiner J., De Marchis E., Gottlieb L., and Sharp A. (2020). Comparing the Performance of Two Social Risk Screening Tools in a Vulnerable Subpopulation. J Family Med Prim Care. 2020 Sep; 9(9): 5026–5034. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7652127/*.

[308] CMS. A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. June 2021. Accessed: November 23, 2021. Available at: *https://innovation.cms.gov/media/document/ahcm-screeningtool-companion*.

food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. Potential sources of these data for incorporation in a tool could include, for example, administrative claims data, electronic clinical data, standardized patient assessments, or patient-reported data and surveys. Additionally, multiple screening tools exist and are publicly available. Facilities could refer to the Social Interventions Research and Evaluation Network (SIREN) website, for example, for comprehensive information about the most widely used HRSN screening tools.[309] [310] SIREN contains descriptions of the content and characteristics of various tools, including information about intended populations, completion time, and number of questions. We encourage facilities to consider digital standardized screening tools and refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49207), where we noted that the use of certified health IT can support capture of HRSN information in an interoperable fashion so that these data can be shared across the care continuum to support coordinated care.

We proposed that the deadline for submission would be the end of the EQRS December data reporting month for the applicable performance period, which is consistent with current reporting deadlines for other ESRD QIP measures (88 FR 42514). For example, the deadline for submission in PY 2027 would be the end of the December data reporting month in CY 2025.

e. Review by the Measure Applications Partnership

We included the Screening for Social Drivers of Health reporting measure as a measure under consideration for the ESRD QIP on the publicly available 2022 MUC List, a list of measures under consideration for use in various Medicare programs.[311] The CBE-convened MAP Health Equity Advisory Group reviewed the MUC List and the Screening for Social Drivers of Health measure (MUC 2022–053) in detail and at the same time as the Screen Positive Rate for Social Drivers of Health measure on December 6–7, 2022 (discussed below).[312] The Health Equity Advisory Group expressed support for the data collection related to social drivers of health, but raised concerns about public reporting of the data and redundancy in asking for the same information of patients. In addition, on December 8–9, 2022, the MAP Rural Health Advisory Group reviewed the 2022 MUC List and the MAP Hospital Workgroup did so on December 13–14, 2022.[313] The Rural Health Advisory Group noted some potential reporting challenges including the potential masking of health disparities that are underrepresented in some areas and that sample size and populations served may be an issue, but expressed that the measure serves as a starting point to determine where screening is occurring. The MAP Hospital Workgroup expressed strong support for the measure but noted that interoperability will be important and cautioned about survey fatigue. The MAP Hospital Workgroup members conditionally supported the measure pending: (1) testing of the measure's reliability and validity; (2) endorsement by a consensus-based entity (CBE); (3) additional details on how potential tools map to the individual drivers, as well as best practices; (4) what resources may be available to assist patients; and (5) alignment with data standards, particularly the GRAVITY project.[314] Thereafter, the MAP Coordinating Committee deliberated on January 24 and 25, 2023, and ultimately voted to conditionally support the Screening for Social Drivers of Health reporting measure for rulemaking with the same conditions.[315]

f. Consensus-Based Entity Endorsement

Although section 1881(h)(2)(B)(i) of the Act generally requires that measures specified by the Secretary for the ESRD QIP be endorsed by the entity with a contract under section 1890(a) of the Act, section 1881(h)(2)(B)(ii) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and, therefore, we believe the exception in section 1881(h)(2)(B)(ii) of the Act applies.

g. Public Display

In the proposed rule, we proposed to publicly display the facility-specific results for the Screening for Social Drivers of Health measure on an annual basis through our *Care Compare* website at: *https://www.medicare.gov/care-compare/.* We stated that we anticipate making the first public report available in January 2027.

We invited public comment on this proposal. The comments we received and our responses are set forth below. We address comments that broadly referred both the Screening for Social Drivers of Health measure and the Screen Positive Rate for Social Drivers of Health measure in this section as well.

Comment: Several commenters expressed support for the Screening for Social Drivers of Health reporting measure, noting that it would help to provide facilities with additional information to help identify and address health disparities in ESRD patients. A few commenters noted that identifying patient social risk factors will allow care providers and community organizations to work together to improve care delivery.

Response: We thank commenters for their support.

[309] Social Interventions Research & Evaluation Network. (2019). Social Needs Screening Tool Comparison Table. Available at: *https://sirenetwork.ucsf.edu/tools-resources/resources/screening-tools-comparison.* Accessed January 18, 2021.

[310] The Social Interventions Research and Evaluation Network (SIREN) at University of California San Francisco was launched in the spring of 2016 to synthesize, disseminate, and catalyze research on the social determinants of health and healthcare delivery.

[311] Centers for Medicare & Medicaid Services. 2022. List of Measures Under Consideration for December 1, 2022. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[312] Centers for Medicare & Medicaid Services. 2022. 2022–2023 MAP Preliminary Recommendations. Health Equity Advisory Group. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[313] Centers for Medicare & Medicaid Services. 2022. 2022–2023 MAP Preliminary Recommendations, Rural Health Advisory Group. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[314] Centers for Medicare & Medicaid Services. (2022). 2022–2023 MAP Final Recommendations. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.* For Information on the GRAVITY project, please see *https://thegravityproject.net/.*

[315] Centers for Medicare & Medicaid Services. 2023. 2022–2023 MAP Final Recommendations. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

Comment: Several commenters expressed support for the proposed Screening for Social Drivers of Health reporting measure and recommended additional changes to the measure specifications. A few of these commenters suggested that the measure screen for additional HRSNs, such as financial needs and caregiver burdens. One commenter, noting the critical role of nurses in cultivating trust and communication with patients as being necessary to help identify and address health disparities among patients while also balancing administrative burden, recommended that CMS take additional actions that would further enable nurses to comprehensively address HRSNs across care settings. One commenter stated that patients who are unable to complete screenings and do not have a legal guardian or caregiver able to complete the screening on their behalf are extremely vulnerable and recommended dialysis facilities be encouraged to support these patients in resource identification.

Response: We thank commenters for their support and will take their recommendations under consideration for future rulemaking. We selected the proposed five HRSN domains based on the successful use of these domains in the screening that was done under the AHC Model. We note that while the Screening for Social Drivers of Health measure requires screening for the five identified HRSNs, facilities may screen for additional HRSNs that they believe may be impacting their patient population. One resource that facilities could consider is the Accountable Health Communities screening tool, which includes questions for eight supplemental domains, including financial strain. Although the Screening for Social Drivers of Health reporting measure excludes patients who are unable to complete the screening and have no legal guardian or caregiver who is able to complete the screening on their behalf, we would nonetheless encourage facilities to support these patients with resource identification.

Comment: Several commenters expressed concern that the proposed Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure would not effectively address poor health outcomes associated with HRSNs. A few of these commenters believed that the measures did not provide sufficient patient or provider support to help empower patients to improve their health outcomes. One commenter noted that the availability of community resources is highly variable depending on location and expressed concern that screening for HRSNs through administering questionnaires may be futile in deprived areas that lack access to such community organizations. One commenter expressed concern that the proposed measures may lead to unintended consequences and further perpetuate health disparities by disincentivizing facilities from providing care to patients with HRSNs or communities with higher rates of HRSNs. One commenter expressed concern that the proposed measures do not distinguish between a patient's social risks and a patient's social needs, noting that the former is determined by screening instrument and the latter is based on a patient's own priorities and preferences. The commenter recommended that CMS develop a measure that focuses on assessing a patient's self-identified needs and priorities while ensuring that resources are available to provide responsive follow-up care.

Response: We thank commenters for their feedback. During the development of both Social Drivers of Health measures, we gave this topic significant consideration. The intent of the two measures is to incentivize facilities to screen their patients for HRSNs in five core domains, as well as to analyze those data to determine whether there is a relationship between the HRSNs and the outcomes experienced by their patients. Facilities could use those data to develop solutions to improve access to care and clinical outcomes among their patient population. Evaluation of the AHC Model concluded that universal screening may identify needs that would otherwise remain undetected.[316] While broad availability of community-based resources that address patients' health-related social needs would be ideal, we believe that one of the benefits of these measures will be identification of opportunities to enable meaningful action, including prioritizing and investing in such resources where feasible. For example, a facility may decide to offer shuttle services for some of its patients if transportation is identified as a barrier to treatment. A facility may also be able to connect patients with local resources to assist with food insecurity, housing instability, or utility difficulties. Beginning to collect the data on patients' HRSNs remains imperative and a crucial step in developing resources for advancing health equity.

We note that identifying and addressing HRSNs is a critical topic for ESRD patients and that there are high levels of health disparities experienced by this patient population. Although we believe that the two measures will not lead to unintended consequences because screening would be required for all eligible patients and facilities would not be penalized based on reported screen positive rates, CMS will monitor measure implementation as part of standard program and measure review and will consider updates to the measures if improvements are identified through this process.

Comment: Several commenters expressed concern that the proposed Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure were not ready for inclusion in the ESRD QIP measure set. A few commenters recommended an endorsement review by the CBE to ensure that such measures will drive improved health outcomes and advance health equity, given the significance of addressing social risk factors and the potential administrative burden associated with the inclusion of new measures. One commenter expressed concern with the proposed measures, recommending that more work be done to address potential reporting challenges and potential masking of health disparities before the measures are incorporated into the ESRD QIP. One commenter noted that these are the first measures aimed at HRSNs that would be used in the ESRD QIP, and the impact of their adoption into a payment program is unknown.

Response: Although we recognize the value of measures undergoing review for potential CBE endorsement, given the urgency of improving health equity, we believe it is important to implement this measure as soon as possible while balancing facilities' need for sufficient time to implement screening and data collection processes, which is why we proposed to adopt this measure beginning with the PY 2027 ESRD QIP. We note that the most recent evaluation of the AHC model, which informed the development of these proposed measures, showed that it was effective in screening beneficiaries for HRSNs, identifying eligible beneficiaries, and referring those beneficiaries to HRSN-related navigation services.[317] We

[316] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt.*

[317] RTI International. (2023). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2023/ahc-second-eval-rpt.*

believe that the success of the AHC model shows that these measures will have a similar impact. Additionally, we note that, under section 1881(h)(2)(B)(ii) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed measures endorsed by consensus organizations and were unable to identify any other measures on this topic endorsed by a consensus organization, and therefore, we believe the exception in section 1881(h)(2)(B)(ii) of the Act applies.

Comment: Several commenters expressed concern with the potential burden associated with the proposed Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure. A few commenters noted that facilities would need additional resources in order to implement and comply with proposed measure requirements. A few of these commenters expressed particular concern regarding staffing constraints. A few commenters expressed concern regarding the administrative burden associated with the data collection and reporting requirements and requested that facilities receive additional resources such as training and funding to support the data collection and reporting efforts associated with the proposed measures. One commenter expressed concern that the administrative burden associated with the proposed measures could divert facility resources from direct patient care and requested an assessment of the administrative burden.

Response: While we understand that implementation of the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure are associated with some burden, as discussed in section VI.C.3 of this final rule, we believe the benefits outweigh the burden because screening for and identifying patients' HRSNs is a critical step towards a facility identifying and understanding how the presence of the screened HRSNs might be impacting patient access to ESRD care and outcomes. We intend to monitor the measures for any unintended or adverse outcomes associated with implementation.

We note that screening can occur any time during the patient's treatment at the facility during the performance period prior to discharge and that, for example, the AHC Screening Tool addresses these 5 HRSNs using a total of 10 questions. Therefore, we believe that facilities will be able to find sufficient time to screen their patients.

Comment: A few commenters expressed concern with the proposed Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure, believing that the goals of the two measures were already effectively covered through other means. One of these commenters noted that facilities are already required to screen their patients for HRSNs as part of ESRD Conditions for Coverage assessments required at 42 CFR 494.90. One of these commenters stated that dialysis facilities are already required to screen patients for multiple non-clinical conditions, noting that CMS previously proposed revisions to the ESRD Medical Evidence Report form (CMS–2728), which includes seven screening questions related to HRSNs that address the same five core domains as these measures. One of these commenters stated that the clinical measures currently included in the ESRD QIP are more effectively aimed at incentivizing beneficial patient outcomes such as preventing avoidable hospitalizations and reducing mortality.

Response: We recognize that there may be overlap between the HRSN data screened for under the proposed measures and data that facilities are reporting for other purposes. However, we note that some of the data cited by commenters is collected on a one-time basis, whereas the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measures require that the screens be conducted annually. This difference in the frequency of the screens will facilitate the ability of facilities to identify HRSNs that develop or change over time. We agree with the commenter that noted the beneficial impact of clinical measures in the ESRD QIP measure set. Given the link between social risk factors and adverse health outcomes, we believe that incentivizing facilities to screen for and identify a patient's HRSNs will similarly lead to better patient health outcomes.

Comment: A few commenters recommended that the measures use a standardized survey to identify and collect HRSN data. One of these commenters noted that because the measure does not require facilities to use a standard screening instrument, facility performance on the measure is not comparable and the reported data will not be meaningful to the public. The commenter recommended that CMS only publicly report whether a facility screens for HRSNs and that CMS not publicly report the percentage of patients at a facility that screens positive for each HRSN. One commenter recommended that CMS provide guidance on the role of Protocol for Responding to & Assessing Patients' Assets, Risks & Experiences (PRAPARE) for screening in dialysis facilities. One commenter suggested that the measure use a standardized survey to identify and collect HRSN data.

Response: We proposed that facilities would be able to choose their own screening tool for purposes of complying with both the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure because we think it is important to provide facilities with the flexibility to choose the screening tool that works best for them. We understand that the absence of a standardized screening tool could introduce some inconsistency in the information collected across facilities because different screening tools may vary in terms of the number of screening questions included or the language used in those screening questions. While we acknowledge the potential benefits of requiring all facilities to use the same screening instrument or a prescribed set of standards around the number or types of screening questions used, we also recognize the benefits of providing facilities with flexibility to customize screening and data collection to their patient populations. We encourage facilities to select screening tools that have undergone thorough testing to ensure they are accurate and reliable. We believe that this measure should promote screening practices which, among other things, help to identify unmet HRSNs.

We disagree with commenter's recommendation that CMS publicly report only whether a facility screens for HRSNs and not the percentage of patients at a facility that screens positive for each HRSN. Public reporting provides a means of delivering important healthcare information to facilities, consumers, and patient advocates on the level of unmet HRSNs among a facility's patient population that might be contributing to the clinical outcomes at the facility. We believe that a facility's ability to identify HRSNs among its patient population should be considered part of the quality of care it provides to its patients. In addition to helping facilities identify these HRSNs among their patient population that could play a factor in clinical outcomes, it also may provide the public with

useful information that could be used to improve resources available to patients.

Although the commenter is correct that PRAPARE may be a useful screening tool for engaging patients in assessing and addressing social drivers of health, we are not requiring that facilities use a specific standardized screening tool for purposes of complying with the proposed measures at this time. For selecting a screening tool, we suggest that facilities refer to evidence-based resources for comprehensive information about the most widely used HRSN screening tools. For example, the Social Interventions Research and Evaluation Network (SIREN) website, housed at the Center for Health and Community at the University of California, San Francisco, contains descriptions of the content and characteristics of various tools, including information about intended populations, completion time, and number of questions.

Comment: One commenter expressed concern with the proposed use of a standardized tool to screen patients for HRSNs, noting that HRSN screening may be accomplished through alternative means such as informal but thorough patient interviewing by a practitioner or predictive modeling using available patient data. The commenter cautioned against penalizing providers for not using a standardized tool to screen for HRSNs, absent evidence showing the superiority of the proposed method.

Response: We did not propose to require facilities to use a standardized screening tool. In the proposed rule, we proposed that facilities would be able to select a screening tool of their choosing for purposes of this measure to give facilities the flexibility to tailor their screen to the needs of their patient population.

Comment: A few commenters requested clarification regarding whether Electronic Data Interchange may be used between systems and the screening tools already in place, including clarification that CMS intends to collect the data through the EQRS. One commenter recommended delaying adoption of the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting because dialysis facilities may need more time to update different EMRs.

Response: Facilities will collect and report the measure data through EQRS. Because we are not requiring facilities to adopt a standardized screening tool, we believe that the proposed measures provide facilities with the flexibility to customize screening and data collection to their local community contexts and patient populations, especially in the initial stages of implementing screening protocols. We note that these measures are proposed for inclusion beginning with PY 2027, so we believe that facilities will have ample time to build out their interfaces and test their systems before measure data reporting requirements officially begin.

Comment: A few commenters recommended that CMS align the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure with the requirements of the Comprehensive Kidney Care Contracting (CKCC) option of the KCC Model.

Response: We thank commenters for the recommendations.

Comment: One commenter recommended that facilities should receive full credit for reporting on these measures, cautioning against potentially penalizing facilities by holding them accountable for social disparities beyond their control.

Response: We proposed that the Screening for Social Drivers of Health measure is calculated as the number of eligible patients at a dialysis facility who are 18 years or older who are treated at the facility during the applicable performance period and are screened by the facility for all five HRSNs divided by the total number of patients 18 years or older on the 1st day of the performance period at that dialysis facility. For the Screen Positive Rate for Social Drivers of Health reporting measure, we proposed that the facility's measure rate would be calculated as the number of eligible patients for whom the facility reports the screening results for all five HRSNs during the performance period over the total number of eligible patients who the facility screened for all five HRSNs during that performance period. To calculate the facility's score on the measure, we would multiply the results of that fraction by ten. We note that patients who opt-out or are unable to complete the screening are excluded from the measure denominators, so that facilities are not penalized if a patient refuses to answer certain screening questions. Facilities will be scored on whether they reported the measure data, not the results of the measure data itself. Although we believe that it is important to encourage facilities to screen their patients for HSRNs and to report data for screen positive rates, we want to avoid potential unintended consequences that may result from scoring facilities on the outcomes of the screen positive rates themselves. That is, we will not score a facility based on its screen positive rates, which may reflect circumstances beyond a facility's control. We believe that these scoring policies will encourage facilities to report the measure data accurately without penalizing facilities for the results of such data.

Comment: One commenter expressed strong concern that the two proposed measures were inappropriate for use in the ESRD QIP, noting the risk of exacerbating long-standing mistrust in the healthcare system among certain patient populations. One commenter recommended that resources be offered to all patients to avoid potential stigma associated with a patient's identified HRSNs. One commenter recommended that ''screening'' be clearly defined to ensure that patients are being actively and directly engaged in these screenings. The commenter expressed strong concern that incentivizing facility performance through data collection and financial penalties would potentially interfere with the autonomy of the facility's patients.

Response: We agree that it is important for the screening for HRSNs to be accomplished in a way that is respectful, person-centered, and engenders trust. We recommend that facilities consider these factors in their selection of a screening tool or other methodology to use for purposes of implementing these measures. We note that the results of a patient's HRSN screening would become part of the patient's medical record and therefore subject to the same privacy protections as the rest of the patient's medical record. We note that identifying and addressing HRSNs is a critical topic for ESRD patients and that there are high levels of health disparities experienced by this patient population. We believe that identifying the HRSNs of ESRD patients will be valuable in helping facilities to identify and understand patients' unmet needs, which may encourage improvements in care coordination with outpatient and community resources, and further support development of patient-centered treatment plans.

Comment: One commenter believed that HRSN screenings should remain voluntary, and clinics should not be penalized if a patient refuses to respond to a question or screening.

Response: Patients who opt-out of a screening or are unable to complete a screening are excluded from the measure denominator, so a facility will not be penalized if a patient declines to respond to a question or opts out of the screening entirely. We encourage facilities to explain to their patients

what the purpose of the screening is and that they may opt out.

Final Rule Action: After considering public comments, we are finalizing our proposal to adopt the Screening for Social Drivers of Health reporting measure as proposed.

3. Adoption of the Screen Positive Rate for Social Drivers of Health Reporting Measure Beginning With PY 2027

a. Background

The impact of social risk factors on health outcomes has been well-established in the literature.[318] [319] [320] [321] [322] The Physicians Foundation reported that 73 percent of the physician respondents to their annual survey agreed that social risk factors such as housing instability and food insecurity would drive health services demand in 2021.[323] Recognizing the need for a more comprehensive approach to closing equity gaps, we have prioritized quality measures that identify social drivers of health among patients served in various care settings and, in turn, support providers in addressing the impact of these drivers on disparities in patient outcomes, healthcare utilization, and costs.[324] [325] [326] Specifically, in the dialysis facility setting, we aim to encourage systematic identification of patients' HRSNs as part of treatment planning, with the intention of promoting linkages with relevant community-based services that address those needs. We also believe that the identification of HRSNs can help facilities devise strategies that improve the quality of care provided to all of their patients and lead to improved health outcomes following establishment of care at the facility.

While the Screening for Social Drivers of Health reporting measure (discussed in section IV.D.2 of this final rule) enables facilities to identify patients with HRSNs, we stated in the CY 2024 ESRD PPS proposed rule (88 FR 42516) that the Screen Positive Rate for Social Drivers of Health measure would allow facilities to capture the magnitude of these needs by reporting the rate of those patients who screen positive for HRSNs and even potentially estimate the impact of individual-level HRSNs on healthcare utilization when evaluating quality of care.[327] [328] [329] These measures complement each other because they would require facilities to report both the percentage of patients they screened (under the Screening for Social Drivers of Health measure) and the results of that screening (under the Screen Positive Rate for Social Drivers of Health measure) in order to potentially identify gaps and develop sustainable solutions at a facility level and a community level. In the proposed rule, we noted that our proposals to adopt these two separate, complementary measures align with other quality reporting programs (88 FR 42516). These two measures have been finalized for the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49191 through 49220), and since publication of the CY 2024 ESRD PPS proposed rule, have been finalized for the PPS-Exempt Cancer Hospital Quality Reporting Program in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59210 through 59222) and the Inpatient Psychiatric Facility Quality Reporting Program in the FY 2024 IPF PPS final rule (88 FR 51107 through 51121).

In the CY 2024 ESRD PPS proposed rule, we proposed to adopt this measure under section 1881(h)(2)(A)(iv) of the Act, which gives the Secretary broad authority to specify measures for the ESRD QIP (88 FR 42516). The Screen Positive Rate for Social Drivers of Health reporting measure would require facilities to screen all patients who are 18 years or older for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety and then report the resulting screen positive rates for each of those domains to CMS. These are the same five core HRSN domains under the Screening for Social Drivers of Health reporting measure, and facilities could use the same screening tool for purposes of both measures. We stated that reporting the screen positive rate for social drivers of health for each domain could inform actionable planning by facilities by helping to enable the development of individual patient action plans for those patients who screen positive (including navigation and referral). Following a positive HRSN screening, facilities could analyze data to understand, for example, whether there are any HRSNs that may be affecting their patients' access to care or contributing to poor outcomes in their patient populations and, in turn, develop appropriate solutions to improve access and outcomes. Thus, this measure has the potential to improve patient outcomes by acknowledging patients' non-clinical needs that nevertheless greatly contribute to adverse clinical outcomes and providing the opportunity for additional support by linking providers with community-based organizations to enhance patient-centered treatment and discharge planning, although such reach out is not required.[330] [331] [332] This

[318] Institute of Medicine 2014. Capturing Social and Behavioral Domains and Measures in Electronic Health Records: Phase 2. Washington, DC: The National Academies Press. Available at: *https://doi.org/10.17226/18951*.

[319] Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at: *https://innovation.cms.gov/innovation-models/ahcm*. Accessed November 23, 2021.

[320] Kaiser Family Foundation. (2021). Racial and Ethnic Health Inequities and Medicare. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/*. Accessed November 23, 2021.

[321] Milkie Vu et al. Predictors of Delayed Healthcare Seeking Among American Muslim Women, Journal of Women's Health 26(6) (2016) at 58; Nadimpalli SB, Cleland CM, Hutchinson MK, Islam N, Barnes LL, Van Devanter N. (2016) The Association between Discrimination and the Health of Sikh Asian Indians. Health Psychology, 35(4), 351–355. *https://doi.org/10.1037/hea0000268*.

[322] Office of the Assistant Secretary for Planning and Evaluation (ASPE). (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress*.

[323] The Physicians Foundation. (2020) 2020 Survey of America's Patients, Part Three. Available at: *https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf*.

[324] Alley, D.E., C.N. Asomugha, P.H. Conway, and D.M. Sanghavi. 2016. Accountable Health Communities–Addressing Social Needs through Medicare and Medicaid. The New England Journal of Medicine 374(1):8–11. Available at: *https://doi.org/10.1056/NEJMp1512532*.

[325] Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at: *https://innovation.cms.gov/innovation-models/ahcm*. Accessed November 23, 2021.

[326] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b*.

[327] Baker, M.C., Alberti, P.M., Tsao, T.Y., Fluegge, K., Howland, R.E., & Haberman, M. (2021). Social Determinants Matter for Hospital Readmission Policy: Insights From New York City. Health Affairs, 40(4), 645–654. Available at: *https://doi.org/10.1377/hlthaff.2020.01742*.

[328] CMS. Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at: *https://innovation.cms.gov/innovation-models/ahcm*. Accessed November 23, 2021.

[329] Hammond, G., Johnston, K., Huang, K., Joynt Maddox, K. (2020). Social Determinants of Health Improve Predictive Accuracy of Clinical Risk Models for Cardiovascular Hospitalization, Annual Cost, and Death. Circulation: Cardiovascular Quality and Outcomes, 13 (6) 290–299. Available at: *https://doi.org/10.1161/CIRCOUTCOMES.120.006752*.

[330] The Physicians Foundation. (2020). Survey of America's Patients, Part Three. Available at: *https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf*.

[331] De Marchis, E., Knox, M., Hessler, D., Willard-Grace, R., Oliyawola, JN, et al. (2019). Physician Burnout and Higher Clinic Capacity to Address Patients' Social Needs. The Journal of the American Board of Family Medicine, 32 (1), 69 through 78.

measure may also prove useful to patients by providing data transparency and signifying facilities' familiarity, expertise, and commitment regarding these issues. Finally, we believe this measure has the potential to facilitate data-informed collaboration with community-based services and focused community investments, including the development of pathways and infrastructure to more seamlessly connect patients to local community resources. Thus, the measure aims to support facilities in leveraging available data, pursuing focused quality improvement activities, and promoting efficient and effective use of their resources. While the measure does not require facilities to take specific actions, we expect that any solution a facility might develop to address a gap it identifies would comply with all applicable Federal non-discrimination laws. We also note that the measure is intended to promote health equity for all patients and is not intended to create a conflict between a CMS requirement and a State's civil rights laws.

b. Overview of Measure

The Screen Positive Rate for Social Drivers of Health measure identifies the proportion of patients at the facility who screened positive for each of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. We proposed that we would require facilities to report these data as five separate rates.[333] Measure specifications for this measure are currently available on the QualityNet website at: *https://qualitynet.cms.gov/esrd/esrdqip*.

(1) Cohort

The cohort for the Screen Positive Rate for Social Drivers of Health is patients, aged 18 years or older who are treated at the facility during the applicable performance period and are not eligible to be excluded from the measure, who were screened by the facility for all five HRSNs, and for whom the facility reports the results of a screen asking whether they have a need in one or more of the following five HRSNs (calculated separately): Food insecurity, housing instability, transportation needs, utility difficulties or interpersonal safety.[334]

(2) Numerator

The numerator consists of the number of patients at a dialysis facility who are 18 years or older who are treated at the facility during the applicable performance period and are not eligible to be excluded from the measure, who were screened for all five HRSNs, and who screened positive for one or more of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, or interpersonal safety.[335]

(3) Denominator

The denominator consists of the number of patients at a dialysis facility who are 18 years or older who are treated at the facility during the applicable performance period and are not eligible to be excluded from the measure, and are screened for an HRSN (food insecurity, housing instability, transportation needs, utility difficulties and interpersonal safety). The following patients are excluded from the denominator: (1) Patients who opt-out of screening; and (2) patients who are themselves unable to complete the screening and have no caregiver able to do so on the patient's behalf.

c. Measure Calculation

We proposed that the facility's measure rate for this measure would be calculated for a payment year as the number of eligible patients for whom the facility reports the screening results for all five HRSNs during the performance period over the total number of eligible patients who the facility screened for all five HRSNs during that performance period. To calculate the facility's score on the measure, we would multiply the results of that fraction by ten. The full equation is set forth here:

$$\left[\frac{\text{Number of Eligible Patients for Whom a Facility Reports Screening Results for all Five HSRNs During the Performance Period}}{\text{Total Number of Eligible Patients who were Screened for all Five HSRNs During the Performance Period}}\right] x10$$

However, for purposes of public reporting only, we proposed to display the facility's screen positive rate for each HRSN separately, for a total of five separate rates. Although we would not score facilities on the results of those five separate rates, we believe that making such data public may help to better inform patients and their caregivers about a facility. We proposed a 12-month period of performance for the measure, and facilities would be required to report annually.

We believe that these policies would encourage facilities to report the measure data appropriately without scoring facilities based on the results of such data, which may be based on circumstances beyond a facility's control. Although we believe that it is important to encourage facilities to screen their patients for HSRNs and to report data for screen positive rates, we want to avoid potential unintended consequences that may result from scoring facilities on the outcomes of the screen positive rates themselves. That is, we do not want to score a facility based on its patients' given socioeconomic factors, which may be based on circumstances beyond a facility's control.

[332] Kung, A., Cheung, T., Knox, M., Willard-Grace, R., Halpern, J., et.al, (2019). Capacity to Address Social Needs Affect Primary Care Clinician Burnout. Annals of Family Medicine. 17 (6), 487 through 494. Available at: *https://doi.org/10.1370/afm.2470*.

[333] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b*.

[334] In the CY 2024 ESRD PPS proposed rule, we stated that the cohort consisted of eligible patients ''who were screened by the facility for an HRSN, and who screened positive for one or more of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties or interpersonal safety.'' (88 FR 42517). This statement describes the numerator, rather than the measure cohort, and we have revised our descriptions of the measure cohort and the measure numerator in this final rule accordingly.

[335] In the CY 2024 ESRD PPS proposed rule, we stated that the numerator consisted of eligible patients ''who were screened for an HRSN, and for whom the facility reports the results of a screen asking whether they have a need in one or more of the following five HRSNs (calculated separately): Food insecurity, housing instability, transportation needs, utility difficulties or interpersonal safety.'' (88 FR 42517). This statement describes the measure cohort, rather than the measure numerator, and we have revised our descriptions of the measure cohort and the measure numerator in this final rule accordingly.

d. Data Collection, Submission and Reporting

In the CY 2024 ESRD PPS proposed rule, we proposed to require facilities to submit data necessary to calculate the numerator and the denominator for this measure once annually within the ESRD Quality Reporting System (EQRS), beginning with PY 2027 (88 FR 42517). We proposed that facilities would be required to submit data on this measure using the same process we have finalized for the submission of data on other measures in the ESRD QIP within EQRS.

e. Review by the Measure Applications Partnership

We included the Screen Positive Rate for Social Drivers of Health reporting measure for consideration in the ESRD QIP on the publicly available 2022 MUC List, a list of measures under consideration for use in various Medicare programs.[336] The CBE-convened MAP Health Equity Advisory Group reviewed the Screen Positive Rate for Social Drivers of Health measure (MUC 2022–050) in detail and at the same time as the Screening for Social Drivers of Health measure on December 6–7, 2022.[337] The Health Equity Advisory Group expressed support for the collection of data related to social health drivers, but raised concerns regarding public reporting and the repetition of asking patients the same questions. In addition, on December 8–9, 2022, the MAP Rural Health Advisory Group reviewed the 2022 MUC List and was also reviewed by the MAP Hospital Workgroup on December 13–14, 2022.[338] The Rural Health Advisory Group noted potential reporting challenges including the potential masking of health disparities that are underrepresented in some areas and that sample size and populations served may be an issue, but also expressed support that the measure seeks to advance the drivers of health and serves as a starting point to determine where screening is occurring. The MAP Hospital Workgroup recommended conditional support for the measure for rulemaking pending endorsement by a CBE to address reliability and validity concerns, attentiveness to how results are shared and contextualized for public reporting, and encouragement for CMS to examine any differences in reported rates by reporting process (to assess whether they are the same or different across dialysis facilities).[339] Thereafter, the MAP Coordinating Committee deliberated on January 24–25, 2023, and ultimately voted to conditionally support the Screen Positive Rate for Social Drivers of Health measure for rulemaking with the same conditions.[340]

f. Consensus-Based Entity Endorsement

Although section 1881(h)(2)(B)(i) of the Act generally requires that measures specified by the Secretary for the ESRD QIP be endorsed by the entity with a contract under section 1890(a) of the Act, section 1881(h)(2)(B)(ii) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and, therefore, we believe the exception in section 1881(h)(2)(B)(ii) of the Act applies.

g. Public Display

In the proposed rule, we proposed to publicly display the ESRD QIP score and facility-specific rates for the Screen Positive Rate for Social Drivers of Health measure on an annual basis beginning in PY 2027 through our *Care Compare* website at: *https://www.medicare.gov/care-compare/*.

We invited public comment on this proposal. The comments we received and our responses are set forth below. We note that we have addressed comments that broadly referred both the Screening for Social Drivers of Health measure and the Screen Positive Rate for Social Drivers of Health measure in section IV.D.2 of this final rule.

Comment: Several commenters expressed support for the proposed Screen Positive Rate for Social Drivers of Health reporting measure. A few of these commenters noted that the proposed measure would provide facilities with important information regarding a patient's potential HRSNs that often impact patient outcomes. A few commenters expressed support because the measure will help identify patient social risk factors, allowing care providers and community organizations to work together to improve care delivery. One commenter expressed support and noted that the transportation challenges and utility insecurity may be particularly important for dialysis patients.

Response: We thank the commenters for their support. We agree that HRSNs are critical factors that impact patient outcomes, and increased knowledge about patients' HRSNs will help facilities ensure that all of their patients receive the highest quality ESRD care. Further, we agree that collecting these data will incentivize facilities to better recognize whether any of the HRSNs in the screening tool are impacting their patients and take steps to improve access and outcomes.

Comment: One commenter expressed support for the proposal to include the Screen Positive Rate for Social Drivers of Health measure as a reporting measure so that facilities are not scored based on the results of the data which reflect factors beyond the facility's control.

Response: We thank the commenter for its support.

Comment: Several commenters recommended additional changes to the measure specifications to encourage follow up after a positive screening. A few commenters recommended that CMS require the development of action plans to address HRSNs or otherwise add requirements for facilities to follow up with patients on identified HRSNs where appropriate. A few commenters recommended that CMS update the measure to require referral and delivery of identified needed services. If services are not available, one commenter suggested that facilities should be responsible for reporting this to relevant Federal, State, or local agencies authorities. One commenter

[336] Centers for Medicare Medicaid Services. 2022. List of Measures Under Consideration for December 1, 2022. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[337] Centers for Medicare Medicaid Services. 2022. 2022–2023 MAP Preliminary Recommendations, Health Equity Advisory Group. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[338] Centers for Medicare Medicaid Services. 2022. MAP Preliminary Recommendations, Rural Health Advisory Group. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[339] Centers for Medicare Medicaid Services. 2023. 2022–2023 MAP Final Recommendations. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[340] Centers for Medicare Medicaid Services. 2023. 2022–2023 MAP Final Recommendations. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

recommended that CMS consider potential uses for the data captured by this measure and propose these uses in future rulemaking.

Response: We thank the commenters for their recommendations, and may consider them in future rulemaking. We believe this measure has the potential to improve patient outcomes by acknowledging patients' HSRN needs that can contribute to adverse clinical outcomes.

Comment: A few commenters expressed concern that the Screen Positive Rate for Social Drivers of Health reporting measure would disincentivize caring for socially vulnerable patients because facilities serving patient populations with high rates of HRSNs would be unfairly penalized for poor performance on the proposed measure. One commenter expressed concern that the proposed Screen Positive Rate for Social Drivers of Health reporting measure will disadvantage facilities by penalizing them based on the existence of patients with HRSNs, rather than the quality of care provided, and recommended that CMS instead offer supplemental payments to facilities that commit to use these supplemental payments to address HRSNs relevant to their patient population.

Response: We believe that identifying the HRSNs of ESRD patients will be valuable in helping facilities to identify and understand patients' unmet needs, which may encourage improvements in care coordination with outpatient and community resources, and further support development of patient-centered treatment plans. We note that identifying and addressing HRSNs is a critical topic for ESRD patients and that there are high levels of health disparities experienced by this patient population. Although we believe that the proposed measure will not lead to unintended consequences because facilities would not be penalized based on reported screen positive rates, CMS will monitor measure implementation and data reporting as part of standard program and measure review and will consider updates to the measure if improvements are identified through this process. Although we appreciate the commenter's suggestion that CMS offer supplemental payments to facilities to address HRSNs relevant to their patient population, we do not have authority under the ESRD QIP statute to offer the supplemental payments suggested by the commenter.

Comment: A few commenters expressed concern with the proposed Screen Positive Rate for Social Drivers of Health reporting measure, stating that data collected for this measure ultimately would not provide consumers with meaningful information relevant to a facility's quality of care. One commenter noted that publicly reported information would be subject to misinterpretation due to existing biases and preconceptions. A few commenters did not support public reporting because the measure reflects characteristics of the facility's patient population, not the facility's performance or quality of care.

Response: We appreciate the commenters' concerns. The measure provides a means of delivering important healthcare information to facilities, consumers, and patient advocates on the level of unmet HRSNs among a facility's patient population that might be contributing to the clinical outcomes experienced at the facility. We believe that a facility's ability to identify these HRSNs among its patient population should be considered part of the quality of care it provides to its patients. In addition to helping facilities identify these HRSNs among their patient population that could play a factor in clinical outcomes, it also may provide the public with useful information that could be used to improve resources available to patients. We intend to conduct outreach and education with providers and patients to share information about the two Social Drivers of Health measures in conjunction with public reporting.

Comment: A few commenters expressed concern regarding the potential burden associated with the proposed measure. Noting the potential burden to facilities, one commenter recommended that facilities receive adequate support and training to facilitate the data collection efforts associated with such measure prior to the measure's implementation. One commenter expressed concern that the measure adds reporting burden to report data that CMS is already collecting. One commenter expressed concern that the proposed Screen Positive Rate for Social Drivers of Health reporting measure would not benefit small facilities that already have individualized care plans for each of their patients, and that the additional burden from the proposed measure outweighs any potential benefit to patients.

Response: While we understand implementation of HRSN screening processes and reporting of the Screen Positive Rate for Social Drivers of Health reporting measure is associated with some burden, as discussed in section VI.C.3 of this final rule, we believe the benefits outweigh the burden because identifying patients' HRSNs is a critical step towards a facility identifying and understanding how the presence of the screened HRSNs might be impacting patient access to ESRD care and outcomes. We appreciate that facilities may already be collecting relevant data and potentially incorporating it into individualized patient care plans. However, we believe that the proposed Screen Positive Rate for Social Drivers of Health reporting measure is an important step towards health equity by supporting facilities in leveraging available data, pursuing focused quality improvement activities, and promoting efficient and effective use of their resources.

Comment: One commenter expressed concern with the proposed Screen Positive Rate for Social Drivers of Health reporting measure, recommending that CMS further explore potential reliability and validity concerns associated with the measure before it is included in the ESRD QIP.

Response: We appreciate the commenter's concern. We note that the most recent evaluation of the AHC model, which informed the development of these proposed measures, showed that it was effective in screening beneficiaries for HRSNs, identifying eligible beneficiaries, and referring those beneficiaries to HRSN-related navigation services. Although facilities in the ESRD QIP can use a screening tool of their choice, we note that multiple screening tools exist and are publicly available. Facilities could refer to the SIREN website, for example, for comprehensive information about the most widely used HRSN screening tools, including validity assessments where available.[341] We note that CMS also performs validity assessments as part of its annual EQRS data validation. Additionally, CMS will monitor measure implementation and data reporting as part of standard program and measure review and will consider updates to the measure if improvements are identified through this process.

Comment: One commenter requested that CMS provide additional information regarding how the data will be used. Commenter also questioned the intervals for collecting the data.

Response: We believe that the data may be used by facilities to inform actionable planning by helping to enable the development of individual patient action plans for those patients who screen positive (including

[341] Social Interventions Research & Evaluation Network. (2019). Social Needs Screening Tool Comparison Table. Available at: *https://sirenetwork.ucsf.edu/tools-resources/resources/screening-tools-comparison.* Accessed October 24, 2023.

navigation and referral). By helping to identify patients' non-clinical needs that nevertheless greatly contribute to adverse clinical outcomes, the data may be used to link providers with community-based organizations to enhance patient-centered treatment and discharge planning, although such reach out is not required. We also note that there are multiple interested parties who will be able to use data regarding facilities' patient populations, including patients and their caregivers, patient advocacy organizations, local community services organizations, and Federal, State, and local policy makers. We also believe that the measure will facilitate systematic gathering of such data in a manner that provides information to facilities on the level of unmet need among their patients that many facilities do not compile currently. Although facilities are reporting the data to CMS for purposes of the measures at this time, CMS at this time does not plan to use the data for any purposes beyond the public reporting being finalized in this final rule.

Comment: One commenter stated that the equation provided does not match the description of the numerator. The commenter also recommended establishing a baseline period for implementation and data validation prior to public reporting.

Response: In the CY 2024 ESRD PPS proposed rule, we stated that the numerator consisted of eligible patients ''who were screened for an HRSN, and for whom the facility reports the results of a screen asking whether they have a need in one or more of the following five HRSNs (calculated separately): Food insecurity, housing instability, transportation needs, utility difficulties or interpersonal safety.'' (88 FR 42517). However, this statement actually describes the measure cohort, rather than the measure numerator. The measure numerator was correctly described in the equation that we proposed to use for scoring facilities on the measure. Therefore, in this final rule we have updated the description of the numerator to match the equation. The numerator now reads, ''The numerator consists of the number of patients at a dialysis facility who are 18 years or older who are treated at the facility during the applicable performance period and are not eligible to be excluded from the measure, who were screened for all five HRSNs, and who screened positive for one or more of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, or interpersonal safety.'' Regarding the commenter's suggestion to establish a baseline period for implementation and data validation, we note that we are finalizing an updated definition of mTPS in IV.B.1 of this final rule which applies to new reporting measures for which there is an insufficient quantity of data available prior to the first performance period. Under our finalized policy, if there is an insufficient quantity of data available prior to the first performance period of a new reporting measure, we will set a proxy median of zero for the reporting measure until we have sufficient data, which will account for the possibility that new reporting measures may have different reporting requirements. We believe this policy will allow the timely inclusion of new reporting measures in the ESRD QIP measure set while also encouraging facilities to report the new or additional data that may be specified by that reporting measure so that they are able to receive credit for reporting. We also believe that by delaying the implementation of these measures until PY 2027 will give facilities ample time to ensure the validity of their data. CMS also performs validity assessments as part of its annual EQRS data validation.

Final Rule Action: After considering public comments, we are finalizing our proposal to adopt the Screen Positive Rate for Social Drivers of Health reporting measure.

4. Performance Period for the PY 2027 ESRD QIP

We continue to believe that our current policy of 12-month performance and baseline periods provide us sufficiently reliable quality measure data for the ESRD QIP. Under this policy, we will adopt CY 2025 as the performance period and CY 2023 as the baseline period for the PY 2027 ESRD QIP.

We did not propose any changes to this policy. We addressed comments and finalized our proposals to apply this performance period to the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure in sections IV.D.2 and IV.D.3 of this final rule.

5. Performance Standards for the PY 2027 ESRD QIP

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as determined appropriate by the Secretary, and must be established prior to the beginning of the performance period for the year involved, as required by section 1881(h)(4)(C) of the Act. We refer readers to the CY 2012 ESRD PPS final rule (76 FR 70277) for a discussion of the achievement and improvement standards that we have established for clinical measures used in the ESRD QIP. We define the terms ''achievement threshold,'' ''benchmark,'' ''improvement threshold,'' and ''performance standard'' in our regulations at § 413.178(a)(1), (3), (7), and (12), respectively. For reporting measures, performance standards are the levels of data submission and completion of other actions specified by CMS that are used to award points to an ESRD facility on the measure (§ 413.178(a)(12)).

a. Performance Standards for Clinical Measures in the PY 2027 ESRD QIP

In the CY 2024 ESRD PPS proposed rule, we erroneously stated that at that time, we did not have the necessary data to assign numerical values to the achievement thresholds, benchmarks, and 50th percentiles of national performance for the clinical measures because we did not have CY 2022 data, and stated our intention to publish these numerical values, using CY 2022 data, in the CY 2024 ESRD PPS final rule (88 FR 42518). We intended to refer to CY 2023 data in the proposed rule, rather than CY 2022 data. Because we do not have CY 2023 data at this time, we are clarifying in this final rule that we will publish these numerical values, using CY 2023 data, in the CY 2025 ESRD PPS final rule.

b. Performance Standards for the Newly Finalized Reporting Measures Beginning With the PY 2027 ESRD QIP

In this final rule, we are finalizing our proposals to add the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure beginning with the PY 2027 ESRD QIP, which we discuss in IV.D.2 and IV.D.3 of this final rule. We are finalizing a 12-month period of performance for both the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure, and facilities will be required to report annually for both measures beginning with the PY 2027 ESRD QIP.

6. Scoring the PY 2027 ESRD QIP

a. Scoring Facility Performance on Clinical Measures

In the CY 2014 ESRD PPS final rule, we finalized policies for scoring

performance on clinical measures based on achievement and improvement (78 FR 72215 through 72216). In the CY 2019 ESRD PPS final rule, we finalized a policy to continue use of this methodology for future payment years (83 FR 57011) and we codified these scoring policies at § 413.178(e). In the CY 2023 ESRD PPS final rule, we updated our scoring methodology beginning with PY 2025 (87 FR 67251 through 67254).

b. Scoring Facility Performance on Reporting Measures

Our policy for scoring performance on reporting measures is codified at § 413.178(e). In section IV.D.2 of this final rule, we are finalizing our proposal to adopt the Screening for Social Drivers of Health reporting measure beginning with PY 2027. We are also finalizing our proposal to adopt the Screen Positive Rate for Social Drivers of Health reporting measure, as discussed in section IV.D.3 of this final rule. As discussed above, we are finalizing in this final rule that a facility will be scored based on the equations described in sections IV.D.2.c and IV.D.3.c of this final rule. We are adopting a 12-month period of performance for the measures, and facilities will be required to report annually. We believe that these scoring policies will encourage facilities to report the measure data appropriately without penalizing facilities for the results of such data, which may be impacted by circumstances beyond a facility's control.

7. Revisions To Measure Domains and To Measure Weights Used To Calculate the Total Performance Score (TPS) Beginning With the PY 2027 ESRD QIP

In the CY 2024 ESRD PPS proposed rule, beginning with PY 2027, we proposed to add the Screening for Social Drivers of Health reporting measure and the Screen Positive for Social Drivers of Health reporting measure to the Reporting Measure Domain (88 FR 42519). To accommodate the new number of measures in the Reporting Measure Domain, we proposed to update the individual measure weights in this domain. We stated our belief that these proposed updates would help to ensure that a facility's individual measure performance has an appropriately proportionate impact on a facility's TPS, while also continuing to further incentivize improvement on clinical measures through those individual measure weights. Consistent with our approach in the CY 2023 ESRD PPS final rule, we proposed to assign individual measure weights to reflect the proposed updated number of measures in the Reporting Measure Domain so that each measure is weighted equally (87 FR 67251 through 67253). Since we proposed to add two new measures to the Reporting Measure Domain beginning with PY 2027, we stated that we would weight each measure within that domain equally at approximately 1.43 percent, which is consistent with our previously finalized approach to weight each measure in the Reporting Measure Domain equally. We noted that although we proposed to change the number of measures in the Reporting Measure Domain and weights of certain individual measures in that domain, we did not propose to change the weights of the five domains themselves, because we believe the proposed updates to individual measures and measure weights did not significantly impact the measure domains themselves such that updating the weights of the measure domains would be required to accommodate the updated individual measure weights. The previously finalized and newly proposed measures that would be included in each domain, along with the proposed new measure weights, beginning with PY 2027, were depicted in Table 22 of the proposed rule (88 FR 42520).

We welcomed public comment on these proposals. The comments we received and our responses are set forth below.

Comment: One commenter recommended that the ESRD QIP measure set be streamlined to focus more weight on clinically meaningful measures.

Response: We agree with the commenter that the weights should reflect clinical value and meaningfulness to patients, which we took into account in developing our measure domains and individual measure weights. We believe that the measure domains and weights will provide facilities with meaningful incentives to improve their performance on measures that are impactful in terms of both clinical value and importance to patients. We note that we have developed the ESRD QIP measure set specifically to ensure that facilities focus on the most relevant clinical topics that will lead to improved quality of care and better outcomes for patients.

Comment: One commenter expressed concern that with the large number of program measures, the reporting measures' weight is disproportionately small compared to the effort to operationalize associated processes, and recommended collaboration with the kidney care community to identify appropriate measures and weights.

Response: We note that the weight of a given measure domain takes into account a number of factors, including clinical evidence, opportunity for improvement, clinical significance, and patient and provider burden (83 FR 56995 through 56996). We also consider (1) the number of measures and measure topics in a domain; (2) how much experience facilities have had with the measures and measure topics in a domain; and (3) how well the measures align with CMS's highest priorities for quality improvement for patients with ESRD (79 FR 66214). We assign weights to the measure domains based on the clinical value and meaningfulness of the measures to patients, and the burden of complying with individual measure requirements. Having taken all of these factors into consideration, we believe that the Reporting Measure Domain weights are appropriate to support high quality health care on all ESRD QIP measures.

Final Rule Action: After considering public comments, we are finalizing our proposals as proposed. As we discussed previously, we are finalizing our proposals to update the measure domains and measure weights beginning with the PY 2027 ESRD QIP as proposed, and therefore provide the updated ESRD QIP measure domains and measure weights in Table 23.

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TABLE 23: Newly Finalized ESRD QIP Measure Domains and Weights Beginning with PY 2027

Measures by Domain	Measure Weight as Percent of TPS
Patient and Family Engagement Measure Domain	**15.00**
ICH CAHPS measure	15.00
Care Coordination Measure Domain	**30.00**
SHR clinical measure	7.50
SRR clinical measure	7.50
PPPW measure	7.50
Clinical Depression Screening and Follow-Up measure*	7.50
Clinical Care Measure Domain	**35.00**
Kt/V Dialysis Adequacy Comprehensive Measure	11.00
Long-Term Catheter Rate clinical measure	12.00
STrR clinical measure	12.00
Safety Measure Domain	**10.00**
NHSN BSI clinical measure	10.00
Reporting Measure Domain	**10.00**
Screening for Social Drivers of Health measure**	1.43
Screen Positive Rate for Social Drivers of Health reporting measure***	1.43
Facility Commitment to Health Equity reporting measure****	1.43
Hypercalcemia reporting measure	1.43
MedRec reporting measure	1.43
NHSN Dialysis Event reporting measure	1.43
COVID-19 HCP Vaccination reporting measure	1.43

*We are finalizing our proposal to convert the Clinical Depression Screening and Follow-Up measure beginning with PY 2026, as discussed in section IV.C.4 of this final rule.
**We are finalizing our proposal to add the Screening for Social Drivers of Health measure beginning with PY 2027, as discussed in section IV.D.2 of this final rule.
***We are finalizing our proposal to add the Screen Positive Rate for Social Drivers of Health reporting measure beginning with PY 2027, as discussed in section IV.D.3 of this final rule.
****We are finalizing our proposal to add the Facility Commitment to Health Equity reporting measure beginning with PY 2026, as discussed in section IV.C.2 of this final rule.

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V. End-Stage Renal Disease Treatment Choices (ETC) Model

A. Background

Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and Children's Health Insurance Program (CHIP) expenditures while preserving or enhancing the quality of care furnished to the beneficiaries of these programs. The purpose of the ETC Model is to test the effectiveness of adjusting certain Medicare payments to ESRD facilities and Managing Clinicians to encourage greater utilization of home dialysis and kidney transplantation, support Beneficiary modality choice, reduce Medicare expenditures, and preserve or enhance the quality of care. As described in the Specialty Care Models final rule (85 FR 61114), beneficiaries with ESRD are among the most medically fragile and high-cost populations served by the Medicare program. ESRD Beneficiaries require dialysis or kidney transplantation to survive, and the majority of ESRD Beneficiaries receiving dialysis receive hemodialysis in an ESRD facility. However, as described in the Specialty Care Models final rule, alternative renal replacement modalities to in-center hemodialysis, including home dialysis and kidney transplantation, are associated with improved clinical outcomes, better quality of life, and lower costs than in-center hemodialysis (85 FR 61264).

The ETC Model is a mandatory payment model. ESRD facilities and Managing Clinicians are selected as ETC Participants based on their location in Selected Geographic Areas—a set of 30 percent of Hospital Referral Regions (HRRs) that have been randomly selected to be included in the ETC Model, as well as HRRs with at least 20 percent of ZIP codes™ located in Maryland.[342] CMS excludes all U.S.

[342] ZIP code™ is a trademark of the United States Postal Service.

Territories from the Selected Geographic Areas.

Under the ETC Model, ETC Participants are subject to two payment adjustments. The first is the Home Dialysis Payment Adjustment (HDPA), which is an upward adjustment on certain payments made to participating ESRD facilities under the ESRD Prospective Payment System (PPS) on home dialysis claims, and an upward adjustment to the Monthly Capitation Payment (MCP) paid to participating Managing Clinicians on home dialysis-related claims. The HDPA applies to claims with claim service dates beginning January 1, 2021 and ending December 31, 2023.

The second payment adjustment under the ETC Model is the Performance Payment Adjustment (PPA). For the PPA, we assess ETC Participants' home dialysis rates and transplant rates during a Measurement Year (MY), which includes 12 months of performance data. Each MY has a corresponding PPA Period—a 6-month period that begins 6 months after the conclusion of the MY. We adjust certain payments for ETC Participants during the PPA Period based on the ETC Participant's home dialysis rate and transplant rate, calculated as the sum of the transplant waitlist rate and the living donor transplant rate, during the corresponding MY.

Based on an ETC Participant's achievement in relation to benchmarks based on the home dialysis rate and transplant rate observed in Comparison Geographic Areas during the Benchmark Year, and the ETC Participant's improvement in relation to their own home dialysis rate and transplant rate during the Benchmark Year, we would make an upward or downward adjustment to certain payments to the ETC Participant. The magnitude of the positive and negative PPAs for ETC Participants increases over the course of the Model. These PPAs apply to claims with claim service dates beginning July 1, 2022 and ending June 30, 2027.

In the CY 2022 ESRD PPS final rule, we finalized a number of changes to the ETC Model. We made adjustments to the calculation of the home dialysis rate (86 FR 61951 through 61955) and the transplant rate (86 FR 61955 through 61959) and updated the methodology for attributing Pre-emptive Living Donor Transplant (LDT) Beneficiaries (86 FR 61950 through 61951). We modified the achievement benchmarking and scoring methodology (86 FR 61959 through 61968), as well as the improvement benchmarking and scoring methodology (86 FR 61968 through 61971). We specified the method and requirements for sharing performance data with ETC Participants (86 FR 61971 through 61984). We also made a number of updates and clarifications to the kidney disease patient education services waivers and made certain related flexibilities available to ETC Participants (86 FR 61984 through 61994). In the CY 2023 ESRD PPS final rule (87 FR 67136) we finalized further changes to the ETC Model. We updated the PPA achievement scoring methodology beginning in the fifth Measurement Year (MY) of the ETC Model, which began on January 1, 2023 (87 FR 67277 through 67278). We also clarified requirements for qualified staff to furnish and bill kidney disease patient education services under the ETC Model's Medicare program waivers (87 FR 67278 through 67280), and finalized our intent to publish participant-level model performance information to the public (87 FR 67280).

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the ETC Model

The CY 2024 ESRD PPS proposed rule appeared in the June 30, 2023, version of the **Federal Register**, with a comment period that ended on August 25, 2023. In that proposed rule, we proposed to modify the ETC Model, effective January 1, 2024, to acknowledge the availability of administrative review of targeted review requests. We received five timely public comments on our proposal, including comments from dialysis organizations and national provider and quality improvement organizations. We also received comments related to issues that we did not discuss in the CY 2024 ESRD PPS proposed rule. These include, for example, general expressions of support for the ETC Model, concerns regarding CMS's methodology for ETC Participant selection and aggregation group construction, a recommendation that CMS develop a tool to measure the experience of Beneficiaries using home modalities, and recommendations regarding the format in which CMS posts ETC Model results. While we generally are not addressing those comments in this final rule, we thank commenters for their input and may consider their recommendations in future rulemaking. In this final rule, we provide a summary the proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the ETC Model. These policies take effect January 1, 2024.

In the Specialty Care Models final rule (85 FR 61114), we established our policies for targeted reviews of the calculation of an ETC Participant's Modality Performance Score (MPS). As described in § 512.390(c), targeted reviews are limited to the calculation of the MPS and may not pertain to the methodologies used to calculate the MPS, home dialysis rate, transplant rates, achievement and improvement benchmarks, or the PPA amounts. ETC Participants have 90 days following the availability of the MPS to submit a targeted review request. CMS responds to each targeted review request that is received within the 90-day time period. CMS may solicit additional information from the ETC Participant in support of the request after which a determination is made as to whether there was an error in the calculation of the ETC Participant's MPS that results in an incorrect PPA being applied during the PPA period. In such a scenario, CMS notifies the ETC Participant and resolves any resulting discrepancy in payment that arises from the application of an incorrect PPA.

In the CY 2024 ESRD PPS proposed rule, we proposed revisions to our regulations at § 512.390 to clarify the ability of the CMS Administrator to review targeted review determinations. In particular, we proposed to add § 512.390(d) to specify that the CMS Administrator may review targeted review requests when administrative review is requested by ETC Participants within 15-calendar days of a targeted review request determination made by CMS.

We proposed that within 45 days of the date of the ETC Participant's request for administrative review, the CMS Administrator may act as follows: (i) decline to review the targeted review request determination made by CMS, (ii) render a final decision based on the CMS Administrator's review of the targeted review request determination, or (iii) choose to take no action on the request for administrative review. We proposed that targeted review request determinations made by the CMS Administrator are considered final if the CMS Administrator declines an ETC Participant's request for administrative review or if the CMS Administrator does not take any action on the ETC Participant's request for administrative review by the end of the 45-day period described.

We also proposed a conforming change to delete the existing provision in § 512.390(c)(5), which states that decisions based on targeted review are final, and there is no further review or appeal.

These changes were proposed to ensure that accountability for the decisions of CMS is vested in a

principal officer and to bring the targeted review process to a more similar posture as other CMS appeals entities that provide for CMS Administrator review. These revisions were also proposed to ensure that ETC Participants are aware that administrative review is available to ETC Participants who wish to seek additional review of the results of a targeted review request.

We solicited comment on this proposal.

Comment: We received five in scope comments timely submitted. All five comments were supportive of our proposed administrative review policy. One provider organization wrote that the proposed policy would increase awareness of the availability of administrative review among ETC Participants. A dialysis organization wrote that the proposed policy would increase transparency and accountability for targeted review determinations made by CMS. A kidney care coalition also noted the proposed policy would support awareness, transparency, and accountability.

Response: We thank the commenters for their support of our proposed administrative review policy.

Final Rule Action: We are finalizing our proposed modifications to the ETC Model regulations at § 512.390 to clarify the ability of the CMS Administrator to review targeted review determinations. We are adding § 512.390(d) to specify that the CMS Administrator may review targeted review requests when administrative review is requested by ETC Participants within 15-calendar days of a targeted review request determination made by CMS.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to OMB for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues.

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

A. ICRs Regarding the JW and JZ Reporting Requirements; Reporting Policy for Discarded Amounts of Renal Dialysis Drugs and Biological Products Paid for Under the ESRD PPS, Section II.B.1.h (OMB Control Number 0938–0997)

As discussed in section II.B.1.h of this final rule, we are finalizing a requirement that beginning January 1, 2025, ESRD facilities must report information on claims about the total number of billing units of any discarded amount of a renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS, using the JW modifier (or any successor modifier that includes the same data). Additionally, we are finalizing a requirement that ESRD facilities report the JZ modifier for all such drugs and biological products with no discarded amounts beginning no later than January 1, 2025. Based on our analysis of ESRD PPS claims as well as the billing guidance in sections 8 and 17 of the Medicare Claims Processing Manual, we have determined that the JW modifier requirement reflects current practices for ESRD facilities and would not significantly increase burden for ESRD facilities. Additionally, the JZ modifier requirement is not expected to increase burden on ESRD facilities because under the guidance provided regarding use of the JW modifier, the ESRD facility should already have processes in place in order to determine, in the case of certain drugs and biological products, whether or not there are any discarded units from a single use container or package, record discarded amounts in the patient medical record, and specify administered and discarded amounts on the claim form. Additionally, as discussed in section II.B.1.h of this final rule, any separately payable drugs or biological products that ESRD facilities bill for using the AY modifier would already be subject to the JW and JZ modifier policies under Medicare Part B. Although we recognize that ESRD facilities may need additional time to train staff and update their systems in order to apply existing processes to a broader scope of renal dialysis drugs and biological products, we continue to anticipate that most ESRD facilities should already be set up to report the JW and JZ modifiers without incurring additional burden.

B. ICRs Regarding the Proposal to Require Time on Machine Data as a Recordkeeping and Cost Reporting Requirement for Outpatient Maintenance Dialysis; Section II.B.1.j (OMB Control Numbers 0938–0997)

We are finalizing a requirement that ESRD facilities submit data and information on ESRD PPS claims regarding the number of minutes between the start and end of hemodialysis treatment, without accounting for any interruptions, received by a beneficiary in center in an ESRD facility effective January 1, 2025. We have developed monetary estimates of the amount of ESRD facility staff time required to calculate and report on claims the minutes of time on machine for each in-center hemodialysis treatment to estimate the cost associated with the finalized requirement to report time on machine data. We have included those estimates in the Regulatory Impact Analysis in section VII.D.2.a of this final rule. We acknowledge the burden associated with this requirement, but we note that the burden associated with the CMS–1450 institutional claim form already accounts for the variability in the number and type of codes submitted for each claim.

C. Additional Information Collection Requirements

1. ESRD QIP—Wage Estimates (OMB Control Numbers 0938–1289 and 0938–1340)

To derive wages estimates, we used data from the U.S. Bureau of Labor Statistics' May 2021 National Occupational Employment and Wage Estimates. In the CY 2016 ESRD PPS final rule (80 FR 69069), we stated that it was reasonable to assume that Medical Records and Health Information Technicians, who are responsible for organizing and managing health information data, are the individuals tasked with submitting measure data to the ESRD Quality Reporting System (EQRS) (formerly, CROWNWeb) and the CDC's NHSN, as well as compiling and submitting patient records for the purpose of data validation studies. In the proposed rule, we stated that the most recently available median hourly wage of a Medical Records Specialist is $22.43 per hour (88 FR 42522).[343] In this final rule, we are updating the median hourly wage to $22.69 per hour, which reflects

[343] *https://www.bls.gov/oes/2021/may/oes292072.htm.* Accessed on January 3, 2023.

the most recently available data.[344] We also calculate fringe benefit and overhead at 100 percent. We adjusted these employee hourly wage estimates by a factor of 100 percent to reflect current HHS department-wide guidance on estimating the cost of fringe benefits and overhead. These are necessarily rough adjustments, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative, and we believe that these are reasonable estimation methods. Therefore, using these assumptions, in the proposed rule we estimated an hourly labor cost of $44.86 as the basis of the wage estimates for all collections of information calculations in the ESRD QIP (88 FR 42522). In this final rule, we are updating our previously estimated hourly labor cost to $45.38 as the basis of the wage estimates for all collections of information calculations in the ESRD QIP.

We used this updated wage estimate, along with updated facility and patient counts, to update our estimate for the total information collection burden in the ESRD QIP for PY 2026 that we discussed in the CY 2024 ESRD PPS proposed rule (88 FR 42522 through 42523) and to estimate the total information collection burden in the ESRD QIP for PY 2027. We provide the re-estimated information collection burden associated with the PY 2026 ESRD QIP and the newly estimated information collection burden associated with the PY 2027 ESRD QIP in section VII.C.3 of this final rule.

2. Estimated Burden Associated With The Data Validation Requirements for PY 2026 and PY 2027 (OMB Control Numbers 0938–1289 and 0938–1340)

In the CY 2020 ESRD PPS final rule, we finalized a policy to adopt the EQRS (formerly, CROWNWeb) data validation methodology that we previously adopted for the PY 2016 ESRD QIP as the methodology we would use to validate EQRS data for all payment years, beginning with PY 2021 (83 FR 57001 through 57002). Under this methodology, 300 facilities are selected each year to submit 10 records to CMS, and we reimburse these facilities for the costs associated with copying and mailing the requested records. The burden associated with these validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. In this final rule, we are updating these burden estimates using a newly available wage estimate of a Medical Records Specialist. In the CY 2020 ESRD PPS final rule, we estimated that it would take each facility approximately 2.5 hours to comply with this requirement (84 FR 60787). If 300 facilities are requested to submit records, we estimated that the total combined annual burden for these facilities would be 750 hours (300 facilities × 2.5 hours). Since we anticipate that Medical Records Specialists or similar administrative staff would submit these data, we estimate that the aggregate cost of the EQRS data validation each year would be approximately $34,035 (750 hours × $45.38), or an annual total of approximately $113.45 ($34,035/300 facilities) per facility in the sample. The burden cost increase associated with these requirements will be submitted to OMB in the revised information collection request (OMB control number 0938–1289; Expiration date: November 30, 2025).

In the CY 2021 ESRD PPS final rule, we finalized our policy to reduce the number of records that a facility selected to participate in the NHSN data validation must submit to a CMS contractor, beginning with PY 2023 (85 FR 71471 through 71472). Under this finalized policy, a facility is required to submit records for 20 patients across any two quarters of the year, instead of 20 records for each of the first two quarters of the year. The burden associated with this policy is the time and effort necessary to submit the requested records to a CMS contractor. Applying this policy for NHSN validation, we estimated that it would take each facility approximately 5 hours to comply with this requirement. If 300 facilities are requested to submit records each year, we estimated that the total combined annual burden hours for these facilities per year would be 1,500 hours (300 facilities × 5 hours). Since we anticipate that Medical Records Specialists or similar staff would submit these data, using the newly available wage estimate of a Medical Records Specialist, we estimate that the aggregate cost of the NHSN data validation each year would be approximately $68,070 (1,500 hours × $45.38), or a total of approximately $226.90 ($68,070/300 facilities) per facility in the sample. While the burden hours estimate would not change, the burden cost updates associated with these requirements will be submitted to OMB in the revised information collection request (OMB control number 0938–1340; Expiration date: November 30, 2025).

3. Estimated EQRS Reporting Requirements for PY 2026 and PY 2027 (OMB Control Number 0938–1289)

To estimate the burden associated with the EQRS reporting requirements (previously known as the CROWNWeb reporting requirements), we look at the total number of patients nationally, the number of data elements per patient-year that the facility would be required to submit to EQRS for each measure, the amount of time required for data entry, the estimated wage plus benefits applicable to the individuals within facilities who are most likely to be entering data into EQRS, and the number of facilities submitting data to EQRS. In the CY 2023 ESRD PPS final rule, we estimated that the burden associated with EQRS reporting requirements for the PY 2026 ESRD QIP was approximately $220 million for approximately 4,908,291 total burden hours (87 FR 67282).

We are finalizing several changes to the ESRD QIP measure set in this final rule that will affect the burden associated with EQRS reporting requirements for PY 2026 or PY 2027. Beginning with PY 2026, we are removing two measures from the ESRD QIP measure set and adding one measure to the ESRD QIP measure set. We note that, although the finalized measure we are adding to the ESRD QIP measure set beginning with PY 2026 is modified from the version of the measure that was proposed, the estimated burden associated with the measure will not change because the modification will not impose additional EQRS reporting requirements on facilities. For PY 2027 and for subsequent years, we are adding two measures to the ESRD QIP measure set. We have re-calculated the burden estimate for PY 2026 to reflect the impact of these finalized policies, using updated estimates of the total number of ESRD facilities, the total number of patients nationally, and wages for Medical Records Specialists or similar staff, as well as a refined estimate of the number of hours needed to complete data entry for EQRS reporting. In the CY 2024 ESRD PPS proposed rule, we estimated that the amount of time required to submit measure data to EQRS would be 2.5 minutes per element and did not use a rounded estimate of the time needed to complete data entry for EQRS reporting (88 FR 42523). We are further updating these estimates in this final rule. There are 126 data elements for 507,837 patients across 7,833 facilities, for a total of 63,987,462

[344] *https://www.bls.gov/oes/current/oes292072.htm.* Accessed on July 18, 2023.

elements (126 data elements × 507,837 patients). At 2.5 minutes per element, this would yield approximately 340.3 hours per facility. Therefore, the PY 2026 burden would be 2,666,144 hours (340.3 hours × 7,833 facilities). Using the wage estimate of a Medical Records Specialist, we estimate that the PY 2026 total burden cost is approximately $120.9 million (2,666,144 hours × $45.38).

There would also be an incremental burden change from PY 2026 to PY 2027 because we are adding two new measures beginning with PY 2027. For PY 2027, there are 136 data elements proposed for 507,837 patients across 7,833 facilities. At 2.5 minutes per element, this would yield approximately 367.3 hours per facility. Therefore, the PY 2027 burden would be 2,877,743 hours (367.3 hours × 7,833 facilities). Using the wage estimate of a Medical Records Specialist, we estimate that the PY 2027 total burden cost would be approximately $130.5 million (2,877,743 hours × $45.38).

We received two comments on the ESRD QIP collection of information discussions. The comments we received and our response is set forth below.

Comment: One commenter stated that because CMS is estimating an increase in facility burden for both PY 2026 and PY 2027, CMS should limit data collection and reporting under the ESRD QIP to those measures that are absolutely necessary to ensure that facilities can spend the maximum time, effort and resources on caring for patients. A second commenter expressed concern that $131 million dollars of increased burden is not sustainable.

Response: We note that we have developed the ESRD QIP measure set specifically to ensure that facilities focus on the most relevant clinical topics that will lead to improved quality of care and better outcomes for patients. We appreciate the commenter's concern regarding the estimated burden for PY 2027, but note that the net increase in burden from PY 2026 (approximately $120.9 million) to PY 2027 (approximately $130.5 million) is estimated to be less than $10 million. By contrast, the estimated burden for PY 2026 is approximately $100 million less than the estimated burden for PY 2025, which is approximately $220 million (87 FR 67282).

If you comment on these information collection, that is, reporting, recordkeeping or third-party disclosure requirements, submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS–1782–F

Fax: (202) 395–6974; or

Email: OIRA_submission@omb.eop.gov.

VII. Regulatory Impact Analysis

A. Statement of Need

1. ESRD PPS

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Affordable Care Act (Pub. L. 111–148), established that beginning CY 2012, and each subsequent year, the Secretary shall annually increase payment amounts by an ESRD market basket percentage increase, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This final rule implements updates and policy changes to the CY 2024 ESRD wage index values, the final combined wage index and TPEAPA budget-neutrality adjustment factor, the outlier payment threshold amounts, and the TPNIES offset amount. Failure to publish this final rule would result in ESRD facilities not receiving appropriate payments in CY 2024 for renal dialysis services furnished to ESRD beneficiaries.

This rule also has several policy changes to improve payment stability and adequacy under the ESRD PPS. These include a new transitional add-on payment adjustment for pediatric patients and a new add-on payment adjustment for certain new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the end of the TDAPA period. We are also finalizing updates to the administrative process for the LVPA, requiring ESRD facilities to report on claims billing units of any discarded amounts of certain drugs and biological products, and requiring ESRD facilities to report ''time on machine'' data on ESRD PPS claims for all in-center hemodialysis treatments. We believe that each of these changes will improve payment stability and adequacy under the ESRD PPS.

2. AKI

This final rule finalizes updates to the payment rate for renal dialysis services furnished by ESRD facilities to individuals with AKI. As discussed in section III.B of this final rule, we are also applying to all AKI dialysis payments the updates to the ESRD PPS base rate and wage index. Failure to publish this final rule would result in ESRD facilities not receiving appropriate payments in CY 2024 for renal dialysis services furnished to patients with AKI in accordance with section 1834(r) of the Act.

3. ESRD QIP

Section 1881(h)(1) of the Act requires CMS to reduce the payments otherwise made to a facility under the ESRD PPS by up to two percent if the facility does not satisfy the requirements of the ESRD QIP for that year. This final rule finalizes updates for the ESRD QIP, including removing the Ultrafiltration Rate reporting measure from the ESRD QIP measure set beginning with PY 2026, removing the Standardized Fistula Rate clinical measure from the ESRD QIP measure set beginning with PY 2026, updating the COVID–19 Vaccination Coverage Among HCP beginning with PY 2026, converting the Clinical Depression Screening and Follow-Up reporting measure to a clinical measure beginning with PY 2026, and adding the Facility Commitment to Health Equity reporting measure to the ESRD QIP measure set beginning with PY 2026. This final rule also finalizes the adoption of the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure to the ESRD QIP measure set beginning with PY 2027.

4. ETC Model

We believe it is necessary to make certain changes to the ETC Model to acknowledge the availability of administrative review of targeted review requests. The policy we are finalizing in this rule is necessary to provide transparency to ETC Participants regarding the avenue available to them should they wish to seek additional review of the results of a targeted review request determination.

B. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 entitled ''Modernizing Regulatory Review'' (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive

Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2))

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 14094 entitled ''Modernizing Regulatory Review'' (hereinafter, the Modernizing E.O.) amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year (adjusted every 3 years for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or Tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) of Executive Order 12866 ($200 million or more in any 1 year). Based on our estimates of the combined impact of the ESRD PPS, ESRD QIP, and ETC provisions in this final rule, OMB has determined this rulemaking is significant per section 3(f)(1) economic effect as measured by the $200 million or more in any 1 year threshold, and hence is also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. Therefore, OMB has reviewed this final rule, and the Department has provided the following assessment of its impact.

C. Impact Analysis

1. ESRD PPS

We estimate that the revisions to the ESRD PPS will result in an increase of approximately $190 million in Medicare payments to ESRD facilities in CY 2024, which includes the amount associated with updates to the outlier thresholds, payment rate update, updates to the wage index, the budget-neutral transitional pediatric ESRD add-on payment adjustment, the beginning of the post-TDAPA add-on payment adjustment, and continuation of the approved TDAPA as identified in Table 11. We note that approximately $10 million in projected CY 2024 expenditures for Jesduvroq (daprodustat) are not included in the detailed economic analysis in Table 24 due to the fact that we do not yet have the required claims data for Jesduvroq, and therefore we cannot estimate impacts at the facility level.

2. AKI

We estimate that the updates to the AKI payment rate will result in an increase of approximately $1 million in Medicare payments to ESRD facilities in CY 2024.

3. ESRD QIP

We estimate that the updates to the ESRD QIP will result in $16 million in estimated payment reductions across all facilities for PY 2026.

4. ETC Model

We estimate that the changes to the ETC Model will not impact the Model's projected direct savings from payment adjustments alone. As described in the CY 2023 ESRD PPS final rule, we estimate that the Model would generate $28 million in direct savings related to payment adjustments over 6.5 years (87 FR 67297 through 67299).

5. Summary of Impacts

We estimate that the combined impact of the policies finalized in this rule on payments for CY 2024 is $190 million based on the estimates of the updates to the ESRD PPS and the AKI payment rates, as well as $10 million in projected new TDAPA spending in CY 2024. We estimate an additional $12 million in costs associated with the final policy to require ESRD facilities to report time on machine data. We estimate the impacts of the ESRD QIP for PY 2026 to be $120.9 million in information collection burden and $16 million in estimated payment reductions across all facilities. Additionally, we estimate the impacts of the ESRD QIP for PY 2027 to be $130.5 million in information collection burden and $13.8 million in estimated payment reductions across all facilities. Finally, we estimate that the changes to the ETC model in this final rule will not impact the Model's projected direct savings from payment adjustments alone.

D. Detailed Economic Analysis

In this section, we discuss the anticipated benefits, costs, and transfers associated with the changes in this final rule. Additionally, we estimate the total regulatory review costs associated with reading and interpreting this final rule.

1. Benefits

Under the CY 2024 ESRD PPS and AKI payment, ESRD facilities will continue to receive payment for renal dialysis services furnished to Medicare beneficiaries under a case-mix adjusted PPS. We continue to expect that making prospective Medicare payments to ESRD facilities will enhance the efficiency of the Medicare program. Additionally, we expect that updating the Medicare ESRD PPS base rate and rate for AKI treatments furnished at ESRD facilities by 2.1 percent based on the CY 2024 ESRDB market basket percentage increase reduced by the CY 2024 productivity adjustment will improve or maintain beneficiary access to high quality care by ensuring that payment rates reflect the best available data on the resources involved in delivering renal dialysis services. We estimate that overall payments under the ESRD PPS will increase by 2.1 percent.

2. Costs

a. ESRD PPS and AKI

As discussed in section II.B.1.j of this final rule, we are finalizing a requirement for ESRD facilities to submit data and information on ESRD PPS claims for renal dialysis services regarding the number of minutes of hemodialysis treatment received by a beneficiary in center in an ESRD facility. This patient-level reporting on resource use will be used to apportion composite rate costs for use in the case-mix adjustment under the ESRD PPS. We estimate that there will be an increase in costs for ESRD facilities associated with this final reporting requirement; however, as we previously noted in the CY 2020 ESRD PPS proposed rule (84 FR 38396 through 38400), we are aware that many ESRD facilities' EHR systems automatically collect this information for every dialysis treatment, minimizing the additional burden of reporting this metric on claims. However, commenters identified that there are additional burdens associated with transmitting

that information from the medical records to the billing system, as many ESRD facilities do not have such processes in place. Therefore, we are updating our burden estimate to include the burden associated with this step in the process.

For those ESRD facilities that use EHRs, we estimate that there will be only very minimal additional staff time required to record such time on machine data on the patient's medical records for renal dialysis services. For those ESRD facilities that do not use EHRs, we estimate that additional staff time will be required to take note of the time at which hemodialysis began and the time at which hemodialysis ended and subtract the start time from the end time to determine the total number of minutes of hemodialysis. Conservatively, we estimate this will require no more than 1 minute per treatment.

For all ESRD facilities, we estimate that additional staff time will be required to compile time on machine data for each patient each month and enter it into the billing system to be submitted. Conservatively, we estimate that this will require no more than 5 minutes per patient month.

To calculate the annual additional ESRD facility staff time that will be associated with recording time on machine data on ESRD PPS claims for renal dialysis services, we multiply the estimated time per treatment by the number of dialysis treatments. Based on the most recent available CY 2022 ESRD PPS claims for this final rule, we estimate there were approximately 30.6 million treatments. However, as discussed in section II.B.1.j, we proposed to limit this reporting requirement to in-center claims. We estimated that approximately 14.8 percent of claims are for home dialysis, and therefore we reduce our estimate of the total number of treatments by 14.8 percent. Additionally, we believe it is reasonable to assume that LDOs will utilize existing systems and processes to document treatment duration in the EHR and send that information to the claim. Based on the latest available data as shown in Table 24, approximately 78.4 percent of treatments were furnished by LDOs. Therefore, we estimate that the additional costs associated with this time on machine reporting requirement will be associated with approximately 5.6 million in-center, non-LDO dialysis treatments per year.

Additionally, ESRD facilities already report time on machine data monthly in the EQRS for a single dialysis session. This means that for a patient who receives 156 dialysis treatments per year, the duration of twelve of those sessions would already be reported in the EQRS. We do not believe there will be any additional staff time required to report time on machine data on ESRD PPS claims for the treatments already reported in EQRS. Therefore, we estimate that the additional staff time that will be needed for reporting time on machine will be for 144 out of 156 treatments per year for the typical patient. For our cost estimate, we multiplied our estimate of 5.6 million in-center dialysis treatments by a factor of (144/156), which equals approximately 5.2 million treatments per year.

To calculate the annual additional ESRD facility staff time that will be associated with calculating and reporting time on machine data on ESRD PPS claims for renal dialysis services, we multiply the estimated time per patient month by the number of dialysis patient months. Based on the most recent available ESRD PPS claims data for this final rule (from CY 2022), we estimate there were approximately 2.2 million patient months for patients receiving in-center hemodialysis. Therefore, we estimate that the additional costs associated with compiling and reporting the data for this time on machine reporting requirement will be associated with approximately 2.2 million in-center dialysis patient months per year.

To derive wages estimates, we used data from the U.S. Bureau of Labor Statistics' May 2022 National Occupational Employment and Wage Estimates. We believe it is reasonable to assume that Medical Records and Health Information Technicians, who are responsible for organizing and managing health information data, are the individuals reporting time on machine data. As discussed in the CY 2016 ESRD PPS final rule (80 FR 69069), this is consistent with our assumptions about the types of employees tasked with submitting measure data to CROWNWeb (now EQRS) and NHSN, as well as compiling and submitting patient records for the purpose of data validation studies. The most recently available mean hourly wage of a Medical Records and Health Information Technician is $24.42 per hour.[345] We also calculate fringe benefit and overhead at 100 percent. We adjusted these employee hourly wage estimates by a factor of 100 percent to reflect current HHS department-wide guidance on estimating the cost of fringe benefits and overhead. We note that these are necessarily rough adjustments, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative, and we believe that these are reasonable estimation methods. Therefore, using these assumptions, we estimate an hourly labor cost of $48.84 as the basis of the wage estimates for the estimate of cost associated with the proposed requirement to report time on machine data on ESRD PPS claims for renal dialysis services.

Based on the figures discussed in the preceding paragraphs, we estimate that total additional staff time each year for ESRD facilities associated with the requirement to record time on machine data is equal to 5.2 million × 1 minute = 5.2 million minutes = 86,667 hours. Additionally, we estimate that the total additional staff time each year for ESRD facilities associated with the calculation and reporting of the time on machine data is equal to 2.2 million × 5 minutes = 11 million minutes = 183,333 hours. We estimate the total annual cost associated with this requirement is equal to (86,667 hours + 183,333 hours) × $47.34 = $12,781,800 per year.

We recognize that some non-LDO ESRD facilities may also choose to adopt an automated process, rather than a manual process. Therefore, the estimate of $12,781,800 represents the upper limit of our burden estimate. For ESRD facilities that choose to utilize existing systems and processes to document treatment duration in the EHR and send that data to the claim, we estimate the burden associated with our requirement to report time on machine data will be minimal.

b. ESRD QIP

For PY 2026 and PY 2027, we have updated the estimated costs associated with the information collection requirements under the ESRD QIP with updated estimates of the total number of ESRD facilities, the total number of patients nationally, wages for Medical Records Specialists or similar staff, and a refined estimate of the number of hours needed to complete data entry for EQRS reporting. We have made no changes to our methodology for calculating the annual burden associated with the information collection requirements for EQRS data validation (previously known as the CROWNWeb validation study) or NHSN data validation. We have updated our methodology for calculating the annual burden associated with the information

[345] *https://www.bls.gov/oes/current/oes292099.htm.*

collection requirements for EQRS reporting based on our measure updates for PY 2026, PY 2027, and subsequent years.

We also updated the payment reduction estimates based on our policies that we have finalized in this final rule, using more recent data for the measures in the ESRD QIP measure set. We estimate that as a result of our previously finalized policies and the policies we have finalized in this final rule for PY 2026, there would be approximately $120.9 million in information collection burden and an additional $16 million in estimated payment reductions across all facilities, for a total estimated impact of $136.9 million.

For PY 2027, we estimate that as a result of our previously finalized policies and the policies we have finalized in this final rule for PY 2027, there would be approximately $130.5 million in information collection burden and $13.8 million in estimated payment reductions across all facilities, for a total estimated impact of $144.3 million.

3. Transfers

We estimate that the updates to the ESRD PPS and AKI payment rate will result in a total increase of approximately $190 million in Medicare payments to ESRD facilities in CY 2024, which includes the amount associated with updates to the outlier thresholds, and updates to the wage index. This estimate includes an increase of approximately $1 million in Medicare payments to ESRD facilities in CY 2024 due to the updates to the AKI payment rate, of which approximately 20 percent is increased beneficiary coinsurance payments. We estimate approximately $150 million in transfers from the Federal Government to ESRD facilities due to increased Medicare program payments and approximately $40 million in transfers from beneficiaries to ESRD facilities due to increased beneficiary coinsurance payments because of this final rule.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this ESRD PPS final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the ESRD PPS final rule, we assume that the total number of unique commenters on this year's ESRD PPS proposed rule, 256, will be the number of reviewers of this ESRD PPS final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this final rule. It is possible that not all commenters reviewed this year's proposed rule in detail, and it is also possible that some reviewers chose not to comment on the ESRD PPS proposed rule. For these reasons we thought that the number of commenters would be a fair estimate of the number of reviewers of this final rule. We invited comments on the approach in estimating the number of entities which will review this final rule but did not receive any comments on this topic. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We solicited comments on this assumption and none were received.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this final rule is $123.06 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it will take approximately 300 minutes (5.00 hours) for the staff to review half of this final rule, which has a total of approximately 150,000 words. For each entity that reviews the rule, the estimated cost is $615.30 (5.00 hours × $123.06). Therefore, we estimate that the total cost of reviewing this regulation is $157,516.80 ($615.30 × 256).

5. Impact Statement and Table

a. CY 2024 End-Stage Renal Disease Prospective Payment System

(1) Effects on ESRD Facilities

To understand the impact of the changes affecting Medicare payments to different categories of ESRD facilities, it is necessary to compare estimated payments in CY 2023 to estimated payments in CY 2024. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of Medicare payments in CY 2023 and CY 2024 contain similar inputs. Therefore, we simulated Medicare payments only for those ESRD facilities for which we can calculate both current Medicare payments and new Medicare payments.

For this final rule, we used CY 2022 data from the Medicare Part A and Part B Common Working Files as of August 4, 2023, as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2022 claims to 2023 and 2024 using various updates. The updates to the ESRD PPS base rate are described in section II.B.1.d of this final rule. Table 24 shows the impact of the estimated CY 2024 ESRD PPS payments compared to estimated Medicare payments to ESRD facilities in CY 2023.

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TABLE 24: Impacts of the Changes in Medicare Payments to ESRD Facilities for CY 2024

Facility Type	Number of Facilities (A)	Number of Treatments (in millions) (B)	Changes to Outlier Policy (C)	TPEAPA (D)	Changes to TDAPA and Post-TDAPA Payments[1,2] (E)	Wage Index Changes (F)	Total Percent Change[3] (G)
All Facilities	7,864	30.6	0.0%	0.0%	0.0%	0.0%	2.1%
Type							
Freestanding	7,507	29.4	0.0%	0.0%	0.0%	0.0%	2.1%
Hospital based	357	1.2	0.0%	0.8%	0.1%	0.2%	3.4%
Ownership Type							
Large dialysis organization	6,123	24.0	0.0%	0.0%	0.0%	0.0%	2.0%
Regional chain	913	3.7	0.0%	0.0%	0.0%	-0.1%	1.9%
Independent	462	1.7	0.0%	0.0%	0.1%	0.6%	2.7%
Hospital based	357	1.2	0.0%	0.8%	0.1%	0.2%	3.4%
Unknown	9	0.0	0.0%	0.0%	0.1%	0.4%	2.6%
Geographic Location							
Rural	1,267	4.3	0.0%	0.0%	0.0%	-0.4%	1.6%
Urban	6,597	26.3	0.0%	0.0%	0.0%	0.1%	2.2%
Census Region							
East North Central	1,228	4.1	0.0%	0.0%	0.0%	-0.4%	1.7%
East South Central	617	2.0	0.0%	0.0%	0.0%	-0.3%	1.7%
Middle Atlantic	895	3.8	0.0%	0.0%	0.0%	0.8%	2.9%
Mountain	441	1.7	0.0%	0.0%	0.0%	-0.7%	1.4%
New England	200	1.0	0.0%	0.0%	0.0%	-0.5%	1.6%
Pacific[4]	986	5.2	0.0%	0.0%	0.0%	0.0%	2.1%
Puerto Rico and Virgin Islands	53	0.1	0.0%	0.0%	0.1%	0.0%	2.1%
South Atlantic	1,830	6.8	0.0%	0.0%	0.0%	0.3%	2.4%
West North Central	495	1.7	0.0%	0.0%	0.0%	-0.3%	1.9%
West South Central	1,119	4.1	0.0%	0.1%	0.0%	0.0%	2.1%
Facility Size							

Facility Type	Number of Facilities (A)	Number of Treatments (in millions) (B)	Changes to Outlier Policy (C)	TPEAPA (D)	Changes to TDAPA and Post-TDAPA Payments[1,2] (E)	Wage Index Changes (F)	Total Percent Change[3] (G)
Less than 4,000 treatments	1,245	1.4	0.0%	0.4%	0.0%	-0.1%	2.5%
4,000 to 9,999 treatments	3,503	10.2	0.0%	0.0%	0.0%	-0.1%	2.0%
10,000 or more treatments	3,116	19.0	0.0%	0.0%	0.0%	0.0%	2.1%
Unknown	0	0.0	0.0%	0.0%	0.0%	0.0%	0.0%
Percentage of Pediatric Patients							
Less than 2%	7,761	30.3	0.0%	0.0%	0.0%	0.0%	2.1%
Between 2% and 19%	38	0.2	0.0%	1.5%	0.1%	-0.5%	3.2%
Between 20% and 49%	9	0.0	0.1%	8.4%	0.1%	-1.1%	9.7%
More than 50%	56	0.0	0.1%	25.3%	0.1%	0.0%	28.4%

[1]This column includes the impact of the end of TDAPA payment for Korsuva® and the start of the proposed post-TDAPA payment adjustment for that drug beginning in April, 2024. This change is not budget neutral, but we estimate the overall change in total payments would be an increase of less than 0.1 percent.

[2] Although TDAPA spending for Jesduvroq (January 1, 2024 – December 31, 2024) is projected at approximately $10 million, this amount is not reflected in Table 24, because Jesduvroq utilization was not yet represented in the claims data used for this table.

[3] This column includes the impact of the final updates in columns (C) through (F) in Table 24, and of the ESRDB market basket percentage increase for CY 2024 of 2.4 percent, reduced by 0.3 percentage point for the productivity adjustment as required by section 1881(b)(14)(F)(i)(II) of the Act. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.

[4] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

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Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the final changes to the outlier payment policy described in section II.B.1.c of this final rule is shown in column C. For CY 2024, the impact on all ESRD facilities because of the final changes to the outlier payment policy would be an increase in estimated Medicare payments of less than 0.1 percent.

Column D shows the effect of the TPEAPA as described in section II.B.1.g of this final rule. This adjustment will be implemented in a budget neutral manner, so the total impact of this change would be 0.0 percent. However, there will be distributional impacts of this final change, primarily a 25.3 percent increase to payments to Pediatric ESRD facilities (with more than 50 percent of patients under age 18). This policy change also corresponds to a 0.8 percent increase to hospital-based ESRD facilities. Because the budget neutrality factor for this policy is so small, the impact analysis found no significant decrease to any ESRD facility as the total decrease in payments for ESRD facilities that predominantly serve adults will still be less than 0.05 percent.

Column E shows the effect of year-over-year payment changes related to the post-TDAPA add-on payment adjustment as described in section II.B.1.i of this final rule and current TDAPA payments. The post-TDAPA add-on payment adjustment will not be budget neutral; however, we estimate the difference between total payments in CY 2023 during which time payment is made using the TDAPA under the ESRD PPS and estimated total payments in CY 2024 under the final post-TDAPA add-on payment adjustment would be less than 0.1 percent. Therefore, the total impact of this change as compared to current TDAPA payments is 0.0 percent.

Column F reflects the effect of the update to the ESRD PPS wage index as described in section II.B.1.b of this final rule. This update will be budget neutral, so the total impact of this policy change is 0.0 percent. However, there will be distributional impacts of this change. The largest increase would be to mid-Atlantic ESRD facilities that would receive 0.8 percent higher payments because of the final updated ESRD PPS wage index. The largest decrease will be to ESRD facilities with more than 20 percent and less than 50 percent pediatric patients, who will receive 1.1 percent lower payments because of the updated ESRD PPS wage index.

Column G reflects the overall impact, that is, the effects of the final outlier

policy changes, the TPEAPA, the post-TDAPA payment adjustment, the updated wage index, and the payment rate update as described in section II.B.1.d of this final rule. The ESRD PPS payment rate update for CY 2024 is 2.1 percent, which reflects the ESRDB market basket percentage increase for CY 2024 of 2.4 percent and the productivity adjustment of 0.3 percent. We expect that overall ESRD facilities will experience a 2.1 percent increase in estimated Medicare payments in CY 2024. The categories of types of ESRD facilities in the impact table show impacts ranging from a 1.4 percent increase to a 28.4 percent increase in their CY 2024 estimated Medicare payments.

(2) Effects on Other Providers

Under the ESRD PPS, Medicare pays ESRD facilities a single bundled payment for renal dialysis services, which may have been separately paid to other providers (for example, laboratories, durable medical equipment suppliers, and pharmacies) by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2024, we estimate that the ESRD PPS will have zero impact on these other providers.

(3) Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2024 will be approximately $6.7 billion. This estimate considers a projected decrease in fee-for-service Medicare ESRD beneficiary enrollment of 4.3 percent in CY 2024.

(4) Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount. As a result of the projected 2.1 percent overall increase in the CY 2024 ESRD PPS payment amounts, we estimate that there will be an increase in beneficiary coinsurance payments of 2.1 percent in CY 2024, which translates to approximately $40 million.

(5) Alternatives Considered

(i) Transitional Pediatric ESRD Add-On Payment Adjustment

As discussed in section II.B.1.g.(4) of this final rule, we proposed and are finalizing to implement a transitional add-on payment adjustment of 30 percent for Pediatric ESRD Patients, which we call the TPEAPA. We also considered, but did not propose, an alternative payment structure which would phase in the adjustment over 3 years starting at 10 percent for the first year and 20 percent for the second year.

(ii) Add-On Payment Adjustment for Certain Renal Dialysis Drugs and Biological Products After the TDAPA Period Ends

As discussed in section II.B.1.i.(3) of this final rule, we proposed and are finalizing an add-on payment adjustment for new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the end of the TDAPA period. We also considered, but did not propose, an alternative methodology for calculating this payment adjustment which would incorporate a reconciliation of all the formerly separately billable drugs against the calculated post-TDAPA payment adjustment. Additionally, we considered but did not propose alternative approaches to applying and calculating this add-on payment adjustment for specific patient populations.

(iii) Reporting Time on Machine Data on ESRD PPS Claims for Renal Dialysis Services

As discussed in section II.B.1.j.(3) of this final rule, we proposed and are finalizing to require ESRD facilities to submit data and information on ESRD PPS claims for renal dialysis services regarding the number of minutes of hemodialysis treatment received by a beneficiary in center in an ESRD facility. This patient-level reporting on resource use would be used to apportion composite rate costs for use in the case-mix adjustment. We also considered, but did not propose, to use dialysis duration data from EQRS to apportion composite rate costs for this purpose. We discuss why we did not propose this alternative in further detail in section II.B.1.j.(3) of this final rule.

(iv) Allowing ESRD Facilities Impacted by a Disaster or Other Emergency To Apply for an Exception From the Treatment Volume Threshold Requirement for the LVPA

As discussed in section II.B.1.f.(3)(a)(ii), we are finalizing our proposal to allow ESRD facilities to receive exceptions for some of the requirements for the LVPA if they are impacted by a disaster or other emergency. One of these exceptions is for ESRD facilities that exceed the 4000-treatment volume threshold due to treating patients who were displaced from an ESRD facility that closed or experienced an operational disruption due to a disaster or other emergency. To receive this exception, we proposed that the ESRD facility must submit a request for the exception, in writing, to CMS by the annual attestation deadline of November 1st. We are finalizing that the deadline for requesting this exception be either the annual attestation deadline or 30 days after the end of the cost-reporting year for which the ESRD facility is attesting, whichever is later. We also considered, but did not finalize, having a deadline of December 31st for the attestation for ESRD facilities impacted by a disaster or other emergency and, therefore, a deadline of December 31st for requesting the exception. We discuss why we are not finalizing this alternative in further detail in section II.B.1.f.(3)(a)(ii) of this final rule.

b. Continuation of Approved Transitional Drug Add-On Payment Adjustments (TDAPA) for New Renal Dialysis Drugs or Biological Products for CY 2024

(1) Korsuva® (difelikefalin)

One renal dialysis drug for which the TDAPA was paid in CY 2022 and CY 2023 will continue to be eligible for the TDAPA in CY 2024. CMS Transmittal 11295,[346] implemented the 2-year TDAPA period specified in § 413.234(c)(1) for Korsuva® (difelikefalin). The TDAPA payment period began on April 1, 2022, and will continue through March 31, 2024. As set forth in § 413.234(c), TDAPA payment is based on 100 percent of average sales price (ASP). If ASP is not available, then the TDAPA is based on 100 percent of wholesale acquisition cost (WAC) and, when WAC is not available, the payment is based on the drug manufacturer's invoice.

We based the CY 2024 impacts on the most current 72x claims data; from May 2022, when utilization first appeared on the claims, through July 2023. During that timeframe, the average monthly TDAPA payment amount for Korsuva® was $1,000,000. In applying that average to the 3 remaining months of the TDAPA payment period in CY 2024, we estimate $3,000,000 in spending ($1,000,000 * 3 = $3,000,000) of which, approximately $600,000 ($3,000,000 * 0.20 = $600,000) would be attributed to beneficiary coinsurance amounts.

(2) Jesduvroq (daprodustat)

On July 27, 2023, CMS Transmittal 12157 [347] implemented the 2-year TDAPA period specified in § 413.234(c)(1) for Jesduvroq (daprodustat). The TDAPA payment

[346] CMS Transmittal 11295 rescinded and replaced CMS Transmittal 11278, dated February 24, 2022 and is available at: *https://www.cms.gov/files/document/r11295CP.pdf.*

[347] CMS Transmittal 12157, dated July 27, 2023 is available at: *https://www.cms.gov/files/document/r12157cp.pdf.*

period began on October 1, 2023, and will continue through September 30, 2025. As stated previously, TDAPA payment is based on 100 percent of ASP. If ASP is not available, then the TDAPA is based on 100 percent of WAC and, when WAC is not available, the payment is based on the drug manufacturer's invoice.

We based our impact analysis on the most current pricing and manufacturer provided volume estimates at the time of this final rule. Estimates are based on the most current, reasonable assumptions but are subject to change based on any changes to the product's label, indication, recommended dosage, safety profile or changes to applicable law, regulations and/or the standard of care.

Jesduvroq is currently priced at $3.91 per 1 milligram unit.[348] Several factors effect dosing, as described in Jesduvroq's Prescribing Information.[349] However, total volume is estimated at 2,623,860 units in CY 2024. Multiplying the 2,623,860 units by the current pricing of $3.91 would result in approximately $10.3 million in CY 2024 spending (2,623,860 * $3.91 = $10,259,293), of which, approximately $2.1 million ($10,259,293 * 0.20 = $2,051,859) would be attributed to beneficiary coinsurance amounts.

c. Payment for Renal Dialysis Services Furnished to Individuals With AKI

(1) Effects on ESRD Facilities

To understand the impact of the changes affecting Medicare payments to different categories of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is necessary to compare estimated Medicare payments in CY 2023 to estimated Medicare payments in CY 2024. To estimate the impact among various types of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is imperative that the Medicare payment estimates in CY 2023 and CY 2024 contain similar inputs. Therefore, we simulated Medicare payments only for those ESRD facilities for which we can calculate both current Medicare payments and new Medicare payments.

For this final rule, we used CY 2022 data from the Medicare Part A and Part B Common Working Files as of August 4, 2023, as a basis for Medicare for renal dialysis services furnished to individuals with AKI. We updated the 2022 claims to 2023 and 2024 using various updates. The updates to the AKI payment amount are described in section III.B of this final rule. Table 25 shows the impact of the estimated CY 2024 Medicare payments for renal dialysis services furnished to individuals with AKI compared to estimated Medicare payments for renal dialysis services furnished to individuals with AKI in CY 2023.

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[348] CMS ESRD PPS Transitional Drug Add-on Payment Adjustment web page. Payment Amounts for New Renal Dialysis Drugs and Biological Products Currently Eligible for the TDAPA. Available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/Drugs-and-Biologicals-Eligible-for-TDAPA.pdf*. Accessed on September 29, 2023.

[349] Jesduvroq Prescribing Information Available at: *https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Jesduvroq/pdf/JESDUVROQ-PI-MG.PDF*. Accessed on September 29, 2023.

TABLE 25: Impacts of the Changes in Medicare Payments for Renal Dialysis Services Furnished to Individuals with AKI for CY 2024

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Wage Index Changes (C)	Total Percent Change[1] (D)
All Facilities	5,110	278.0	-0.1%	2.0%
Type				
Freestanding	4,990	272.6	-0.1%	2.0%
Hospital based	120	5.4	0.1%	2.1%
Ownership Type				
Large dialysis organization	4,234	229.8	-0.1%	1.9%
Regional chain	576	29.1	-0.1%	1.9%
Independent	179	13.7	0.6%	2.7%
Hospital based[2]	120	5.4	0.1%	2.1%
Unknown	1	0.0	0.2%	2.2%
Geographic Location				
Rural	863	43.0	-0.4%	1.6%
Urban	4,247	235.0	0.0%	2.0%
Census Region				
East North Central	853	44.8	-0.5%	1.6%
East South Central	386	19.5	-0.2%	1.8%
Middle Atlantic	534	32.5	0.7%	2.7%
Mountain	301	19.5	-0.8%	1.2%
New England	146	6.7	-0.3%	1.8%
Pacific[3]	621	42.5	-0.2%	1.8%
Puerto Rico and Virgin Islands	5	0.1	0.0%	2.1%
South Atlantic	1,235	67.4	0.1%	2.2%
West North Central	320	13.2	-0.2%	1.8%
West South Central	709	31.7	0.0%	2.1%
Facility Size				
Less than 4,000 treatments	513	17.3	-0.1%	2.0%
4,000 to 9,999 treatments	2,312	114.1	-0.1%	2.0%
10,000 or more treatments	2,285	146.6	-0.1%	2.0%
Unknown	0	0.0	0.0%	0.0%
Percentage of Pediatric Patients				
Less than 2%	5,096	277.4	-0.1%	2.0%

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Wage Index Changes (C)	Total Percent Change[1] (D)
Between 2% and 19%	11	0.6	-1.4%	0.6%
Between 20% and 49%	1	0.1	-1.6%	0.5%
More than 50%	2	0.0	-0.7%	1.4%

[1] This column includes the impact of the updates in columns (C) as well as the impact of the TPEAPA budget-neutrality adjustment factor in Table 25, and of the ESRDB market basket percentage increase for CY 2024 of 2.4 percent, reduced by 0.3 percentage point for the productivity adjustment as required by section 1881(b)(14)(F)(i)(II) of the Act. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.

[2] Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

[3] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

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Column A of the impact table indicates the number of ESRD facilities for each impact category, and column B indicates the number of AKI dialysis treatments (in thousands). Column C shows the effect of the CY 2024 wage indices.

Column D shows the overall impact, that is, the effects of the combined wage index and TPEAPA budget-neutrality adjustment factor, wage index updates, and the payment rate update of 2.1 percent, which reflects the ESRDB market basket percentage increase for CY 2024 of 2.4 percent and the productivity adjustment of 0.3 percentage point. We expect that overall ESRD facilities will experience a 2.0 percent increase in estimated Medicare payments in CY 2024. The categories of types of ESRD facilities in the impact table show impacts ranging from an increase of 0.5 percent to 2.7 percent in their CY 2024 estimated Medicare payments.

(2) Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we proposed to update the payment rate for renal dialysis services furnished by ESRD facilities to beneficiaries with AKI. The only two Medicare providers and suppliers authorized to provide these outpatient renal dialysis services are hospital outpatient departments and ESRD facilities. The patient and his or her physician make the decision about where the renal dialysis services are furnished. Therefore, this change would have zero impact on other Medicare providers.

(3) Effects on the Medicare Program

We estimate approximately $70 million will be paid to ESRD facilities in CY 2024 because of patients with AKI receiving renal dialysis services in an ESRD facility at the lower ESRD PPS base rate versus receiving those services only in the hospital outpatient setting and paid under the outpatient prospective payment system, where services were required to be administered prior to the TPEA.

(4) Effects on Medicare Beneficiaries

Currently, beneficiaries have a 20 percent coinsurance obligation when they receive AKI dialysis in the hospital outpatient setting. When these services are furnished in an ESRD facility, the patients will continue to be responsible for a 20 percent coinsurance. Because the AKI dialysis payment rate paid to ESRD facilities is lower than the outpatient hospital PPS's payment amount, we expect beneficiaries to pay less coinsurance when AKI dialysis is furnished by ESRD facilities.

(5) Alternatives Considered

As we discussed in the CY 2017 ESRD PPS proposed rule (81 FR 42870), we considered adjusting the AKI payment rate by including the ESRD PPS case-mix adjustments, and other adjustments at section 1881(b)(14)(D) of the Act, as well as not paying separately for AKI specific drugs and laboratory tests. We ultimately determined that treatment for AKI is substantially different from treatment for ESRD, and the case-mix adjustments applied to ESRD patients may not be applicable to AKI patients, and as such, including those policies and adjustments is inappropriate. We continue to monitor utilization and trends of items and services furnished to individuals with AKI for purposes of refining the payment rate in the future. This monitoring will assist us in developing knowledgeable, data-driven proposals.

d. ESRD QIP

(1) Effects of the PY 2026 ESRD QIP on ESRD Facilities

The ESRD QIP is intended to prevent reductions in the quality of ESRD dialysis facility services provided to beneficiaries. The general methodology that we use to calculate a facility's TPS is described in our regulations at § 413.178(e).

Any reductions in the ESRD PPS payments as a result of a facility's performance under the PY 2026 ESRD QIP will apply to the ESRD PPS payments made to the facility for services furnished in CY 2026, as codified in our regulations at § 413.177.

For the PY 2026 ESRD QIP, we estimate that, of the 7,833 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 30.56 percent or 2,394 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2026. Among an estimated 2,394 facilities that would receive a payment reduction, approximately 64 percent or 1,544 facilities would receive the smallest payment reduction of 0.5 percent. We are updating the estimated impact of the PY 2026 ESRD QIP that we provided in the CY 2023 ESRD PPS final rule (87 FR 67293 through 67296). Based on our final policies, the updated total estimated payment reductions for all the 2,394 facilities expected to

receive a payment reduction in PY 2026 would be approximately $15,990,524.

Facilities that do not receive a TPS do not receive a payment reduction.

Table 26 shows the updated overall estimated distribution of payment reductions resulting from the PY 2026 ESRD QIP.

TABLE 26: Updated Estimated Distribution of PY 2026 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	5167	68.34%
0.5%	1544	20.42%
1.0%	628	8.31%
1.5%	194	2.57%
2.0%	28	0.37%

*272 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction for PY 2026, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there were available data from EQRS and Medicare claims. Payment reduction estimates were calculated using the most recent data available (specified in Table 27) in accordance with the policies finalized in this final rule. Measures used for the simulation are shown in Table 27.

TABLE 27: Data Used to Update the Estimated PY 2026 ESRD QIP Payment Reductions

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2019-Dec 2019	Jan 2022-Dec 2022
SRR	Jan 2019-Dec 2019	Jan 2022-Dec 2022
SHR	Jan 2019-Dec 2019	Jan 2022-Dec 2022
PPPW	Jan 2019-Dec 2019	Jan 2022-Dec 2022
Kt/V Dialysis Adequacy Comprehensive	Jan 2019-Dec 2019	Jan 2022-Dec 2022
VAT		
% Catheter	Jan 2019-Dec 2019	Jan 2022-Dec 2022
STrR	Jan 2019-Dec 2019	Jan 2022-Dec 2022
NHSN BSI	Jan 2019-Dec 2019	Jan 2022-Dec 2022
Clinical Depression	Jan 2021-Dec 2021	Jan 2022-Dec 2022

For all measures except the SHR clinical measure, the SRR clinical measure, and the STrR measure, measures with less than 11 patients for a facility were not included in that facility's TPS. For the SHR clinical measure and the SRR clinical measure, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, to be included in the facility's TPS. For the STrR clinical measure, facilities were required to have at least 10 patient-years at risk to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table consistent with the final policies outlined in section IV.C of this final rule. Facility reporting measure scores were estimated using available data from CY 2022. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2026 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2022 and December 2022 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 28 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2026. The table also details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and facility type (hospital based and freestanding facilities). Given that the

performance period used for these calculations differs from the performance period we are using for the PY 2026 ESRD QIP, the actual impact of the PY 2026 ESRD QIP may vary significantly from the values provided here.

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TABLE 28: Updated Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2026

	Number of Facilities	Number of Treatments 2019 (in millions)	Number of Facilities with QIP Score	Number of Facilities Expected to Receive a Payment Reduction	Payment Reduction (percent change in total ESRD payments)
All Facilities	7,833	29.8	7,561	2,394	-0.23%
Facility Type:					
Freestanding	7,481	28.6	7,232	2,252	-0.22%
Hospital-based	352	1.1	329	142	-0.36%
Ownership Type:					
Large Dialysis	6,068	23.2	5,882	1,622	-0.18%
Regional Chain	901	3.6	877	346	-0.31%
Independent	451	1.7	434	264	-0.60%
Hospital-based (non-chain)	352	1.1	329	142	-0.36%
Unknown	61	0.0	39	20	-0.35%
Facility Size:					
Large Entities	6,969	26.9	6,759	1,968	-0.19%
Small Entities[1]	803	2.9	763	406	-0.50%
Unknown	61	0.0	39	20	-0.35%
Rural Status:					
1) Yes	1,264	4.2	1,211	277	-0.15%
2) No	6,569	25.6	6,350	2,117	-0.24%
Census Region:					
Northeast	1,093	4.7	1,050	333	-0.22%
Midwest	1,718	5.7	1,649	526	-0.23%
South	3,555	12.5	3,439	1,164	-0.25%
West	1,404	6.6	1,362	344	-0.16%
US Territories[2]	63	0.2	61	27	-0.28%
Census Division:					
Unknown	11	0.1	10	5	-0.40%
East North Central	1,223	4.0	1,176	409	-0.25%
East South Central	616	2.0	593	186	-0.22%
Middle Atlantic	893	3.7	854	283	-0.23%
Mountain	438	1.6	429	107	-0.17%
New England	200	1.0	196	50	-0.18%
Pacific	966	5.0	933	237	-0.16%
South Atlantic	1,820	6.5	1,758	643	-0.28%
West North Central	495	1.7	473	117	-0.18%
West South Central	1,119	4.0	1,088	335	-0.22%
US Territories[2]	52	0.1	51	22	-0.26%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,267	1.5	1,100	364	-0.28%
4,000-9,999 treatments	3,294	9.2	3,203	856	-0.19%
Over 10,000 treatments	3,272	19.0	3,258	1,174	-0.24%

[1]Small Entities include hospital-based and satellite facilities, and non-chain facilities based on EQRS.
[2]Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

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(3) Effects of the PY 2027 ESRD QIP on ESRD Facilities

For the PY 2027 ESRD QIP, we are updating the estimated effect that we presented in the CY 2024 ESRD PPS proposed rule (88 FR 42534 through 42536). In this final rule, we estimate that, of the 7,833 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 28.88 percent or 2,262 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2027. Among an estimated 2,262 facilities that would receive a payment reduction, approximately 70 percent or 1,584 facilities would receive the smallest payment reduction of 0.5 percent. The total payment reductions for all the 2,262 facilities expected to receive a payment reduction is approximately $13,847,479. Facilities that do not receive a TPS do not receive a payment reduction.

Table 29 shows the overall estimated distribution of payment reductions resulting from the PY 2027 ESRD QIP.

TABLE 29: Estimated Distribution of PY 2027 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	5362	70.33%
0.5%	1584	20.78%
1.0%	568	7.45%
1.5%	97	1.27%
2.0%	13	0.17%

*Note: 209 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction in PY 2027, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there were available data from EQRS and Medicare claims. Payment reduction estimates were calculated using the most recent data available (specified in Table 30) in accordance with the policies finalized in this final rule. Measures used for the simulation are shown in Table 30.

TABLE 30: Data Used to Estimate PY 2027 ESRD QIP Payment Reductions

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2019-Dec 2019	Jan 2022-Dec 2022
SRR	Jan 2019-Dec 2019	Jan 2022-Dec 2022
SHR	Jan 2019-Dec 2019	Jan 2022-Dec 2022
PPPW	Jan 2019-Dec 2019	Jan 2022-Dec 2022
Kt/V Dialysis Adequacy Comprehensive	Jan 2019-Dec 2019	Jan 2022-Dec 2022
VAT		
% Catheter	Jan 2019-Dec 2019	Jan 2022-Dec 2022
STrR	Jan 2019-Dec 2019	Jan 2022-Dec 2022
NHSN BSI	Jan 2019-Dec 2019	Jan 2022-Dec 2022
Clinical Depression	Jan 2021-Dec 2021	Jan 2022-Dec 2022

For all measures except the SHR clinical measure, the SRR clinical measure, and the STrR measure, measures with less than 11 patients for a facility were not included in that facility's TPS. For the SHR and SRR measures, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, to be included in the facility's TPS. For the STrR clinical measure, facilities were required to have at least 10 patient-years at risk to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table that incorporates the previously finalized policies and the policies we have finalized in this final rule outlined in section IV.D of this final rule. Facility reporting measure scores were estimated using available data from CY 2022. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2027 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2022 and December 2022 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 31 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2027. The table details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period we are using for the PY 2027 ESRD QIP, the actual impact of the PY 2027 ESRD QIP may vary significantly from the values provided here.

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TABLE 31: Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2027

	Number of Facilities	Number of Treatments 2019 (in millions)	Number of Facilities with QIP Score	Number of Facilities Expected to Receive a Payment Reduction	Payment Reduction (percent change in total ESRD payments)
All Facilities	7,833	29.8	7,624	2,262	-0.20%
Facility Type:					
Freestanding	7,481	28.6	7,292	2,127	-0.19%
Hospital-based	352	1.1	332	135	-0.30%
Ownership Type:					
Large Dialysis	6,068	23.2	5,904	1,534	-0.16%
Regional Chain	901	3.6	882	322	-0.26%
Independent	451	1.7	446	254	-0.50%
Hospital-based (non-chain)	352	1.1	332	135	-0.30%
Unknown	61	0.0	60	17	-0.18%
Facility Size:					
Large Entities	6,969	26.9	6,786	1,856	-0.17%
Small Entities[1]	803	2.9	778	389	-0.42%
Unknown	61	0.0	60	17	-0.18%
Rural Status:					
1) Yes	1,264	4.2	1,223	274	-0.14%
2) No	6,569	25.6	6,401	1,988	-0.21%
Census Region:					
Northeast	1,093	4.7	1,066	301	-0.19%
Midwest	1,718	5.7	1,663	507	-0.20%
South	3,555	12.5	3,464	1,118	-0.22%
West	1,404	6.6	1,369	313	-0.15%
US Territories[2]	63	0.2	62	23	-0.20%
Census Division:					
Unknown	11	0.1	11	5	-0.31%
East North Central	1,223	4.0	1,187	397	-0.22%
East South Central	616	2.0	600	176	-0.19%
Middle Atlantic	893	3.7	869	259	-0.20%
Mountain	438	1.6	430	100	-0.16%
New England	200	1.0	197	42	-0.14%
Pacific	966	5.0	939	213	-0.14%
South Atlantic	1,820	6.5	1,771	619	-0.24%
West North Central	495	1.7	476	110	-0.15%
West South Central	1,119	4.0	1,093	323	-0.19%
US Territories[2]	52	0.1	51	18	-0.18%
Facility Size (# of total treatments):					
Less than 4,000 treatments	1,267	1.5	1,163	359	-0.23%
4,000-9,999 treatments	3,294	9.2	3,203	822	-0.17%
Over 10,000 treatments	3,272	19.0	3,258	1,081	-0.21%

[1]Small Entities include hospital-based and satellite facilities, and non-chain facilities based on EQRS.
[2]Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

(4) Effects on Other Providers

The ESRD QIP is applicable to ESRD facilities. We are aware that several of our measures impact other providers. For example, with the introduction of the SRR clinical measure in PY 2017 and the SHR clinical measure in PY 2020, we anticipate that hospitals may experience financial savings as facilities work to reduce the number of unplanned readmissions and hospitalizations. We are exploring various methods to assess the impact these measures have on hospitals and other facilities, such as through the impacts of the Hospital Readmissions Reduction Program and the Hospital-Acquired Condition Reduction Program, and we intend to continue examining the interactions between our quality programs to the greatest extent feasible.

(5) Effects on the Medicare Program

For PY 2027, we estimate that the ESRD QIP would contribute approximately $13,847,478.73 in Medicare savings. For comparison, Table 32 shows the payment reductions that we estimate will be applied by the ESRD QIP from PY 2018 through PY 2027.

TABLE 32: Estimated ESRD QIP Aggregate Payment Reductions for Payment Years 2018 through 2027

Payment Year	Estimated Payment Reductions
PY 2027	$13,847,479
PY 2026	$15,990,524
PY 2025	$32,457,693 (87 FR 67297)
PY 2024	$17,104,031 (86 FR 62011)
PY 2023	$5,548,653 (87 FR 67297)
PY 2022	$0[350] (86 FR 62011)
PY 2021	$32,196,724 (83 FR 57062)
PY 2020	$31,581,441 (81 FR 77960)
PY 2019	$15,470,309 (80 FR 69074)
PY 2018	$11,576,214 (79 FR 66257)

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(6) Effects on Medicare Beneficiaries

The ESRD QIP is applicable to ESRD facilities. Since the Program's inception, there is evidence of improved performance on ESRD QIP measures. As we stated in the CY 2018 ESRD PPS final rule, one objective measure we can examine to demonstrate the improved quality of care over time is the improvement of performance standards (82 FR 50795). As the ESRD QIP has refined its measure set and as facilities have gained experience with the measures included in the Program, performance standards have generally continued to rise. We view this as evidence that facility performance (and therefore the quality of care provided to Medicare beneficiaries) is objectively improving. We are in the process of monitoring and evaluating trends in the quality and cost of care for patients under the ESRD QIP, incorporating both existing measures and new measures as they are implemented in the Program. We will provide additional information about the impact of the ESRD QIP on beneficiaries as we learn more. However, in future years we are interested in examining these impacts through the analysis of available data from our existing measures.

(7) Alternatives Considered

In section IV.C.5 of this final rule, we are finalizing the removals of the Ultrafiltration Rate reporting measure and the Standardized Fistula Rate clinical measure, beginning with PY 2026. We considered not removing these measures. However, we concluded that removing these two measures was appropriate under our previously finalized measure removal factors. This approach will help to ensure that a facility's performance is assessed based on measures that continue to be meaningful parts of the ESRD QIP measure set.

e. ETC Model

(1) Overview

The ETC Model is a mandatory payment model designed to test payment adjustments to certain dialysis and dialysis-related payments, as discussed in the Specialty Care Models final rule (85 FR 61114), the CY 2022 ESRD PPS final rule (86 FR 61874), and the CY 2023 ESRD PPS final rule (87 FR 67136) for ESRD facilities and for Managing Clinicians for claims with dates of service from January 1, 2021, to June 30, 2027. The requirements for the ETC Model are set forth in 42 CFR part 512, subpart C. We proposed to revise our regulations at § 512.390 to acknowledge the ability of the CMS Administrator to review the results of ETC Participants' targeted review requests. For the results of the detailed economic analysis of the ETC Model and a description of the methodology used to perform the analysis, see the Specialty Care Models final rule (85 FR 61114).

(2) Data and Methods

A stochastic simulation was created to estimate the financial impacts of the ETC Model relative to baseline expenditures, where baseline expenditures were defined as data from CYs 2018 and 2019 without the changes applied. The simulation relied upon statistical assumptions derived from retrospectively constructed ESRD facilities' and Managing Clinicians' Medicare dialysis claims, transplant claims, and transplant waitlist data reported during 2018 and 2019, the most recent years of complete data available before the start of the ETC Model. Both datasets and the risk-adjustment methodologies for the ETC Model were developed by the CMS Office of the Actuary (OACT).

Table 33 summarizes the estimated impact of the ETC Model when the achievement benchmarks for each year are set using the average of the home dialysis rates for year *t*-1 and year *t*-2 for the HRRs randomly selected for participation in the ETC Model. We estimate that the Medicare program would save a net total of $43 million from the PPA and HDPA between January 1, 2021, and June 30, 2027 less $15 million in increased training and education expenditures. Therefore, the net impact to Medicare spending is estimated to be $28 million in savings. This is consistent with the net impact to Medicare spending estimated for the CY 2022 ESRD PPS final rule, in which the net impact to Medicare spending was also estimated to be $28 million in savings (86 FR 62014 through 62016). Making administrative review available to ETC Participants who wish to seek additional review of a targeted review determination is not expected to change this estimate.

(3) Medicare Estimate—Primary Specification, Assume Rolling Benchmark

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[350] In the CY 2022 ESRD PPS final rule, we adopted a special scoring methodology and payment policy for PY 2022 due to significant impacts related to the COVID–19 public health emergency (86 FR 61918 through 61919). Under this policy, we did not apply any payment reductions to ESRD facilities for PY 2022.

TABLE 33: Estimates of Medicare Program Savings (Rounded $M) for ESRD Treatment Choices (ETC) Model

	Year of Model							
	2021	2022	2023	2024	2025	2026	2027	6.5 Year Total*
Net Impact to Medicare Spending	15	9	-1	-9	-12	-19	-9	-28
Overall PPA Net & HDPA	14	7	-3	-11	-15	-22	-12	-43
Clinician PPA Downward Adjustment		-1	-2	-2	-3	-3	-2	-13
Clinician PPA Upward Adjustment		0	1	1	1	1	1	6
Clinician PPA Net		0	-1	-1	-2	-2	-1	-7
Clinician HDPA	0	0	0					0
Facility Downward Adjustment		-9	-20	-25	-31	-39	-21	-145
Facility Upward Adjustment		5	12	15	18	19	10	79
Facility PPA Net		-3	-8	-10	-14	-20	-11	-66
Facility HDPA	14	10	6					29
Total PPA Downward Adjustment		-9	-22	-27	-34	-43	-23	-158
Total PPA Upward Adjustment		6	13	16	19	21	11	84
Total PPA Net		-4	-9	-11	-15	-22	-12	-73
Total HDPA	14	10	6					30
Kidney Disease Patient Education Services Costs	0	1	1	1	1	1	1	5
HD Training Costs	1	1	1	1	2	2	2	10

*Totals may not sum due to rounding and from beneficiaries that have dialysis treatment spanning multiple years. Negative spending reflects a reduction in Medicare spending. The kidney disease patient education services benefit costs are less than $1M each year, but are rounded up to $1M to show what years they apply to. Similarly, the HD Training Costs are less than $1M for years 2021-2024, but are rounded up to $1M to indicate that costs were applied those years.

In Table 33, negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase. The results for this table were generated from an average of 400 simulations under the assumption that benchmarks are rolled forward with a 1.5-year lag. For a detailed description of the key assumptions underlying the impact estimate, see the Specialty Care Models final rule (85 FR 61353) and the CY 2022 ESRD PPS final rule (86 FR 60214 through 60216).

(4) Effects on the Home Dialysis Rate, the Transplant Rate, and Kidney Transplantation

The changes in this final rule will not impact the findings reported for the effects of the ETC Model on the home dialysis rate or the transplant rate described in the Specialty Care Models final rule (85 FR 61355) and the CY 2022 ESRD PPS final rule (86 FR 62017).

(5) Effects on Kidney Disease Patient Education Services and HD Training Add-Ons

The changes in this final rule will not impact the findings reported for the effects of the ETC Model on kidney disease patient education services and HD training add-ons described in the Specialty Care Models final rule (85 FR 61355) and the CY 2023 ESRD PPS final rule (87 FR 67136).

(6) Effects on Medicare Beneficiaries

Providing the option for ETC Participants to seek administrative review of targeted review determinations will not impact the findings reported for the effects of ETC Model on Medicare beneficiaries in lieu of the ETC Model's likelihood of incentivizing ESRD facilities and Managing Clinicians to improve access to home dialysis and transplantation for Medicare beneficiaries. Further details on the impact of the ETC Model on ESRD Beneficiaries may be found in the Specialty Care Models final rule (85 FR 61357), the CY 2022 ESRD PPS final rule (86 FR 61874), or the CY 2023 ESRD PPS final rule (87 FR 67136).

(7) Alternatives Considered

In this final rule, we are finalizing the proposal to revise our regulations at § 512.390 to acknowledge the availability of administrative review of targeted review requests. We considered retaining our current process, in which targeted review determinations are final with no further review or appeal; however, we believe that providing for administrative review of targeted review determinations is important to provide ETC Participants with transparency regarding the avenue that is available should they wish to seek review of their targeted review determination, to vest accountability for the decisions of CMS in a principal officer, and to bring the

ETC Model into alignment with other CMS programs.

E. Accounting Statement

As required by OMB Circular A–4 (available at *Https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), we have prepared an accounting statement in Table 34 showing the classification of the impact associated with the provisions of this final rule.

TABLE 34: Accounting Statement: Classification of Estimated Transfers and Costs/Savings

ESRD PPS and AKI (CY 2024)	
Category	**Transfers**
Annualized Monetized Transfers	$150 million
From Whom to Whom	Federal Government to ESRD facilities
Category	**Transfers**
Increased Beneficiary Co-insurance Payments	$40 million
From Whom to Whom	Beneficiaries to ESRD facilities
ESRD PPS (CY 2025)	
Category	**Costs**
Increased Reporting Burden for Time on Machine	$13 million
For Whom	ESRD Facilities
ESRD QIP for PY 2026	
Category	Transfers
Annualized Monetized Transfers	-$16.0 million
From Whom to Whom	Federal Government to ESRD facilities
ESRD QIP for PY 2027	
Category	Transfers
Annualized Monetized Transfers	-$13.8 million
From Whom to Whom	Federal Government to ESRD facilities
ETC Model for July 1, 2022, through June 30, 2027	
Category	**Transfers**
Annualized Monetized Transfers	$0.03 million
From Whom to Whom	Federal Government to ESRD facilities and Managing Clinicians

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F. Regulatory Flexibility Act Analysis (RFA)

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations of 50,000 or less, and therefore, they are not enumerated or included in this estimated RFA analysis. Individuals and states are not included in the definition of a small entity. Therefore, the number of small entities estimated in this RFA analysis includes the number of ESRD facilities that are either considered small businesses or nonprofit organizations.

According to the Small Business Administration's (SBA) size standards, an ESRD facility is classified as a small business if it has total revenues of less than $41.5 million in any 1 year. For the purposes of this analysis, we exclude the ESRD facilities that are owned and operated by LDOs and regional chains, which would have total revenues of more than $8.1 billion in any year when the total revenues for all locations are combined for each business (LDO or regional chain), and are not, therefore, considered small businesses. Because we lack data on individual ESRD facilities' receipts, we cannot determine the number of small proprietary ESRD facilities or the proportion of ESRD facilities' revenue derived from Medicare payments. Therefore, we assume that all ESRD facilities that are not owned by LDOs or regional chains are considered small businesses. Accordingly, we consider the 462 facilities that are independent and 357 facilities that are hospital-based, as shown in the ownership category in Table 24, to be small businesses. These facilities represent approximately 10 percent of all ESRD facilities in our data set.

Additionally, we identified in our analytic file that there are 796 facilities that are considered nonprofit organizations, which is approximately 10 percent of all ESRD facilities in our data set. In total, accounting for the 370 nonprofit ESRD facilities that are also considered small businesses, there are 1,245 ESRD facilities that are either small businesses or nonprofit organizations, which is approximately 16 percent of all ESRD facilities in our data set.

For the ESRD PPS updates in this final rule, a hospital-based ESRD facility (as defined by type of ownership, not by type of ESRD facility) is estimated to receive a 3.4 percent increase in Medicare payments for CY 2024. An

independent facility (as defined by ownership type) is likewise estimated to receive a 2.7 percent increase in Medicare payments for CY 2024. As shown in Table 24, we estimate that the overall revenue impact of this final rule on all ESRD facilities is a positive increase to Medicare payments by approximately 2.1 percent.

For AKI dialysis, we are unable to estimate whether patients will go to ESRD facilities, however, we have estimated there is a potential for $70 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities.

For the ESRD QIP, we estimate that of the 2,394 ESRD facilities expected to receive a payment reduction as a result of their performance on the PY 2026 ESRD QIP, 406 are ESRD small entity facilities. We present these findings in Table 25 (''Estimated Distribution of PY 2026 ESRD QIP Payment Reductions'') and Table 27 (''Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2026'').

Regarding the ETC Model, in the Specialty Care Models final rule, we described our assumption, for the purposes of the regulatory impact analysis, that the great majority of Managing Clinicians are small entities by nature of meeting the SBA definition of a small business, but that the greater majority of ESRD facilities are not, as they are owned, either partially or entirely, by organizations that do not meet the SBA definition of a small entity. We described the low volume threshold exclusions and aggregation policies used in the ETC Model and our assessment that, in conjunction with the fact that the ETC Model affects Medicare payment only for select services furnished to Medicare FFS beneficiaries; the ETC Model will not have a significant impact on spending for a substantial number of small entities. For the purposes of this final rule, we have determined that the policy to clarify the ability of the CMS Administrator to review targeted review determinations will not change the assessment that the ETC Model will not have a significant impact on spending for a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this final rule would have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 121 rural hospital-based ESRD facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 121 rural hospital-based ESRD facilities will experience an estimated 2.2 percent increase in payments. Therefore, the Secretary has certified that this final rule would not have a significant impact on the operations of a substantial number of small rural hospitals. Clarifying the ability of the CMS Administrator to review ETC Model targeted review determinations is not expected to change the Secretary's assessment.

G. Unfunded Mandates Reform Act Analysis (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2023, that threshold is approximately $177 million. This final rule will not impose a mandate that will result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of more than $177 million in any 1 year. Moreover, HHS interprets UMRA as applying only to unfunded mandates. We do not interpret Medicare payment rules as being unfunded mandates but simply as conditions for the receipt of payments from the Federal Government for providing services that meet Federal standards. This interpretation applies whether the facilities or providers are private, State, local, or Tribal.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of State, local, or Tribal governments.

I. Congressional Review Act

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

VIII. Files Available to the Public

The Addenda for the annual ESRD PPS proposed and final rule will no longer appear in the **Federal Register**. Instead, the Addenda will be available only through the internet and will be posted on CMS's website under the regulation number, CMS–1782–F, at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.* In addition to the Addenda, limited data set files (LDS) are available for purchase at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/EndStageRenalDiseaseSystemFile.* Readers who experience any problems accessing the Addenda or LDS files, should contact CMS by sending an email to CMS at the following mailbox: *ESRDPayment@cms.hhs.gov.* Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 24, 2023.

List of Subjects

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 512

Administrative practice and procedure, Health care, Health facilities, Health insurance, Medicare, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 1. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395m, 1395x(v), 1395x(kkk), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 2. Section 413.178 is amended by revising paragraphs (a)(8) and (c) to read as follows:

§ 413.178 ESRD quality incentive program.

(a) * * *

(8) *Minimum total performance score (mTPS)* means, with respect to a payment year except payment year 2023, the total performance score that an ESRD facility would receive if it performed at the 50th percentile of national ESRD facility performance on all clinical measures during the baseline period, and it performed at the median of national ESRD facility performance on all reporting measures using data from the most recently available year before the performance period.

* * * * *

(c) *ESRD QIP measure selection, retention, and removal*—(1) *ESRD QIP measure selection.* CMS specifies measures for the ESRD QIP for a payment year and groups the measures into domains. The measures for a payment year include:

(i) Measures on anemia management that reflect the labeling approved by the Food and Drug Administration for such management;

(ii) Measures on dialysis adequacy;

(iii) To the extent feasible, a measure (or measures) of patient satisfaction;

(iv) To the extent feasible, measures on iron management, bone mineral metabolism, and vascular access (including for maximizing the placement of arterial venous fistula);

(v) Beginning with the 2016 payment year, measures specific to the conditions treated with oral-only drugs and that are, to the extent feasible, outcomes-based; and

(vi) Other measures that CMS specifies.

(2) *Use of endorsed measures*—(i) *General rule.* Measures specified by CMS under paragraph (c)(1) of this section will be endorsed by the entity with a contract under section 1890(a) of the Social Security Act, unless the exception in paragraph (c)(2)(ii) of this section applies.

(ii) *Exception.* CMS may specify a measure under paragraph (c)(1) of this section that does not meet the requirement in paragraph (c)(2)(i) of this section if:

(A) CMS has determined that a specified area or medical topic is appropriate for inclusion in the ESRD QIP;

(B) CMS has not identified a feasible and practical measure with respect to that specified area or medical topic that has been endorsed by the entity with a contract under section 1890(a) of the Social Security Act; and

(C) CMS has given due consideration to measures that have been endorsed or adopted by a consensus organization.

(3) *Updating of measure specifications.* CMS uses rulemaking to make substantive updates to the specifications of measures used in the ESRD QIP. CMS announces technical measure specification updates through the QualityNet website (*https://qualitynet.cms.gov*) and listserv announcements.

(4) *Measure retention.* All measures specified for the ESRD QIP measure set remain in the measure set unless CMS, through rulemaking, removes or replaces them.

(5) *Measure removal factors*—(i) *General rule.* CMS may remove or replace a measure based on one or more of the following factors:

(A) *Factor 1.* Measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made.

(B) *Factor 2.* Performance or improvement on a measure does not result in better or the intended patient outcomes.

(C) *Factor 3.* A measure no longer aligns with current clinical guidelines or practice.

(D) *Factor 4.* A more broadly applicable (across settings, populations, or conditions) measure for the topic or a measure that is more proximal in time to desired patient outcomes for the particular topic becomes available.

(E) *Factor 5.* A measure that is more strongly associated with desired patient outcomes for the particular topic becomes available.

(F) *Factor 6.* Collection or public reporting of a measure leads to negative or unintended consequences.

(G) *Factor 7.* It is not feasible to implement the measure specifications.

(H) *Factor 8.* The costs associated with a measure outweigh the benefit of its continued use in the program.

(ii) *Exception.* CMS may retain a measure that meets one or more of the measure removal factors described in paragraph (c)(5)(i) of this section for reasons including, but not limited to, that the measure addresses a gap in quality that is so significant that removing the measure would lower the quality of care furnished by facilities, or that the measure is statutorily required.

(iii) *Patient safety exception.* Upon a determination by CMS that the continued requirement for facilities to submit data on a measure raises specific patient safety concerns, CMS may elect to immediately remove the measure from the ESRD QIP measure set. CMS will, upon removal of the measure—

(A) Provide notice to facilities and the public at the time CMS removes the measure, along with a statement of the specific patient safety concerns that would be raised if facilities continued to submit data on the measure; and

(B) Provide notice of the removal in the **Federal Register**.

* * * * *

■ 3. Section 413.198 is amended by revising paragraphs (a) and (b)(3)(iii) and adding paragraphs (b)(5) and (6) to read as follows:

§ 413.198 Recordkeeping and cost reporting requirements for outpatient maintenance dialysis.

(a) *Purpose and scope.* This section implements sections 1881(b)(2)(B)(i) and 1881(b)(14) of the Act by specifying recordkeeping and cost reporting requirements for ESRD facilities under part 494 of this chapter. The records and reports will enable CMS to determine the costs incurred in furnishing outpatient maintenance dialysis as defined in § 413.170(a).

* * * * *

(b) * * *

(3) * * *

(iii) Flow from the provision of luxury items or services (items or services substantially in excess of or more expensive than those generally considered necessary for the provision of needed health services); or

* * * * *

(5) Each ESRD facility must submit data and information of the types and in the formats established by CMS for the purpose of estimating patient-level and facility-level variation in resource use involved in furnishing renal dialysis services. Beginning January 1, 2025, the data and information must include, but is not limited to the following:

(i) Information reported on ESRD prospective payment system (PPS) claims for renal dialysis services regarding the number of minutes between the start and end of hemodialysis treatment, without accounting for any interruptions, received by a beneficiary in center in an ESRD facility;

(ii) Information reported on ESRD PPS claims about the total number of billing units (or the expected number of billing units, for renal dialysis drugs and biological products provided to beneficiaries for use while receiving home dialysis services as defined in § 413.217 of this chapter or oral forms of renal dialysis drugs and biological products), of any discarded amount of a renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the

ESRD PPS, using the JW modifier (or any successor modifier that includes the same data); and

(iii) Information reported on ESRD PPS claims about any renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS for which there is no discarded amount (or no discarded amount expected, for renal dialysis drugs and biological products provided to beneficiaries for use while receiving home dialysis services as defined in § 413.217 of this chapter or oral forms of renal dialysis drugs and biological products), using the JZ modifier (or any successor modifier that includes the same data).

(6) Beginning January 1, 2025, each ESRD facility must document in the beneficiary's medical record any discarded amounts of a renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS.

■ 4. Section 413.230 is amended by revising paragraphs (d) and (e) and adding paragraph (f) to read as follows:

§ 413.230 Determining the per treatment payment amount.

* * * * *

(d) Any transitional drug add-on payment adjustment under § 413.234(c);

(e) Any transitional add-on payment adjustment for new and innovative equipment and supplies under § 413.236(d); and

(f) Any add-on payment adjustment for new renal dialysis drugs or biological products in existing ESRD PPS functional categories after the payment period for the transitional drug add-on payment adjustment has ended, as described in § 413.234(c)(3) and (g).

■ 5. Section 413.232 is amended by revising paragraphs (b)(1) and (2) and (g) introductory text and adding paragraphs (g)(5) and (6) to read as follows:

§ 413.232 Low-volume adjustment.

* * * * *

(b) * * *

(1) Furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent, except as specified in paragraphs (g)(4) and (5) of this section) preceding the payment year; and

(2) Has not opened, closed, or received a new provider number due to a change in ownership (except where the change in ownership results in a change in facility type) in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year, except as specified in paragraph (g)(6) of this section.

* * * * *

(g) To receive the low-volume adjustment, an ESRD facility must include in its attestation provided pursuant to paragraph (e) of this section a statement that the ESRD facility meets the definition of a low-volume facility in paragraph (b) of this section. To determine eligibility for the low-volume adjustment, the MAC on behalf of CMS relies upon as filed or final settled 12-consecutive month cost reports, except as specified in paragraphs (g)(4) and (5) of this section, for the 3 cost reporting years preceding the payment year to verify the number of treatments, except that:

* * * * *

(5) For payment year 2024 and subsequent payment years, an ESRD facility may attest in the attestation specified in paragraph (e) of this section that it would have met the requirements of paragraph (b)(1) of this section, except that for one or more of the most recent 3 cost reporting years the facility furnished 4,000 or more treatments because of temporary patient-shifting as a result of the closure or operational disruption of another ESRD facility due to a disaster or other emergency. For the purposes of the exception in this paragraph (g)(5), temporary patient-shifting is defined as providing renal dialysis services to one or more displaced patient(s) at any time through the end of the CY following the 12-month period beginning when an ESRD facility first begins providing renal dialysis services to one or more displaced patients. For any facility that so attests—

(i) The facility must also attest that it furnished treatments equal to or in excess of 4,000 in the cost reporting year due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility resulting from a disaster or other emergency;

(ii) The facility must request an exception under this paragraph (g)(5) from CMS, in the form and manner specified by CMS, no later than the attestation deadline specified in paragraph (e) of this section or 30 days after the end of the cost reporting year, whichever is later, for each cost reporting year that the facility furnishes treatments equal to or in excess of 4,000 due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility resulting from a disaster or other emergency;

(iii) Within 30 days of CMS's receipt of the facility's request, CMS will review the request and either approve the request based on a determination that the ESRD facility furnished treatments equal to or in excess of 4,000 in the cost reporting year due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility resulting from a disaster or other emergency, or deny the request, and will notify the facility and the MAC of its decision;

(iv) If CMS approves the request, the ESRD facility is paid the low-volume adjustment on claims for Medicare beneficiaries, on the basis of the exception in this paragraph (g)(5), during the payment year in which the temporary patient-shifting occurred, so long as all other requirements for the low-volume adjustment are met. For any future payment year, the ESRD facility would not be prevented from receiving the low-volume adjustment if the ESRD facility meets or exceeds the 4,000 treatment threshold in a cost reporting year due to temporary patient-shifting as a result of the disaster or other emergency that resulted in another ESRD facility's closure or operational disruption, so long as all other requirements for the low-volume adjustment are met; and

(v) The facility must maintain documentation of the number of displaced patients treated and information about the ESRD facility or facilities that closed or experienced operational disruptions due to a disaster or other emergency and previously treated those patients, and must provide such supporting documentation to CMS and the MAC upon request.

(6) In the case of an ESRD facility that closes due to a disaster or other emergency and later reopens, the ESRD facility may attest in the attestation specified in paragraph (e) of this section that CMS has granted an exception to the requirements specified in paragraph (b)(2) of this section because it closed due to a disaster or other emergency. For any facility that so attests—

(i) The ESRD facility would need to request such an exception from CMS, in the form and manner specified by CMS, within 60 days of the facility's closure, and the ESRD facility must inform the MAC of this request in writing;

(ii) With 30 days of CMS's receipt of the facility's request, CMS will review the request and either approve the request based on a determination that the ESRD facility closed due to a disaster or other emergency, or deny the request, and will inform both the facility and the MAC of its decision; and

(iii) If CMS approves the request, the exception under this paragraph (g)(6) will be applicable for a period

consisting of the remainder of the cost reporting year (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent, except as specified in paragraph (g)(4) of this section) in which the closure occurred and the following full 2 cost reporting years. After this period the ESRD facility would follow the general attestation process for the low-volume adjustment specified in paragraph (e) of this section and this paragraph (g).

(iv) The ESRD facility that attests under this paragraph (g)(6) to have closed due to a disaster or other emergency would need to notify CMS and the MAC, in the form and manner specified by CMS, within 30 days reopening and providing renal dialysis services. Within 30 days of CMS's receipt of the facility's notification, CMS will confirm receipt to the facility and the MAC of the facility's notification and the ESRD facility will be able to receive the low-volume adjustment as of the date of reopening, so long as all other requirements for the low-volume adjustment are met.

(v) The ESRD facility must maintain documentation regarding its closure, and must provide such supporting documentation to CMS and/or the MAC upon request.

* * * * *

■ 6. Section 413.234 is amended by:
■ a. Adding paragraph (b)(1)(iii);
■ b. Revising paragraph (c)(1)(i); and
■ c. Adding paragraphs (c)(1)(ii), (c)(3), and (g).

The additions and revision read as follows:

§ 413.234 Drug designation process.

* * * * *

(b) * * *

(1) * * *

(iii) The new renal dialysis drug or biological product is paid for using the add-on payment adjustment described in paragraphs (c)(3) and (g) of this section, referred to as the post-transitional drug add-on payment adjustment (TDAPA) add-on payment adjustment.

* * * * *

(c) * * *

(1) * * *

(i) Following payment of the transitional drug add-on payment adjustment, the new renal dialysis drug or biological product is paid the post-TDAPA add-on payment adjustment as set forth in paragraphs (c)(3) and (g) of this section.

(ii) Following payment of the transitional drug add-on payment adjustment the ESRD PPS base rate will not be modified.

* * * * *

(3) For any new renal dialysis drug or biological product that is eligible for payment using the transitional drug add-on payment adjustment described in paragraphs (b)(1)(iii) and (c)(1) of this section, CMS applies a post-TDAPA add-on payment adjustment to all ESRD PPS claims that is calculated using the methodology set forth in paragraph (g) of this section. CMS will apply the post-TDAPA add-on payment adjustment beginning 8 calendar quarters after the first calendar quarter in which the transitional drug add-on payment adjustment is paid for the applicable product, and ending 12 calendar quarters after the end of the last calendar quarter in which the transitional drug add-on payment adjustment is paid for the applicable product. If CMS stops receiving the latest full calendar quarter of ASP data for the applicable renal dialysis drug or biological product during the applicable time period specified in paragraph (c)(1) of this section or during the 3-year period following such applicable time period, CMS will not pay any post-TDAPA add-on payment adjustment for such product in any future year.

* * * * *

(g) *Post-TDAPA add-on payment adjustment methodology.* CMS uses the following methodology to calculate the post-TDAPA add-on payment adjustment described in paragraph (c)(3) of this section:

(1) CMS bases the calculation on the most recent 12-month period of utilization for the new renal dialysis drug or biological product and the most recent available full calendar quarter of ASP data. If the most recent full calendar quarter of ASP data reflects zero or negative sales, then the calculation is based on 100 percent of WAC and, when WAC is not available, the payment is based on the drug manufacturer's invoice.

(2) CMS calculates the post-TDAPA add-on payment adjustment annually as the expenditure for the new renal dialysis drug or biological product divided by the total number of ESRD PPS treatments during the same period.

(3) CMS applies a reduction factor to the post-TDAPA add-on payment adjustment for case mix standardization to reflect estimated increases resulting from the application of the patient-level adjustments as described in paragraph (g)(5) of this section. This reduction factor is calculated based on the patient-level adjustments (as described in § 413.235) applicable to the most recent 12-month period of utilization of ESRD PPS claims.

(4) The amount of the post-TDAPA add-on payment adjustment is equal to 65 percent of the amount calculated in paragraph (g)(2) of this section, multiplied by the reduction factor specified in paragraph (g)(3) of this section, and multiplied by the latest available forecast of annual growth in the ESRD bundled market basket composite price proxy for pharmaceuticals.

(5) The post-TDAPA add-on payment adjustment that is applied to an ESRD PPS claim is adjsuted by any applicable patient-level case-mix adjustments under § 413.235.

■ 7. Section 413.235 is amended by revising paragraph (b) to read as follows:

§ 413.235 Patient-level adjustments.

* * * * *

(b) CMS adjusts the per treatment base rate for Pediatric ESRD Patients in accordance with section 1881(b)(14)(D)(iv)(I) of the Act as follows:

(1) To account for patient age and treatment modality; and

(2) Beginning January 1, 2024, to provide a per-treatment transitional add-on payment adjustment of 30 percent of the per treatment payment amount under § 413.230 for renal dialysis services furnished to Pediatric ESRD Patients during calendar years 2024, 2025, and 2026.

* * * * *

■ 8. Section 413.236 is amended by revising paragraph (b)(2) to read as follows:

§ 413.236 Transitional add-on payment adjustment for new and innovative equipment and supplies.

* * * * *

(b) * * *

(2) Is new, meaning a complete application has been submitted to CMS under paragraph (c) of this section within 3 years of the date of the Food and Drug Administration (FDA) marketing authorization;

* * * * *

PART 512—RADIATION ONCOLOGY MODEL AND END STAGE RENAL DISEASE TREATMENT CHOICES MODEL

■ 9. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

■ 10. Section 512.390 is amended by removing paragraph (c)(5) and adding paragraph (d).

The addition reads as follows:

§ 512.390 Notification, data sharing, and targeted review.

* * * * *

(d) *Review of targeted review decisions.* The Administrator may review a targeted review request when administrative review is requested by an ETC Participant within 15-calendar days of a targeted review request determination made by CMS.

(1) *Administrative review.* Within 45 days of the date of the ETC Participant's request for administrative review, the CMS Administrator may act as follows:

(i) Decline to review a targeted review request determination made by CMS;

(ii) Render a final decision based on the CMS Administrator's review of the targeted review request determination; or

(iii) Choose to take no action on the request for administrative review.

(2) *Administrative review determinations.* The targeted review determination made by the CMS Administrator is final if the CMS Administrator declines an ETC Participant's request for administrative review or if the CMS Administrator does not take any action on the ETC Participant's request for administrative review by the end of the 45-day period described in paragraph (d)(1) of this section. CMS–1782–F

Dated: October 25, 2023.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2023–23915 Filed 10–27–23; 4:15 pm]

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Part IV

Department of Energy

10 CFR Part 430
Energy Conservation Program: Energy Conservation Standards for Dehumidifiers; Proposed Rule

DEPARTMENT OF ENERGY

10 CFR Part 430

[EERE–2019–BT–STD–0043]

RIN 1904–AE61

Energy Conservation Program: Energy Conservation Standards for Dehumidifiers

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

ACTION: Notice of proposed rulemaking and announcement of public meeting.

SUMMARY: The Energy Policy and Conservation Act, as amended (''EPCA''), prescribes energy conservation standards for various consumer products and certain commercial and industrial equipment, including dehumidifiers. EPCA also requires the U.S. Department of Energy (''DOE'') to periodically determine whether more stringent standards would be technologically feasible and economically justified, and would result in significant energy savings. In this notice of proposed rulemaking (''NOPR''), DOE proposes amended energy conservation standards for dehumidifiers, and also announces a public meeting to receive comment on these proposed standards and associated analyses and results.

DATES:

Comments: DOE will accept comments, data, and information regarding this NOPR no later than January 5, 2024.

Meeting: DOE will hold a public meeting via webinar on Thursday, December 14, 2023, from 1:00 p.m. to 4:00 p.m. See section VII of this document, ''Public Participation,'' for webinar registration information, participant instructions, and information about the capabilities available to webinar participants.

Comments regarding the likely competitive impact of the proposed standard should be sent to the U.S. Department of Justice (''DOJ'') contact listed in the **ADDRESSES** section on or before December 6, 2023.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *www.regulations.gov* under docket number EERE–2019–BT–STD–0043. Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–2019–BT–STD–0043, by any of the following methods:

Email: Dehumidifiers2019STD0043@ee.doe.gov. Include docket number EERE–2019–BT–STD–0043 in the subject line of the message.

Postal Mail: Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–1445. If possible, please submit all items on a compact disc (''CD''), in which case it is not necessary to include printed copies.

Hand Delivery/Courier: Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–1445. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimiles (''faxes'') will be accepted. For detailed instructions on submitting comments and additional information on this process, see section IV of this document.

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

The docket web page can be found at *www.regulations.gov/docket/EERE-2019-BT-STD-0043.* The docket web page contains instructions on how to access all documents, including public comments, in the docket. See section VII of this document for information on how to submit comments through *www.regulations.gov.*

EPCA requires the Attorney General to provide DOE a written determination of whether the proposed standard is likely to lessen competition. The U.S. Department of Justice Antitrust Division invites input from market participants and other interested persons with views on the likely competitive impact of the proposed standard. Interested persons may contact the Division at *energy.standards@usdoj.gov* on or before the date specified in the **DATES** section. Please indicate in the subject line of your email the title and docket number of this proposed rulemaking.

FOR FURTHER INFORMATION CONTACT:

Dr. Carl Shapiro, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–2J, 1000 Independence Avenue SW, Washington, DC 20585–0121. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

Mr. Peter Cochran, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–9496. Email: *Peter.Cochran@hq.doe.gov.*

For further information on how to submit a comment, review other public comments and the docket, or participate in the public meeting, contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

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I. Synopsis of the Proposed Rule

The Energy Policy and Conservation Act, Public Law 94–163, as amended (''EPCA''),[1] authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. (42 U.S.C. 6291–6317) Title III, Part B of EPCA [2] established the Energy Conservation Program for Consumer Products Other Than Automobiles. (42 U.S.C. 6291–6309) These products include dehumidifiers, the subject of this proposed rulemaking.

Pursuant to EPCA, any new or amended energy conservation standard must be designed to achieve the maximum improvement in energy efficiency that DOE determines is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) Furthermore, the new or amended standard must result in a significant conservation of energy. (42 U.S.C. 6295(o)(3)(B)) EPCA also provides that not later than 6 years after issuance of any final rule establishing or amending a standard, DOE must publish either a notice of determination that standards for the product do not need to be amended, or a NOPR including new proposed energy conservation standards (proceeding to a final rule, as appropriate). (42 U.S.C. 6295(m))

In accordance with these and other statutory provisions discussed in this document, DOE analyzed the benefits and burdens of four trial standard levels (''TSLs'') for dehumidifiers. The TSLs and their associated benefits and burdens are discussed in detail in sections V.A through V.C of this document. As discussed in section V.C of this document, DOE has tentatively determined that TSL 3 represents the maximum improvement in energy efficiency that is technologically feasible and economically justified. The proposed standards, which are expressed in Integrated Energy Factor (''IEF''), or the volume of water in liters (''L'') removed by a kilowatt hour (''kWh'') of energy, are shown in Table I.1. These proposed standards, if adopted, would apply to all dehumidifiers listed in Table I.1. manufactured in, or imported into, the United States starting on the date 3 years after the publication of the final rule for this proposed rulemaking.

[1] All references to EPCA in this document refer to the statute as amended through the Energy Act of 2020, Public Law 116–260 (Dec. 27, 2020), which reflect the last statutory amendments that impact Parts A and A–1 of EPCA.

[2] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

TABLE I.1—PROPOSED ENERGY CONSERVATION STANDARDS FOR DEHUMIDIFIERS

Portable dehumidifier product capacity (pints/day)	Minimum integrated energy factor (L/kWh)
25.00 or less	1.70
25.01–50.00	2.01
50.01 or more	3.10
Whole-home dehumidifier product case volume (cubic feet):	
8.0 or less	2.22
More than 8.0	3.81

A. Benefits and Costs to Consumers

Table I.2 presents DOE's evaluation of the economic impacts of the proposed standards on consumers of dehumidifiers, as measured by the average life-cycle cost (''LCC'') savings and the simple payback period (''PBP'').[3] The average LCC savings are positive for all product classes, and the PBP is less than the average lifetime of dehumidifiers, which is estimated to be 10 years for portable dehumidifiers and 12 years for whole-home dehumidifiers (see section IV.F.6 of this document).

TABLE I.2—IMPACTS OF PROPOSED ENERGY CONSERVATION STANDARDS ON CONSUMERS OF DEHUMIDIFIERS

Product class	Average LCC savings (2022$)	Simple payback period (years)
Portable dehumidifiers, ≤25.00 pints/day	$42	0.9
Portable dehumidifiers, 25.01–50.00 pints/day	81	0.6
Portable dehumidifiers, >50.00 pints per day	31	4.8
Whole-home dehumidifiers, ≤8.0 cubic feet case volume	56	6.4
Whole-home dehumidifiers, >8.0 cubic feet case volume	146	5.7

DOE's analysis of the impacts of the proposed standards on consumers is described in section IV.F of this document.

B. Impact on Manufacturers [4]

The industry net present value (INPV) is the sum of the discounted cash flows to the industry from the base year through the end of the analysis period (2023–2057). Using a real discount rate of 8.4 percent, DOE estimates that the INPV for manufacturers of dehumidifiers in the case without amended standards is $158.3 million. Under the proposed standards, the change in INPV is estimated to range from −3.3 percent to −2.1 percent, which is approximately −$5.2 million to −$3.3 million. In order to bring products into compliance with amended standards, it is estimated that the industry would incur total conversion costs of $6.9 million.

DOE's analysis of the impacts of the proposed standards on manufacturers is described in section IV.J of this document. The analytic results of the manufacturer impact analysis (''MIA'') are presented in section V.B.2 of this document.

C. National Benefits and Costs

DOE's analyses indicate that the proposed energy conservation standards for dehumidifiers would save a significant amount of energy. Relative to the case without amended standards, the lifetime energy savings for dehumidifiers purchased in the 30-year period that begins in the anticipated year of compliance with the amended standards (2028–2057) amount to 0.33 quadrillion British thermal units (''Btu''), or quads.[5] This represents a savings of 5.8 percent relative to the energy use of these products in the case without amended standards (referred to as the ''no-new-standards case'').

The cumulative net present value (''NPV'') of total consumer benefits of the proposed standards for dehumidifiers ranges from $1.26 billion (at a 7-percent discount rate) to $2.61 billion (at a 3-percent discount rate). This NPV expresses the estimated total value of future operating cost savings minus the estimated increased product costs for dehumidifiers purchased from 2028 through 2057.

In addition, the proposed standards for dehumidifiers are projected to yield significant environmental benefits. DOE estimates that the proposed standards would result in cumulative emission reductions (over the same period as for energy savings) of 6.94 million metric tons (''Mt'') [6] of carbon dioxide (''CO_2''), 1.76 thousand tons of sulfur dioxide (''SO_2''), 11.81 thousand tons of nitrogen oxides (''NO_X''), 51.94 thousand tons of methane (''CH_4''), 0.06 thousand tons of nitrous oxide (''N_2O''), and 0.01 tons of mercury (''Hg'').[7]

DOE estimates the value of climate benefits from a reduction in greenhouse gases (''GHG'') using four different estimates of the social cost (''SC'') of

[3] The average LCC savings refer to consumers that are affected by a standard and are measured relative to the efficiency distribution in the no-new-standards case, which depicts the market in the compliance year in the absence of new or amended standards (see section IV.F.9 of this document). The simple PBP, which is designed to compare specific efficiency levels, is measured relative to the baseline product (see section IV.C of this document).

[4] All monetary values in this document are expressed in 2022 dollars.

[5] The quantity refers to full-fuel-cycle (''FFC'') energy savings. FFC energy savings includes the energy consumed in extracting, processing, and transporting primary fuels (*i.e.,* coal, natural gas, petroleum fuels), and, thus, presents a more complete picture of the impacts of energy efficiency standards. For more information on the FFC metric, see section IV.H.2 of this document.

[6] A metric ton is equivalent to 1.1 short tons. Results for emissions other than CO_2 are presented in short tons.

[7] DOE calculated emissions reductions relative to the no-new-standards case, which reflects key assumptions in the *Annual Energy Outlook 2023* (''*AEO2023*''). *AEO2023* reflects, to the extent possible, laws and regulations adopted through mid-November 2022, including the Inflation Reduction Act. See section IV.K of this document for further discussion of AEO2023 assumptions that affect air pollutant emissions.

CO_2 (''SC–CO_2''), the social cost of methane (''SC–CH_4''), and the social cost of nitrous oxide (''SC–N_2O''). Together these represent the social cost of GHG (''SC–GHG''). DOE used interim SC–GHG values (in terms of benefit per ton of GHG avoided) developed by the Interagency Working Group on the Social Cost of Greenhouse Gases (''IWG'').[8] The derivation of these values is discussed in section IV.L of this document. For presentational purposes, the climate benefits associated with the average SC–GHG at a 3-percent discount rate are estimated to be $0.40 billion. DOE does not have a single central SC–GHG point estimate and emphasizes the importance and value of considering the benefits calculated using all four sets of SC–GHG estimates.

DOE estimated the monetary health benefits of SO_2 and NO_X emissions reductions using benefit per ton estimates from the Environmental Protection Agency,[9] as discussed in section IV.L of this document. DOE estimated the present value of the health benefits would be $0.33 billion using a 7-percent discount rate, and $0.74 billion using a 3-percent discount rate.[10] DOE is currently only monetizing health benefits from changes in ambient fine particulate matter ($PM_{2.5}$) concentrations from two precursors (SO_2 and NO_X), and from changes in ambient ozone from one precursor (for NO_X), but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions.

Table I.3 summarizes the monetized economic benefits and costs expected to result from the proposed standards for dehumidifiers. There are other important unquantified effects, including certain unquantified climate benefits, unquantified public health benefits from the reduction of toxic air pollutants and other emissions, unquantified energy security benefits, and distributional effects, among others.

TABLE I.3—SUMMARY OF MONETIZED BENEFITS AND COSTS OF PROPOSED ENERGY CONSERVATION STANDARDS FOR DEHUMIDIFIERS

[Trial Standard Level (''TSL'') 3]

	Billion ($2022)
3% discount rate	
Consumer Operating Cost Savings	2.75
Climate Benefits*	0.40
Health Benefits**	0.74
Total Benefits†	3.89
Consumer Incremental Product Costs‡	0.14
Net Benefits	3.75
Change in Producer Cashflow (INPV)‡‡	(0.005)–(0.003)
7% discount rate	
Consumer Operating Cost Savings	1.34
Climate Benefits* (3% discount rate)	0.40
Health Benefits**	0.33
Total Benefits†	2.07
Consumer Incremental Product Costs‡	0.08
Net Benefits	1.99
Change in Producer Cashflow (INPV)‡‡	(0.005)–(0.003)

Note: This table presents the costs and benefits associated with dehumidifiers shipped in 2028–2057. These results include consumer, climate, and health benefits that accrue after 2057 from the products shipped in 2028–2057.

*Climate benefits are calculated using four different estimates of the social cost of carbon (SC–CO_2), methane (SC–CH_4), and nitrous oxide (SC–N_2O) (model average at 2.5-percent, 3-percent, and 5-percent discount rates; 95th percentile at a 3-percent discount rate) (see section IV.L of this document). Together these represent the global SC–GHG. For presentational purposes of this table, the climate benefits associated with the average SC–GHG at a 3-percent discount rate are shown, but DOE does not have a single central SC–GHG point estimate. To monetize the benefits of reducing GHG emissions this analysis uses the interim estimates presented in the Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates Under Executive Order 13990 published in February 2021 by the Interagency Working Group on the Social Cost of Greenhouse Gases (IWG).

**Health benefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions. See section IV.L of this document for more details.

†Total and net benefits include those consumer, climate, and health benefits that can be quantified and monetized. For presentation purposes, total and net benefits for both the 3-percent and 7-percent cases are presented using the average SC–GHG with 3-percent discount rate, but DOE does not have a single central SC–GHG point estimate and emphasizes the importance and value of considering the benefits calculated using all four sets of SC–GHG estimates.

‡Costs include incremental equipment costs as well as installation costs.

‡‡Operating Cost Savings are calculated based on the life cycle costs analysis and national impact analysis as discussed in detail below. *See* sections IV.F and IV.H of this document. DOE's national impacts analysis includes all impacts (both costs and benefits) along the distribution chain beginning with the increased costs to the manufacturer to manufacture the product and ending with the increase in price experienced by the consumer. DOE also separately conducts a detailed analysis on the impacts on manufacturers (*i.e.,* manufacturer impact analysis, or ''MIA''). *See* section IV.J of this document. In the detailed MIA, DOE models manufacturers' pricing decisions based on assumptions regarding investments, conversion costs, cashflow, and margins. The MIA produces a range of impacts, which is the rule's expected impact on the INPV. The change in INPV is the present value of all changes in industry cash flow, including changes in production costs, capital expenditures, and manufacturer profit margins. Change in INPV is calculated using the industry weighted average cost of capital value of 8.4 percent that is estimated in the manufacturer impact analysis (*see* chapter 12 of the NOPR TSD for a complete description of the industry weighted average cost of capital). For dehumidifiers, the change in INPV ranges from −$5 million to −$3 million. DOE accounts for that range of likely impacts in analyzing whether a trial standard level is economically justified. *See* section V.C of this document. DOE is presenting the range of impacts to the INPV under two markup scenarios: the Preservation of Gross Margin scenario, which is the manufacturer markup scenario used in the calculation of Consumer Operating Cost Savings in this table; and the Preservation of Operating Profit Markup scenario, where DOE assumed manufacturers would not be able to increase per-unit operating profit in proportion to increases in manufacturer production costs. DOE includes the range of estimated INPV in the above table, drawing on the MIA explained further in section IV.J of this document to provide additional context for assessing the estimated impacts of this proposal to society, including potential changes in production and consumption, which is consistent with OMB's Circular A–4 and E.O. 12866. If DOE were to include the INPV into the net benefit calculation for this proposed rule, the net benefits would range from $3.74 billion to $3.75 billion at 3-percent discount rate and would range from $1.98 billion to $1.99 billion at 7-percent discount rate. DOE seeks comment on this approach.

[8] To monetize the benefits of reducing GHG emissions this analysis uses the interim estimates presented in the *Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates Under Executive Order 13990* published in February 2021 by the IWG. (''February 2021 SC–GHG TSD''). *www.whitehouse.gov/wp-content/uploads/2021/02/TechnicalSupportDocument_SocialCostofCarbonMethaneNitrousOxide.pdf.*

[9] U.S. EPA. Estimating the Benefit per Ton of Reducing Directly Emitted $PM_{2.5}$, $PM_{2.5}$ Precursors and Ozone Precursors from 21 Sectors. Available at *www.epa.gov/benmap/estimating-benefit-ton-reducing-pm25-precursors-21-sectors.*

[10] DOE estimates the economic value of these emissions reductions resulting from the considered trial standard levels (''TSLs'') for the purpose of complying with the requirements of Executive Order 12866.

The benefits and costs of the proposed standards can also be expressed in terms of annualized values. The monetary values for the total annualized net benefits are (1) the reduced consumer operating costs, minus (2) the increase in product purchase prices and installation costs, plus (3) the value of climate and health benefits of emission reductions, all annualized.[11]

The national operating cost savings are domestic private U.S. consumer monetary savings that occur as a result of purchasing the covered products and are measured for the lifetime of dehumidifiers shipped between 2028 and 2057. The benefits associated with reduced emissions achieved as a result of the proposed standards are also calculated based on the lifetime of dehumidifiers shipped between 2028 and 2057. Total benefits for both the 3-percent and 7-percent cases are presented using the average GHG social costs with a 3-percent discount rate. Estimates of SC–GHG values are presented for all four discount rates in section V.B.6 of this document.

Table I.4 presents the total estimated monetized benefits and costs associated with the proposed standard, expressed in terms of annualized values. The results under the primary estimate are as follows.

Using a 7-percent discount rate for consumer benefits and costs and health benefits from reduced NO_X and SO_2 emissions, and the 3-percent discount rate case for climate benefits from reduced GHG emissions, the estimated cost of the standards proposed in this rule is $8.55 million per year in increased equipment costs, while the estimated annual benefits are $142.04 million in reduced equipment operating costs, $22.85 million in climate benefits, and $34.54 million in health benefits. In this case, the net benefit would amount to $190.89 million per year.

Using a 3-percent discount rate for all benefits and costs, the estimated cost of the proposed standards is $7.89 million per year in increased equipment costs, while the estimated annual benefits are $157.99 million in reduced operating costs, $22.85 million in climate benefits, and $42.30 million in health benefits. In this case, the net benefit would amount to $215.24 million per year.

TABLE I.4—ANNUALIZED BENEFITS AND COSTS OF PROPOSED ENERGY CONSERVATION STANDARDS FOR DEHUMIDIFIERS

[TSL 3]

	Million 2022$/year		
	Primary estimate	Low-net-benefits estimate	High-net-benefits estimate
3% discount rate			
Consumer Operating Cost Savings	157.99	153.04	163.15
Climate Benefits*	22.85	22.66	22.93
Health Benefits**	42.30	41.95	42.42
Total Benefits†	223.14	217.65	228.50
Consumer Incremental Product Costs‡	7.89	7.94	7.77
Net Benefits	215.24	209.71	220.74
Change in Producer Cashflow (INPV)‡‡	(0.5)–(0.3)	(0.5)–(0.3)	(0.5)–(0.3)
7% discount rate			
Consumer Operating Cost Savings	142.04	138.10	146.50
Climate Benefits* (3% discount rate)	22.85	22.66	22.93
Health Benefits**	34.54	34.31	34.64
Total Benefits†	199.44	195.07	204.06
Consumer Incremental Product Costs‡	8.55	8.58	8.44
Net Benefits	190.89	186.49	195.62
Change in Producer Cashflow (INPV)‡‡	(0.5)–(0.3)	(0.5)–(0.3)	(0.5)–(0.3)

Note: This table presents the costs and benefits associated with dehumidifiers shipped in 2028–2057. These results include consumer, climate, and health benefits that accrue after 2057 from the products shipped in 2028 – 2057. The Primary, Low Net Benefits, and High Net Benefits Estimates utilize projections of energy prices from the AEO 2023 Reference case, Low Economic Growth case, and High Economic Growth case, respectively. In addition, incremental equipment costs reflect a medium decline rate in the Primary Estimate, a low decline rate in the Low Net Benefits Estimate, and a high decline rate in the High Net Benefits Estimate. The methods used to derive projected price trends are explained in sections IV.F.1 and IV.H.3 of this document. Note that the Benefits and Costs may not sum to the Net Benefits due to rounding.

* Climate benefits are calculated using four different estimates of the global SC–GHG (see section IV.L of this document). For presentational purposes of this table, the climate benefits associated with the average SC–GHG at a 3-percent discount rate are shown, but DOE does not have a single central SC–GHG point estimate and emphasizes the importance and value of considering the benefits calculated using all four sets of SC–GHG estimates. To monetize the benefits of reducing GHG emissions this analysis uses the interim estimates presented in the Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates Under Executive Order 13990 published in February 2021 by the Interagency Working Group on the Social Cost of Greenhouse Gases (IWG).

** Health benefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits, but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions. See section IV.L of this document for more details.

† Total benefits for both the 3-percent and 7-percent cases are presented using the average SC–GHG with 3-percent discount rate, but DOE does not have a single central SC–GHG point estimate.

‡‡ Costs include incremental equipment costs as well as installation costs.

[11] To convert the time series of costs and benefits into annualized values, DOE calculated a present value in 2023, the year used for discounting the NPV of total consumer costs and savings. For the benefits, DOE calculated a present value associated with each year's shipments in the year in which the shipments occur (*e.g.,* 2030), and then discounted the present value from each year to 2023. Using the present value, DOE then calculated the fixed annual payment over a 30-year period, starting in the compliance year, that yields the same present value.

‡‡ Operating Cost Savings are calculated based on the life cycle costs analysis and national impact analysis as discussed in detail below. *See* sections IV.F and IV.H of this document. DOE's national impacts analysis includes all impacts (both costs and benefits) along the distribution chain beginning with the increased costs to the manufacturer to manufacture the product and ending with the increase in price experienced by the consumer. DOE also separately conducts a detailed analysis on the impacts on manufacturers (*i.e.,* manufacturer impact analysis, or ''MIA''). *See* section IV.J of this document. In the detailed MIA, DOE models manufacturers' pricing decisions based on assumptions regarding investments, conversion costs, cashflow, and margins. The MIA produces a range of impacts, which is the rule's expected impact on the INPV. The change in INPV is the present value of all changes in industry cash flow, including changes in production costs, capital expenditures, and manufacturer profit margins. The annualized change in INPV is calculated using the industry weighted average cost of capital value of 8.4 percent that is estimated in the manufacturer impact analysis (*see* chapter 12 of the NOPR TSD for a complete description of the industry weighted average cost of capital). For dehumidifiers, the annualized change in INPV ranges from −$0.5 million to −$0.3 million. DOE accounts for that range of likely impacts in analyzing whether a trial standard level is economically justified. *See* section V.C of this document. DOE is presenting the range of impacts to the INPV under two markup scenarios: the Preservation of Gross Margin scenario, which is the manufacturer markup scenario used in the calculation of Consumer Operating Cost Savings in this table; and the Preservation of Operating Profit Markup scenario, where DOE assumed manufacturers would not be able to increase per-unit operating profit in proportion to increases in manufacturer production costs. DOE includes the range of estimated annualized change in INPV in the above table, drawing on the MIA explained further in section IV.J of this document to provide additional context for assessing the estimated impacts of this proposal to society, including potential changes in production and consumption, which is consistent with OMB's Circular A–4 and E.O. 12866. If DOE were to include the INPV into the annualized net benefit calculation for this proposed rule, the annualized net benefits would range from $214.8 million to $214.9 million at 3-percent discount rate and would range from $190.4 million to $190.6 million at 7-percent discount rate. DOE seeks comment on this approach.

DOE's analysis of the national impacts of the proposed standards is described in sections IV.H, IV.K, and IV.L of this document.

D. Conclusion

DOE has tentatively concluded that the proposed standards represent the maximum improvement in energy efficiency that is technologically feasible and economically justified, and would result in the significant conservation of energy. Specifically, with regards to technological feasibility, products achieving these standard levels are already commercially available for all product classes covered by this proposal. As for economic justification, DOE's analysis shows that the benefits of the proposed standard exceed, to a great extent, the burdens of the proposed standards.

Using a 7-percent discount rate for consumer benefits and costs and NO_X and SO_2 reduction benefits, and a 3-percent discount rate case for GHG social costs, the estimated cost of the proposed standards for dehumidifiers is $8.55 million per year in increased product costs, while the estimated annual benefits are $142.04 million in reduced product operating costs, $22.85 million in climate benefits, and $34.54 million in health benefits. The net benefit amounts to $190.89 million per year.

The significance of energy savings offered by a new or amended energy conservation standard cannot be determined without knowledge of the specific circumstances surrounding a given rulemaking.[12] For example, some covered products and equipment have substantial energy consumption occur during periods of peak energy demand. The impacts of these products on the energy infrastructure can be more pronounced than products with relatively constant demand. Accordingly, DOE evaluates the significance of energy savings on a case-by-case basis.

As previously mentioned, the standards are projected to result in estimated national energy savings of 0.33 quad full-fuel-cycle (''FFC''), the equivalent of the primary annual energy use of 3.5 million homes. In addition, they are projected to reduce CO_2 emissions by 6.94 Mt, SO_2 emissions by 1.76 thousand tons, NO_X emissions by 11.81 thousand tons, CH_4 emissions by 51.94 thousand tons, N_2O emissions by 0.06 thousand tons, Hg emissions by 0.01 tons. Based on these findings, DOE has initially determined the energy savings from the proposed standard levels are ''significant'' within the meaning of 42 U.S.C. 6295(o)(3)(B). The basis for these tentative conclusions is detailed in the remainder of this document and the accompanying technical support document (''TSD'').

DOE also considered more stringent energy efficiency levels as potential standards and is still considering them in this rulemaking. However, DOE has tentatively concluded that the potential burdens of more stringent energy efficiency levels would outweigh the projected benefits.

Based on consideration of the public comments DOE receives in response to this document and related information collected and analyzed during the course of this rulemaking effort, DOE may adopt energy efficiency levels presented in this document that are either higher or lower than the proposed standards, or some combination of level(s) that incorporate the proposed standards in part.

II. Introduction

The following section briefly discusses the statutory authority underlying this proposed rule as well as some of the relevant historical background related to the establishment of standards for dehumidifiers.

A. Authority

EPCA authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. Title III, Part B of EPCA established the Energy Conservation Program for Consumer Products Other Than Automobiles. These products include dehumidifiers, the subject of this document. (42 U.S.C. 6295(cc)) EPCA prescribed initial energy conservation standards for these products. *Id.* EPCA further provides that, not later than 6 years after the issuance of any final rule establishing or amending a standard, DOE must publish either a notice of determination that standards for the product do not need to be amended, or a NOPR including new proposed energy conservation standards (proceeding to a final rule, as appropriate). (42 U.S.C. 6295(m)(1))

The energy conservation program under EPCA consists essentially of four parts: (1) testing, (2) labeling, (3) the establishment of Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA specifically include definitions (42 U.S.C. 6291), test procedures (42 U.S.C. 6293), labeling provisions (42 U.S.C. 6294), energy conservation standards (42 U.S.C. 6295), and the authority to require information and reports from manufacturers (42 U.S.C. 6296).

Federal energy efficiency requirements for covered products established under EPCA generally supersede State laws and regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6297(a)–(c)) DOE may, however, grant waivers of Federal preemption for particular State laws or regulations, in accordance with the procedures and other provisions set forth under EPCA. (42 U.S.C. 6297(d))

[12] Procedures, Interpretations, and Policies for Consideration in New or Revised Energy Conservation Standards and Test Procedures for Consumer Products and Commercial/Industrial Equipment, 86 FR 70892, 70901 (Dec. 13, 2021).

Subject to certain criteria and conditions, DOE is required to develop test procedures to measure the energy efficiency, energy use, or estimated annual operating cost of each covered product. (42 U.S.C. 6295(o)(3)(A) and 42 U.S.C. 6295(r)) Manufacturers of covered products must use the prescribed DOE test procedure as the basis for certifying to DOE that their products comply with the applicable energy conservation standards adopted under EPCA and when making representations to the public regarding the energy use or efficiency of those products. (42 U.S.C. 6293(c) and 42 U.S.C. 6295(s)) Similarly, DOE must use these test procedures to determine whether the products comply with standards adopted pursuant to EPCA. (42 U.S.C. 6295(s)) The DOE test procedures for dehumidifiers appear at title 10 of the Code of Federal Regulations (''CFR'') part 430, subpart B, appendix X1.

DOE must follow specific statutory criteria for prescribing new or amended standards for covered products, including dehumidifiers. Any new or amended standard for a covered product must be designed to achieve the maximum improvement in energy efficiency that the Secretary of Energy determines is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A) Furthermore, DOE may not adopt any standard that would not result in the significant conservation of energy. (42 U.S.C. 6295(o)(3))

Moreover, DOE may not prescribe a standard: (1) for certain products, including dehumidifiers, if no test procedure has been established for the product, or (2) if DOE determines by rule that the standard is not technologically feasible or economically justified. (42 U.S.C. 6295(o)(3)(A)–(B)) In deciding whether a proposed standard is economically justified, DOE must determine whether the benefits of the standard exceed its burdens. (42 U.S.C. 6295(o)(2)(B)(i)) DOE must make this determination after receiving comments on the proposed standard, and by considering, to the greatest extent practicable, the following seven statutory factors:

(1) The economic impact of the standard on manufacturers and consumers of the products subject to the standard;

(2) The savings in operating costs throughout the estimated average life of the covered products in the type (or class) compared to any increase in the price, initial charges, or maintenance expenses for the covered products that are likely to result from the standard;

(3) The total projected amount of energy (or as applicable, water) savings likely to result directly from the standard;

(4) Any lessening of the utility or the performance of the covered products likely to result from the standard;

(5) The impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the standard;

(6) The need for national energy and water conservation; and

(7) Other factors the Secretary of Energy (''Secretary'') considers relevant. (42 U.S.C. 6295(o)(2)(B)(i)(I)–(VII))

Further, EPCA establishes a rebuttable presumption that a standard is economically justified if the Secretary finds that the additional cost to the consumer of purchasing a product complying with an energy conservation standard level will be less than three times the value of the energy savings during the first year that the consumer will receive as a result of the standard, as calculated under the applicable test procedure. (42 U.S.C. 6295(o)(2)(B)(iii))

EPCA also contains what is known as an ''anti-backsliding'' provision, which prevents the Secretary from prescribing any amended standard that either increases the maximum allowable energy use or decreases the minimum required energy efficiency of a covered product. (42 U.S.C. 6295(o)(1)) Also, the Secretary may not prescribe an amended or new standard if interested persons have established by a preponderance of the evidence that the standard is likely to result in the unavailability in the United States in any covered product type (or class) of performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as those generally available in the United States. (42 U.S.C. 6295(o)(4))

Additionally, EPCA specifies requirements when promulgating an energy conservation standard for a covered product that has two or more subcategories. DOE must specify a different standard level for a type or class of product that has the same function or intended use, if DOE determines that products within such group: (A) consume a different kind of energy from that consumed by other covered products within such type (or class); or (B) have a capacity or other performance-related feature which other products within such type (or class) do not have and such feature justifies a higher or lower standard. (42 U.S.C. 6295(q)(1)) In determining whether a performance-related feature justifies a different standard for a group of products, DOE must consider such factors as the utility to the consumer of the feature and other factors DOE deems appropriate. *Id.* Any rule prescribing such a standard must include an explanation of the basis on which such higher or lower level was established. (42 U.S.C. 6295(q)(2))

Finally, pursuant to the amendments contained in the Energy Independence and Security Act of 2007 (''EISA 2007''), Public Law 110–140, any final rule for new or amended energy conservation standards promulgated after July 1, 2010, is required to address standby mode and off mode energy use. (42 U.S.C. 6295(gg)(3)) Specifically, when DOE adopts a standard for a covered product after that date, it must, if justified by the criteria for adoption of standards under EPCA (42 U.S.C. 6295(o)), incorporate standby mode and off mode energy use into a single standard, or, if that is not feasible, adopt a separate standard for such energy use for that product. (42 U.S.C. 6295(gg)(3)(A)–(B)) DOE's current test procedures for dehumidifiers address standby mode and off mode energy use. In this proposed rulemaking, DOE intends to incorporate such energy use into any amended energy conservation standards that it may adopt.

B. Background

1. Current Standards

In a final rule published on June 13, 2016 (''June 2016 Final Rule''), DOE prescribed the current energy conservation standards for dehumidifiers manufactured on and after June 13, 2019. 81 FR 38338. These standards are set forth in DOE's regulations at 10 CFR 430.32(v)(2).

TABLE II.1—FEDERAL ENERGY CONSERVATION STANDARDS FOR DEHUMIDIFIERS

Portable dehumidifier product capacity (pints/day)	Minimum integrated energy factor (L/kWh)
25.00 or less	1.30

TABLE II.1—FEDERAL ENERGY CONSERVATION STANDARDS FOR DEHUMIDIFIERS—Continued

Portable dehumidifier product capacity (pints/day)	Minimum integrated energy factor (L/kWh)
25.01–50.00	1.60
50.01 or more	2.80
Whole-home dehumidifier product case volume (cubic feet)	
8.0 or less	1.77
More than 8.0	2.41

2. History of Standards Rulemaking for Dehumidifiers

On June 4, 2021, DOE published a Request for Information (''June 2021 RFI'') in the **Federal Register** to collect data and information to inform its decision, consistent with its obligations under EPCA, as to whether the Department should proceed with an energy conservation standards rulemaking for an amended energy conservation standard for dehumidifiers. 86 FR 29964, 29965.

DOE published a notice of public meeting and availability of the preliminary TSD on June 22, 2022 (''June 2022 Preliminary Analysis''). 87 FR 37240. DOE received comments in response to the June 2022 Preliminary Analysis from the interested parties listed in Table II.2.

TABLE II.2—JUNE 2022 PRELIMINARY ANALYSIS WRITTEN COMMENTS

Commenter(s)	Abbreviation	Comment number in the docket	Commenter type
Appliance Standards Awareness Project, American Council for an Energy-Efficient Economy, National Consumer Law Center, Natural Resources Defense Council, Northwest Energy Efficiency Alliance.	Joint Commenters	21	Efficiency Organizations.
Association of Home Appliance Manufacturers	AHAM	22	Trade Association.
Madison Indoor Air Quality	MIAQ	20	Manufacturer.

A parenthetical reference at the end of a comment quotation or paraphrase provides the location of the item in the public record.[13] To the extent that interested parties have provided written comments that are substantively consistent with any oral comments provided during the July 19, 2022, public meeting, DOE cites the written comments throughout this document. Any oral comments provided during the webinar that are not substantively addressed by written comments are summarized and cited separately throughout this document.

C. Deviation From Appendix A

In accordance with section 3(a) of 10 CFR part 430, subpart C, appendix A (''appendix A''), DOE notes that it is deviating from the provision in appendix A regarding the pre-NOPR stages for an energy conservation standards rulemaking. Section 6(a)(2) of appendix A states that if the Department determines it is appropriate to proceed with a rulemaking, the preliminary stages of a rulemaking to issue or amend an energy conservation standard that DOE will undertake will include a framework document and preliminary analysis, or an advance notice of proposed rulemaking. While DOE published a preliminary analysis for this proposed rulemaking, DOE did not publish a framework document in conjunction with the preliminary analysis. 87 FR 37240. DOE notes, however, chapter 2 of the June 2022 Preliminary TSD that accompanied the June 2022 Preliminary Analysis—entitled Analytical Framework, Comments from Interested Parties, and DOE Responses—describes the general analytical framework that DOE uses in evaluating and developing potential amended energy conservation standards. DOE also previously published the June 2021 RFI, in which DOE identified and sought comment on the analyses that would be conducted in support of an energy conservation standards rulemaking for dehumidifiers. 86 FR 29964, 29965–29966. As such, publication of a separate framework document would be largely redundant of previously published documents.

Section 6(f)(2) of appendix A specifies that the length of the public comment period for a NOPR will vary depending upon the circumstances of the particular proposed rulemaking, but will not be less than 75 calendar days. For this NOPR, DOE has opted to instead provide a 60-day comment period. DOE requested comment in the June 2021 RFI on the technical and economic analyses and provided stakeholders a 45-day comment period, after granting a 15-day comment period extension. 86 FR 29964 and 86 FR 34639. Additionally, DOE provided a 60-day comment period for the June 2022 Preliminary Analysis. 87 FR 37240, 37241. The analytical methods used for this NOPR are similar to those used in previous rulemaking documents. As such, DOE believes a 60-day comment period is appropriate and will provide interested parties with a meaningful opportunity to comment on the proposed rule. Section 8(d)(1) of appendix A specifies that test procedure rulemakings establishing methodologies used to evaluate proposed energy conservation standards will be finalized prior to publication of a NOPR proposing new or amended energy conservation standards. Additionally, new test procedures and amended test procedures that impact measured energy use or efficiency will be finalized at least 180 days prior to the close of the

[13] The parenthetical reference provides a reference for information located in the docket of DOE's rulemaking to develop energy conservation standards for dehumidifiers (Docket No. EERE–2019–BT–STD–0043, which is maintained at *www.regulations.gov*). The references are arranged as follows: (commenter name, comment docket ID number, page of that document).

comment period for (1) a NOPR proposing new or amended energy conservation standards or (2) a notice of proposed determination that standards do not need to be amended. In the dehumidifier test procedure final rule published on July 26, 2023, (July 2023 Test Procedure Final Rule), DOE amended the test procedures for dehumidifiers. 88 FR 48035. DOE determined that the amendments adopted will not alter (*i.e.,* will not impact) the measured efficiency of dehumidifiers. *Id.* As such, the requirement that the amended test procedure be finalized at least 180 days prior to the close of the comment period for this NOPR does not apply.

III. General Discussion

DOE developed this proposal after considering oral and written comments, data, and information from interested parties that represent a variety of interests. The following discussion addresses issues raised by these commenters.

A. Scope of Coverage

This NOPR covers those consumer products that meet the definition of ''dehumidifier'' as codified at 10 CFR 430.2.

EPCA defines a dehumidifier as a product that is a self-contained, electrically operated, and mechanically encased assembly, consisting of a refrigerated surface (evaporator) that condenses moisture from the atmosphere, a refrigerating system with an electric motor, an air-circulating fan, and a means for collecting or disposing of the condensate. (42 U.S.C. 6291(34)) In a final rule published on July 31, 2015 (''July 2015 Test Procedure Final Rule''), DOE clarified that this definition of a dehumidifier, codified at 10 CFR 430.2, does not apply to portable air conditioners, room air conditioners, or packaged terminal air conditioners. 80 FR 45802, 45804–45805 (July 31, 2015). DOE also added definitions for portable dehumidifiers and whole-home dehumidifiers to 10 CFR 430.2. Portable dehumidifiers are designed to operate within the dehumidified space without ducting attached, although ducting may be attached optionally. Whole-home dehumidifiers are designed to be installed with inlet ducting for return process air and outlet ducting that supplies dehumidified process air to one or more locations in the dehumidified space. 10 CFR 430.2 DOE further established that dehumidifiers that are able to operate as both a portable and whole-home dehumidifier would be tested and rated for both configurations. 80 FR 45802, 45805–45806. *See* section IV.A.1 of this document for discussion of the product classes analyzed in this NOPR.

B. Test Procedure

EPCA sets forth generally applicable criteria and procedures for DOE's adoption and amendment of test procedures. (42 U.S.C. 6293) Manufacturers of covered products must use these test procedures to certify to DOE that their product complies with energy conservation standards and to quantify the efficiency of their product. DOE's current energy conservation standards for dehumidifiers are expressed in terms of IEF in L/kWh. 10 CFR 430.32(v)(2) and 10 CFR part 430, subpart B, appendix X1.

C. Technological Feasibility

1. General

In each energy conservation standards rulemaking, DOE conducts a screening analysis based on information gathered on all current technology options and prototype designs that could improve the efficiency of the products or equipment that are the subject of the proposed rulemaking. As the first step in such an analysis, DOE develops a list of technology options for consideration in consultation with manufacturers, design engineers, and other interested parties. DOE then determines which of those means for improving efficiency are technologically feasible. DOE considers technologies incorporated in commercially available products or in working prototypes to be technologically feasible. *See* sections 6(b)(3)(i) and 7(b)(1) of appendix A to 10 CFR part 430 subpart C (''appendix A'').

After DOE has determined that particular technology options are technologically feasible, it further evaluates each technology option in light of the following additional screening criteria: (1) practicability to manufacture, install, and service; (2) adverse impacts on product utility or availability; (3) adverse impacts on health or safety; and (4) unique pathway proprietary technologies. *See* sections 6(b)(3)(ii)–(v) and 7(b)(2)–(5) of appendix A. Section IV.B of this document discusses the results of the screening analysis for dehumidifiers, particularly the designs DOE considered, those it screened out, and those that are the basis for the standards considered in this proposed rulemaking. For further details on the screening analysis for this proposed rulemaking, see chapter 4 of the NOPR TSD.

2. Maximum Technologically Feasible Levels

When DOE proposes to adopt a new or amended standard for a type or class of covered product, it must determine the maximum improvement in energy efficiency or maximum reduction in energy use that is technologically feasible for such product. (42 U.S.C. 6295(p)(1)) Accordingly, in the engineering analysis, DOE determined the maximum technologically feasible (''max-tech'') improvements in energy efficiency for dehumidifiers, using the design parameters for the most efficient products available on the market or in working prototypes. The max-tech levels that DOE determined for this proposed rulemaking are described in section IV.C.1.b of this document and in chapter 5 of the NOPR TSD.

D. Energy Savings

1. Determination of Savings

For each trial standard level (''TSL''), DOE projected energy savings from application of the TSL to dehumidifiers purchased in the 30-year period that begins in the year of compliance with the proposed standards (2028–2057).[14] The savings are measured over the entire lifetime of dehumidifiers purchased in the previous 30-year period. DOE quantified the energy savings attributable to each TSL as the difference in energy consumption between each standards case and the no-new-standards case. The no-new-standards case represents a projection of energy consumption that reflects how the market for a product would likely evolve in the absence of amended energy conservation standards.

DOE used its national impact analysis (''NIA'') spreadsheet model to estimate national energy savings (''NES'') from potential amended or new standards for dehumidifiers. The NIA spreadsheet model (described in section IV.H of this document) calculates energy savings in terms of site energy, which is the energy directly consumed by products at the locations where they are used. For electricity, DOE reports national energy savings in terms of primary energy savings, which is the savings in the energy that is used to generate and transmit the site electricity. DOE also calculates NES in terms of FFC energy savings. The FFC metric includes the energy consumed in extracting, processing, and transporting primary

[14] Each TSL is composed of specific efficiency levels for each product class. The TSLs considered for this NOPR are described in section V.A of this document. DOE conducted a sensitivity analysis that considers impacts for products shipped in a 9-year period.

fuels (*i.e.,* coal, natural gas, petroleum fuels), and thus presents a more complete picture of the impacts of energy conservation standards.[15] DOE's approach is based on the calculation of an FFC multiplier for each of the energy types used by covered products or equipment. For more information on FFC energy savings, see section IV.H.1 of this document.

2. Significance of Savings

To adopt any new or amended standards for a covered product, DOE must determine that such action would result in significant energy savings. (42 U.S.C. 6295(o)(3)(B))

The significance of energy savings offered by a new or amended energy conservation standard cannot be determined without knowledge of the specific circumstances surrounding a given rulemaking.[16] For example, some covered products and equipment have most of their energy consumption occur during periods of peak energy demand. The impacts of these products on the energy infrastructure can be more pronounced than products with relatively constant demand. Accordingly, DOE evaluates the significance of energy savings on a case-by-case basis, taking into account the significance of cumulative FFC national energy savings, the cumulative FFC emissions reductions, and the need to confront the global climate crisis, among other factors.

As stated, the standard levels proposed in this document are projected to result in national energy savings of 0.33 quad, the equivalent of the primary annual energy use of 3.5 million homes. Based on the amount of FFC savings, the corresponding reduction in emissions, and the need to confront the global climate crisis, DOE has initially determined the energy savings from the proposed standard levels are ''significant'' within the meaning of 42 U.S.C. 6295(o)(3)(B).

E. Economic Justification

1. Specific Criteria

As noted previously, EPCA provides seven factors to be evaluated in determining whether a potential energy conservation standard is economically justified. (42 U.S.C. 6295(o)(2)(B)(i)(I)–(VII)) The following sections discuss how DOE has addressed each of those seven factors in this proposed rulemaking.

a. Economic Impact on Manufacturers and Consumers

In determining the impacts of a potential new or amended standard on manufacturers, DOE conducts an MIA, as discussed in section IV.J of this document. DOE first uses an annual cash-flow approach to determine the quantitative impacts. This step includes both a short-term assessment—based on the cost and capital requirements during the period between when a regulation is issued and when entities must comply with the regulation—and a long-term assessment over a 30-year period. The industry-wide impacts analyzed include (1) INPV, which values the industry on the basis of expected future cash flows, (2) cash flows by year, (3) changes in revenue and income, and (4) other measures of impact, as appropriate. Second, DOE analyzes and reports the impacts on different types of manufacturers, including impacts on small manufacturers. Third, DOE considers the impact of standards on domestic manufacturer employment and manufacturing capacity, as well as the potential for standards to result in plant closures and loss of capital investment. Finally, DOE takes into account cumulative impacts of various DOE regulations and other regulatory requirements on manufacturers.

For individual consumers, measures of economic impact include the changes in LCC and PBP associated with new or amended standards. These measures are discussed further in the following section. For consumers in the aggregate, DOE also calculates the national net present value of the consumer costs and benefits expected to result from particular standards. DOE also evaluates the impacts of potential standards on identifiable subgroups of consumers that may be affected disproportionately by a standard.

b. Savings in Operating Costs Compared To Increase in Price (LCC and PBP)

EPCA requires DOE to consider the savings in operating costs throughout the estimated average life of the covered product in the type (or class) compared to any increase in the price of, or in the initial charges for, or maintenance expenses of, the covered product that are likely to result from a standard. (42 U.S.C. 6295(o)(2)(B)(i)(II)) DOE conducts this comparison in its LCC and PBP analysis.

The LCC is the sum of the purchase price of a product (including its installation) and the operating expense (including energy, maintenance, and repair expenditures) discounted over the lifetime of the product. The LCC analysis requires a variety of inputs, such as product prices, product energy consumption, energy prices, maintenance and repair costs, product lifetime, and discount rates appropriate for consumers. To account for uncertainty and variability in specific inputs, such as product lifetime and discount rate, DOE uses a distribution of values, with probabilities attached to each value.

The PBP is the estimated amount of time (in years) it takes consumers to recover the increased purchase cost (including installation) of a more-efficient product through lower operating costs. DOE calculates the PBP by dividing the change in purchase cost due to a more stringent standard by the change in annual operating cost for the year that standards are assumed to take effect.

For its LCC and PBP analysis, DOE assumes that consumers will purchase the covered products in the first year of compliance with new or amended standards. The LCC savings for the considered efficiency levels are calculated relative to the case that reflects projected market trends in the absence of new or amended standards. DOE's LCC and PBP analysis is discussed in further detail in section IV.F of this document.

c. Energy Savings

Although significant conservation of energy is a separate statutory requirement for adopting an energy conservation standard, EPCA requires DOE, in determining the economic justification of a standard, to consider the total projected energy savings that are expected to result directly from the standard. (42 U.S.C. 6295(o)(2)(B)(i)(III)) As discussed in section III.D of this document, DOE uses the NIA spreadsheet models to project national energy savings.

d. Lessening of Utility or Performance of Products

In establishing product classes and in evaluating design options and the impact of potential standard levels, DOE evaluates potential standards that would not lessen the utility or performance of the considered products. (42 U.S.C. 6295(o)(2)(B)(i)(IV)) Based on data available to DOE, the standards proposed in this document would not reduce the utility or performance of the products under consideration in this proposed rulemaking.

[15] The FFC metric is discussed in DOE's statement of policy and notice of policy amendment. 76 FR 51282 (Aug. 18, 2011), as amended at 77 FR 49701 (Aug. 17, 2012).

[16] Procedures, Interpretations, and Policies for Consideration in New or Revised Energy Conservation Standards and Test Procedures for Consumer Products and Commercial/Industrial Equipment, 86 FR 70892, 70901 (Dec. 13, 2021).

e. Impact of Any Lessening of Competition

EPCA directs DOE to consider the impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from a proposed standard. (42 U.S.C. 6295(o)(2)(B)(i)(V)) It also directs the Attorney General to determine the impact, if any, of any lessening of competition likely to result from a proposed standard and to transmit such determination to the Secretary within 60 days of the publication of a proposed rule, together with an analysis of the nature and extent of the impact. (42 U.S.C. 6295(o)(2)(B)(ii)) DOE will transmit a copy of this proposed rule to the Attorney General with a request that the DOJ provide its determination on this issue. DOE will publish and respond to the Attorney General's determination in the final rule. DOE invites comment from the public regarding the competitive impacts that are likely to result from this proposed rule. In addition, stakeholders may also provide comments separately to DOJ regarding these potential impacts. See the **ADDRESSES** section for information to send comments to DOJ.

f. Need for National Energy Conservation

DOE also considers the need for national energy and water conservation in determining whether a new or amended standard is economically justified. (42 U.S.C. 6295(o)(2)(B)(i)(VI)) The energy savings from the proposed standards are likely to provide improvements to the security and reliability of the Nation's energy system. Reductions in the demand for electricity also may result in reduced costs for maintaining the reliability of the Nation's electricity system. DOE conducts a utility impact analysis to estimate how standards may affect the Nation's needed power generation capacity, as discussed in section IV.M of this document.

DOE maintains that environmental and public health benefits associated with the more efficient use of energy are important to take into account when considering the need for national energy conservation. The proposed standards are likely to result in environmental benefits in the form of reduced emissions of air pollutants and GHGs associated with energy production and use. DOE conducts an emissions analysis to estimate how potential standards may affect these emissions, as discussed in section IV.K of this document; the estimated emissions impacts are reported in section V.B.6 of this document. DOE also estimates the economic value of emissions reductions resulting from the considered TSLs, as discussed in section IV.L of this document.

g. Other Factors

In determining whether an energy conservation standard is economically justified, DOE may consider any other factors that the Secretary deems to be relevant. (42 U.S.C. 6295(o)(2)(B)(i)(VII)) To the extent DOE identifies any relevant information regarding economic justification that does not fit into the other categories described previously, DOE could consider such information under ''other factors.''

2. Rebuttable Presumption

As set forth in 42 U.S.C. 6295(o)(2)(B)(iii), EPCA creates a rebuttable presumption that an energy conservation standard is economically justified if the additional cost to the consumer of a product that meets the standard is less than three times the value of the first year's energy savings resulting from the standard, as calculated under the applicable DOE test procedure. DOE's LCC and PBP analyses generate values used to calculate the effects that proposed energy conservation standards would have on the payback period for consumers. These analyses include, but are not limited to, the 3-year payback period contemplated under the rebuttable-presumption test. In addition, DOE routinely conducts an economic analysis that considers the full range of impacts to consumers, manufacturers, the Nation, and the environment, as required under 42 U.S.C. 6295(o)(2)(B)(i). The results of this analysis serve as the basis for DOE's evaluation of the economic justification for a potential standard level (thereby supporting or rebutting the results of any preliminary determination of economic justification). The rebuttable presumption payback calculation is discussed in section IV.F.9 of this document.

IV. Methodology and Discussion of Related Comments

This section addresses the analyses DOE has performed for this proposed rulemaking with regard to dehumidifiers. Separate subsections address each component of DOE's analyses.

DOE used several analytical tools to estimate the impact of the standards proposed in this document. The first tool is a spreadsheet that calculates the LCC savings and PBP of potential amended or new energy conservation standards. The national impacts analysis uses a second spreadsheet set that provides shipment projections and calculates national energy savings and net present value of total consumer costs and savings expected to result from potential energy conservation standards. DOE uses the third spreadsheet tool, the Government Regulatory Impact Model (''GRIM''), to assess manufacturer impacts of potential standards. These three spreadsheet tools are available on the DOE website for this proposed rulemaking: *www.regulations.gov/docket/EERE-2019-BT-STD-0043.* Additionally, DOE used output from the latest version of the Energy Information Administration's (''EIA's'') *Annual Energy Outlook* (''AEO''), a widely known energy projection for the United States, for the emissions and utility impact analyses.

A. Market and Technology Assessment

DOE develops information in the market and technology assessment that provides an overall picture of the market for the products concerned, including the purpose of the products, the industry structure, manufacturers, market characteristics, and technologies used in the products. This activity includes both quantitative and qualitative assessments, based primarily on publicly available information. The subjects addressed in the market and technology assessment for this proposed rulemaking include (1) a determination of the scope of the rulemaking and product classes, (2) manufacturers and industry structure, (3) existing efficiency programs, (4) shipments information, (5) market and industry trends; and (6) technologies or design options that could improve the energy efficiency of dehumidifiers. The key findings of DOE's market assessment are summarized in the following sections. See chapter 3 of the NOPR TSD for further discussion of the market and technology assessment.

1. Product Classes

When evaluating and establishing energy conservation standards, DOE must specify a different standard level for a type or class of product that has the same function or intended use, if DOE determines that products within such group: (A) consume a different kind of energy from that consumed by other covered products within such type (or class); or (B) have a capacity or other performance-related feature which other products within such type (or class) do not have and such feature justifies a higher or lower standard. (42 U.S.C. 6295(q)(1)) In determining whether a performance-related feature justifies a

different standard for a group of products, DOE must consider such factors as the utility to the consumer of the feature and other factors DOE deems appropriate. *Id.* Any rule prescribing such a standard must include an explanation of the basis on which such higher or lower level was established. (42 U.S.C. 6295(q)(2))

DOE currently defines separate energy conservation standards using five dehumidifier product classes (10 CFR 430.32(v)(2)):

Portable dehumidifiers have three product classes based on the product capacity: Product Class 1 are those with a capacity of 25.00 pints/day or less, Product Class 2 dehumidifiers have a capacity of 25.01 to 50.00 pints/day, and Product Class 3 dehumidifiers have a capacity of 50.01 pints/day or more. Whole-home dehumidifiers have two product classes based on product case volume: Product Class 4 dehumidifiers have a case volume of 8.0 cubic feet or less, and Product Class 5 have a case volume of more than 8.0 cubic feet.

According to MIAQ, many of the units that are meant to be placed in the crawlspace of a home meet the portable dehumidifier definition due to their installation and configuration but have the same manufacturer production cost (''MPC'') as whole-home dehumidifiers. MIAQ stated that DOE did not clearly distinguish the difference between typical portable dehumidifiers and portable crawlspace dehumidifiers in the June 2022 Preliminary Analysis and requested that DOE keep this difference in mind when updating the TSD. (MIAQ, No. 20 at pp. 1–2)

Dehumidifiers are classified based on their ducting configuration during consumer use, according to the definitions established in 10 CFR 430.2. Portable dehumidifiers operate in applications that require space dehumidification without ducting. Whole-home dehumidifiers operate with ducting, typically in conjunction with a heating, ventilating, and air conditioning (''HVAC'') system. Dehumidifiers installed in basement crawlspaces without ducting are classified as portable dehumidifiers. DOE is not aware of any specific performance-related feature that would justify a new product class for portable dehumidifiers installed in basement crawlspaces. Therefore, when conducting the engineering analysis, as discussed further in section IV.C of this document and chapter 5 of the NOPR TSD, DOE considered the MPCs of a variety of units in the largest portable dehumidifier product class, Product Class 3.

2. Technology Options

In the preliminary market analysis and technology assessment, DOE identified 16 technology options that would be expected to improve the efficiency of dehumidifiers, as measured by the DOE test procedure.

TABLE IV.2—TECHNOLOGY OPTIONS FOR DEHUMIDIFIERS

1. Microchannel heat exchangers.
2. Built-in hygrometer/humidistat.
3. Improved compressor efficiency.
4. Improved condenser and evaporator performance.
5. Improved controls.
6. Improved defrost methods.
7. Improved demand-defrost controls.
8. Improved fan and fan-motor efficiency.
9. Improved flow-control devices.
10. Low-standby-loss electronic controls.
11. Washable air filters.
12. Pre-cooling air-to-air heat exchangers.
13. Heat pipes.
14. Improved refrigeration system insulation.
15. Refrigerant-desiccant systems.
16. Alternative refrigerants.

Several commenters provided feedback on some of these technology options. These comments are summarized below, along with DOE's responses.

a. Improved Compressor Efficiency

MIAQ stated that finding suitable high-efficiency compressors at the capacities and price points needed for dehumidifiers is a challenge, particularly with the transition to new refrigerants. According to MIAQ, the whole-home and crawlspace dehumidifier industry does not have sufficient volume to garner the full attention of compressor manufacturers. (MIAQ, No. 20 at p. 2)

DOE has considered MIAQ's comments regarding high-efficiency compressor availability, and for the reasons discussed in chapter 3 of the NOPR TSD, expects that by the time that compliance is required with any new dehumidifier standards, dehumidifier manufacturers will transition to compressors utilizing R–32 in place of compressors designed for the refrigerants currently in use. DOE acknowledges that there is significant uncertainty regarding the availability of the highest-efficiency single-speed compressors designed for operation with R–32 refrigerant that were analyzed for the June 2022 Preliminary Analysis, particularly in the smallest capacities. For this NOPR analysis, DOE has limited the improved compressor efficiency technology option to the maximum R–32 compressor efficiency that was observed within its teardown sample of dehumidifiers, to ensure that such compressors are already commercially available to the dehumidifier industry. Furthermore, should this NOPR proceed to a final rule, compliance with any amended standards would not be required until 3 years after a final rule is published. DOE expects that this 3-year compliance period would provide adequate time for dehumidifier original equipment manufacturers (''OEMs'') to source a sufficient supply of more efficient R–32 compressors ahead of anticipated demand. DOE expects that standards, if adopted, would therefore provide sufficient time and regulatory certainty for manufacturers and compressor suppliers to establish additional capacity in the supply chain, if needed.

MIAQ reiterated its comment on the June 2022 Dehumidifier Test Procedure NOPR [17] that variable-speed compressors do not provide sufficient energy savings to justify the significant increase in cost required to implement this technology, especially in the consumer product market. (MIAQ, No. 20 at p. 3)

In the June 2022 Preliminary Analysis, DOE considered variable-speed compressors as part of the technology assessment, but took into account only their full-load efficiency. As discussed in chapter 3 of the preliminary TSD, the DOE test procedure at appendix X1 does not attribute any partial-load efficiency improvements to variable-speed dehumidifiers as the test procedures for room air conditioners and portable air conditioners do for units with variable-speed compressors, because variable-speed dehumidifiers must maintain a constant evaporator temperature below the dew point regardless of the amount of moisture present in the room. This provides no opportunity for energy savings. DOE also noted the costs associated with implementing variable-speed compressors and accounted for these costs in the engineering analysis where appropriate.

Since publication of the June 2022 Preliminary Analysis, additional market research, manufacturer interviews, and input from commenters led DOE to understand that variable-speed compressors do not offer efficiency benefits sufficient to justify the costs and design challenges associated with implementing them for dehumidifiers. Therefore, in the analysis for this NOPR, DOE did not consider variable-speed compressors as a design option to improve compressor efficiency. *See* chapter 3 of the NOPR TSD for

[17] *See* posted comment on *www.regulations.gov,* Docket No. EERE–2019–BT–TP–0026–0008–0015.

additional discussion about variable-speed compressors.

AHAM requested that DOE evaluate whether the use of variable-frequency drives and similar high frequency components will lead to increased nuisance tripping of ground-fault circuit-interrupters (''GFCIs'') and associated cost implications. According to AHAM, nuisance tripping may require a consumer to call an electrician to change a breaker or replace a unit and could lead to less efficient operation, as continuous dehumidification over time is more efficient than interrupted dehumidification. (AHAM, No. 22 at p. 7)

DOE is aware that when implementing variable-frequency drives, as for both variable-speed compressors and fan blower electronically commutated motors (''ECMs''), it is possible that GFCI systems will trip without a fault present, requiring a manual reset of the dehumidifier by the consumer. However, DOE understands that GFCI tripping, even for units with variable-speed drives, can generally be mitigated through the use of best practices for reducing leakage current, such as minimizing ECM cable length and ensuring that filtered and unfiltered cables are separated to whatever extent possible to reduce leakage current. Additionally, optimizing the variable-frequency controller power filter to reduce total leakage current to levels below the GFCI detection limits can prevent GFCI tripping. Furthermore, DOE does not have any information on the prevalence of nuisance tripping events or on the potential impact of such trips on consumer utility or dehumidifier energy use. DOE notes that despite the potential for nuisance tripping, a wide range of appliances on the market today, including dehumidifiers, implement variable-frequency drives in their designs. The inclusion of these variable-frequency drive designs in units on the market suggests that they do not have a significant impact on the consumer utility of these products. Therefore, DOE is continuing to consider ECMs for fan blowers as a technology option for the NOPR engineering analysis. However, for the reasons discussed above, DOE did not consider variable-speed compressors as a technology option to improve compressor efficiency in this NOPR analysis.

b. Washable Air Filters

MIAQ did not support the use of washable air filters and stated that in a limited study washable filters were changed less frequently than disposable filters, leading to reduced airflow and reduced efficiency. (MIAQ, No. 20 at p. 3)

DOE understands that the efficiency impacts due to air filters are dependent on regular consumer maintenance. As DOE noted in the technology assessment in chapter 3 of the preliminary TSD, it is difficult to predict the amount of energy savings that could be realized with the addition of washable air filters, as it is dependent on the specific dehumidifier model and use characteristics, and on the degree to which the consumer takes advantage of this feature. DOE also noted in the preliminary TSD that most dehumidifiers incorporate an air filter and that most manufacturers design the air filters to be removable and washable. Therefore, DOE did not consider washable air filters as a design option to improve efficiency in the engineering analysis for the June 2022 Preliminary Analysis. The information that MIAQ provided regarding the efficiency impacts of washable air filters further supports DOE's preliminary determination not to include washable air filters as a design option in the engineering analysis, and in light of the uncertainty and lack of sufficient data as to any efficiency benefit associated with them and the prevalence of them in dehumidifiers already on the market, DOE has tentatively removed from consideration washable air filters as a technology option in this NOPR.

c. Air-to-Air Heat Exchangers

According to MIAQ, air-to-air heat exchangers add significant cost and complexity to the design, MPC, and installation of the unit and typically push the unit into the greater than 8 cubic foot category where minimum efficiency values are considerably higher. (MIAQ, No. 20 at p. 3)

DOE considers the costs of design options in the engineering analysis. Although DOE is aware that air-to-air heat exchangers are implemented in many whole-home dehumidifiers with case volumes greater than 8 cubic feet, DOE did not implement air-to-air heat exchangers as a design option to achieve higher efficiency levels in the NOPR engineering analysis because dehumidifiers with size constraints that allow air-to-air heat exchangers already implement them and they require too much case volume increase to implement for other units. (*See* chapter 5 of the NOPR TSD for additional details.)

d. Alternative Refrigerants

The Joint Commenters supported DOE's decision to consider R–32 compressors as a design option for dehumidifiers due to their significant potential to improve efficiencies, and agreed that R–32 will likely be acceptable for use in dehumidifiers by the time amended standards come into effect. The Joint Commenters noted that in July 2022, the U.S. Environmental Protection Agency (''EPA'') proposed to list R–32 as acceptable for use in new residential dehumidifiers. (Joint Commenters, No. 21 at p. 1)

MIAQ requested that DOE consider the impact on efficiency that any new refrigerant would have on dehumidifiers. Although some refrigerants may provide efficiency improvements, optimizing the unit's performance would require time and the assistance of component suppliers. (MIAQ, No. 20 at p. 3)

DOE is aware that new refrigerant regulations from entities such as the California Air Resource Board (''CARB'') are prompting an industry-wide refrigerant changeover. Based on feedback received during the manufacturer interview process, DOE expects that the process of redesigning and optimizing dehumidifiers for new refrigerants such as R–32 will be part of the typical new unit design process, not a result of any amended standards that DOE may adopt. Additionally, DOE estimates that the implementation of R–32 in dehumidifiers is unlikely to result in an efficiency increase due to the refrigerant changeover alone, although compressors designed for R–32 may be slightly more efficient than compressors designed for R–410a due to other design improvements. Therefore, given this industry-wide refrigerant changeover expected to occur by the compliance date of any new dehumidifier standards, in this NOPR analysis DOE considered the impact of compressor improvements on overall dehumidifier efficiency only for those compressors using R–32, assuming that manufacturers will already have transitioned to refrigeration systems optimized for the new refrigerant.

DOE requests comment on the effects of EPA and CARB regulations on refrigerant choices and on whether changes in refrigerant will affect manufacturer's ability to achieve the efficiency levels in the NOPR analysis and the availability of high-efficiency R–32 compressors.

For further discussion of the cumulative regulatory burden, see section V.B.2.e of this document.

e. Low-Standby-Loss Electronic Controls

According to AHAM, low standby-loss electronic controls save as little as 1 watt of power and have a minimal impact to overall energy savings that

does not warrant the cost of implementing this technology option, and should therefore have been screened out by DOE. (AHAM, No. 22 at p. 4)

In the engineering analysis, DOE accounts for the cost relative to the efficiency benefit of all technologies that pass the screening analysis and are considered, as discussed. See chapter 3 of the NOPR TSD for discussion of the potential efficiency benefits of low-standby-loss electronic controls and chapter 5 of the NOPR TSD for further discussion of the costs of this technology.

f. Multi-Circuited Evaporator and Secondary Condenser Coils

Since publication of the June 2022 Preliminary Analysis, DOE became aware of at least one whole-home dehumidifier on the market that implements a novel refrigeration loop design. This patented design ''causes part of the refrigerant within the system to evaporate and condense twice in one refrigeration cycle, thereby increasing the compressor capacity over typical systems without adding any additional power to the compressor.'' [18] DOE has observed that this technology has resulted in a unit that is at least 4-percent more efficient than any other unit available on the market and a significant reduction in case volume compared to units with similar dehumidification capacities. Therefore, DOE has included multi-circuited evaporator and secondary condenser coil refrigerant systems as an additional technology option for this NOPR. See chapter 3 of the NOPR TSD for additional discussion of this technology.

B. Screening Analysis

DOE uses the following five screening criteria to determine which technology options are suitable for further consideration in an energy conservation standards rulemaking:

(1) *Technological feasibility.* Technologies that are not incorporated in commercial products or in commercially viable, existing prototypes will not be considered further.

(2) *Practicability to manufacture, install, and service.* If it is determined that mass production of a technology in commercial products and reliable installation and servicing of the technology could not be achieved on the scale necessary to serve the relevant market at the time of the projected compliance date of the standard, then that technology will not be considered further.

(3) *Impacts on product utility.* If a technology is determined to have a significant adverse impact on the utility of the product to subgroups of consumers, or result in the unavailability of any covered product type with performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as products generally available in the United States at the time, it will not be considered further.

(4) *Safety of technologies.* If it is determined that a technology would have significant adverse impacts on health or safety, it will not be considered further.

(5) *Unique-pathway proprietary technologies.* If a technology has proprietary protection and represents a unique pathway to achieving a given efficiency level, it will not be considered further, due to the potential for monopolistic concerns.

10 CFR part 430, subpart C, appendix A, sections 6(b)(3) and 7(b).

In summary, if DOE determines that a technology, or a combination of technologies, fails to meet one or more of the listed five criteria, it will be excluded from further consideration in the engineering analysis. The reasons for eliminating any technology are discussed in the following sections.

The subsequent sections include comments from interested parties pertinent to the screening criteria, DOE's evaluation of each technology option against the screening analysis criteria, and whether DOE determined that a technology option should be excluded (''screened out'') based on the screening criteria.

1. Screened-Out Technologies

In the June 2022 Preliminary Analysis, DOE screened out pre-cooling air-to-air heat exchangers and heat pipes from the analysis for portable dehumidifiers with capacities up to and including 50 pints/day. DOE determined that these dehumidifiers could not accommodate the significant increases in case size and weight required to implement these technologies without a significant adverse effect on consumer utility (screening criterion 3).

AHAM agreed that implementation of pre-cooling air-to-air heat exchangers is applicable only to high-capacity portable dehumidifiers in Product Class 3 and requested that DOE recognize that current dehumidifier casings may not accommodate the increase in components and product size associated with this technology option. (AHAM, No. 22 at p. 4)

For the reasons given in the June 2022 Preliminary Analysis, DOE is maintaining the same approach to air-to-air heat exchangers and heat pipes in this NOPR analysis. See chapter 4 of the NOPR TSD for further discussion.

DOE is also screening out multi-circuited evaporator and secondary condenser coil refrigerant systems, a technology newly considered for the NOPR per section IV.A.2.f of this document, because it represents a unique-pathway proprietary technology. See chapter 4 of the NOPR TSD for further discussion.

2. Remaining Technologies

Through a review of each technology, DOE tentatively concludes that all of the other identified technologies listed in section IV.A.2 of this document meet all five screening criteria to be examined further as design options in DOE's NOPR analysis. In summary, DOE did not screen out the following technology options:

TABLE IV.3—RETAINED DESIGN OPTIONS FOR DEHUMIDIFIERS

1. Microchannel heat exchangers.
2. Built-in hygrometer/humidistat.
3. Improved compressor efficiency.
4. Improved condenser and evaporator performance.
5. Improved controls.
6. Improved defrost methods.
7. Improved demand-defrost controls.
8. Improved fan and fan-motor efficiency.
9. Improved flow-control devices.

[18] U.S. Patent No. 10,845,069.

TABLE IV.3—RETAINED DESIGN OPTIONS FOR DEHUMIDIFIERS—Continued

10. Low-standby-loss electronic controls.
11. Pre-cooling air-to-air heat exchanger (high-capacity portable and whole-home dehumidifiers only).
12. Heat pipes (high-capacity portable and whole-home dehumidifiers only).
13. Improved refrigeration system insulation.
14. Refrigerant-desiccant systems.
15. Alternative refrigerants.

DOE has initially determined that these technology options are technologically feasible because they are being used or have previously been used in commercially available products or working prototypes. DOE also finds that all of the remaining technology options meet the other screening criteria (*i.e.,* practicable to manufacture, install, and service and do not result in adverse impacts on consumer utility, product availability, health, or safety, unique-pathway proprietary technologies). For additional details, see chapter 4 of the NOPR TSD.

C. Engineering Analysis

The purpose of the engineering analysis is to establish the relationship between the efficiency and cost of dehumidifiers. There are two elements to consider in the engineering analysis; the selection of efficiency levels to analyze (*i.e.,* the ''efficiency analysis'') and the determination of product cost at each efficiency level (*i.e.,* the ''cost analysis''). In determining the performance of higher-efficiency products, DOE considers technologies and design option combinations not eliminated by the screening analysis. For each product class, DOE estimates the baseline cost, as well as the incremental cost for the product at efficiency levels above the baseline. The output of the engineering analysis is a set of cost-efficiency ''curves'' that are used in downstream analyses (*i.e.,* the LCC and PBP analyses and the NIA).

1. Efficiency Analysis

DOE typically uses one of two approaches to develop energy efficiency levels for the engineering analysis: (1) relying on observed efficiency levels in the market (*i.e.,* the efficiency-level approach), or (2) determining the incremental efficiency improvements associated with incorporating specific design options to a baseline model (*i.e.,* the design-option approach). Using the efficiency-level approach, the efficiency levels established for the analysis are determined based on the market distribution of existing products (in other words, based on the range of efficiencies and efficiency level ''clusters'' that already exist on the market). Using the design option approach, the efficiency levels established for the analysis are determined through detailed engineering calculations and/or computer simulations of the efficiency improvements from implementing specific design options that have been identified in the technology assessment. DOE may also rely on a combination of these two approaches. For example, the efficiency-level approach (based on actual products on the market) may be extended using the design option approach to ''gap fill'' levels (to bridge large gaps between other identified efficiency levels) and/or to extrapolate to the max-tech level (particularly in cases where the max-tech level exceeds the maximum efficiency level currently available on the market).

In this proposed rulemaking, DOE relied on a combination of these two methods in developing cost estimates at each efficiency level for dehumidifiers, structured around the reverse engineering approach. For each product class, DOE analyzed a few units from different manufacturers to ensure the analysis was representative of various designs on the market. The analysis involved reviewing publicly available cost and performance information, physically disassembling commercially available products and modeling equipment cost while removing costs associated with non-efficiency related components or features. From this information, DOE estimated the MPCs for a range of products currently available on the market. DOE then considered the incremental steps manufacturers may take to reach higher efficiency levels. In its modeling, DOE started with the baseline MPC and added the expected design options at each higher efficiency level to estimate incremental MPCs. *See* chapter 5 of the NOPR TSD for additional detail on the dehumidifiers analyzed.

DOE analyzed six efficiency levels (''ELs'') as part of the engineering analysis for portable dehumidifiers with capacities less than or equal to 50 pints/day: (1) the current DOE standard (baseline); (2) an intermediate level above the baseline but below the ENERGY STAR® level, representing units that exist on the market above the baseline but are not ENERGY STAR units (EL 1); (3) the ENERGY STAR efficiency criterion (EL 2); (4) the level of the most efficient units available on the market (EL 3); (5) an intermediate level below the maximum technologically feasible (max-tech) efficiency that represents the implementation of more efficient compressors and fan motors on the market without any changes to the unit chassis (EL 4); and (6) the max-tech efficiency (EL 5).

For portable dehumidifiers with capacities of 50.01 pints/day and above, the distribution of efficiencies that are available on the market and the technology options feasible for this product class required DOE to analyze different efficiency levels, as follows: (1) the current DOE standard (baseline); (2) an intermediate level above the baseline but below the ENERGY STAR level, representing units that exist on the market above the baseline but are not ENERGY STAR units (EL 1); (3) the ENERGY STAR efficiency criterion (EL 2); (4) an intermediate level below max tech that represents the implementation of more efficient compressors and fan motors on the market (EL 3); and (5) the max-tech efficiency (EL 4).

For whole-home dehumidifiers with case volumes of 8 cubic feet or below, likewise, the distribution of efficiencies that are available on the market and the technology options feasible for this product class required DOE to analyze different efficiency levels, as follows: (1) the current DOE standard (baseline); (2) the ENERGY STAR efficiency criterion (EL 1); (3) an intermediate level below max tech, representing the level of the most efficient units available on the market (EL 2); and (4) the max-tech efficiency (EL 3).

For whole-home dehumidifiers with case volumes larger than 8 cubic feet, likewise, the distribution of efficiencies that are available on the market and the technology options feasible for this product class required DOE to analyze different efficiency levels, as follows: (1) the current DOE standard (baseline); (2) an intermediate level above the baseline but below the ENERGY STAR level, representing the level of the most efficient units available on the market

(EL 1); (3) the ENERGY STAR efficiency criterion (EL 2); (4) an intermediate level below max tech that represents the implementation of more efficient compressors and fan motors on the market and some increase to heat exchanger size relative to EL 2 (EL 3); and (5) the max-tech efficiency (EL 4).

a. Baseline Efficiency

For each product/equipment class, DOE generally selects a baseline model as a reference point for each class, and measures changes resulting from potential energy conservation standards against the baseline. The baseline model in each product/equipment class represents the characteristics of a product/equipment typical of that class (*e.g.,* capacity, physical size). Generally, a baseline model is one that just meets current energy conservation standards, or, if no standards are in place, the baseline is typically the most common or least efficient unit on the market.

For representative units for teardowns and the NOPR, DOE selected three baseline units that fell within two of the five dehumidifier product classes (Product Class 1 and Product Class 2) as reference points for each analyzed product class, against which DOE measured changes that would result from amended energy conservation standards to support the engineering, LCC, and PBP analyses. Baseline units for two of the other three product classes (Product Class 3 and Product Class 5) were not readily available on the market for analysis. Additionally, as discussed in chapter 5 of the preliminary TSD, for whole-home dehumidifiers with case volumes of 8 cubic feet or less, DOE does not expect that efficiencies and overall designs have changed since the previous standards rulemaking, given that the whole-home dehumidifier standards adopted in the June 2016 Final Rule were the baseline level at the time. For this reason, DOE did not select additional baseline units in Product Class 4 for teardown as part of the NOPR analysis. However, DOE found that higher-efficiency models could provide insight into technologies that were likely to be implemented in baseline units to improve efficiency. Therefore, for product classes where baseline units were not available, DOE estimated the MPC of baseline units by evaluating which design options would need to be removed from the higher-efficiency unit analyzed in order to reduce its efficiency to the baseline level. The baseline units in each of the analyzed product classes represent the basic characteristics of equipment in that class.

MIAQ stated in response to the June 2022 Preliminary Analysis that the current energy conservation standards for portable dehumidifier product classes are not appropriate or in the best interest of the Nation's energy consumption. According to MIAQ, the jump in baseline efficiency from 1.60 L/kWh at the 25.01–50.00 pints/day capacity up to 2.80 L/kWh for larger-capacity units is too drastic and would force MPC and manufacturer selling price (''MSP'') to escalate far above that of smaller dehumidifiers. According to MIAQ, as consumers purchase sufficient dehumidifier capacity match the latent load of their dwelling, this could be through a more expensive, higher-efficiency dehumidifier at an efficiency of 2.80 L/kWh or through multiple less-expensive and less-efficient dehumidifiers at an efficiency of 1.30 L/kWh. MIAQ stated that as MPC and MSP on these two types of units are drastically different, anecdotal evidence indicates many consumers have two or more dehumidifiers in their basement or crawlspace consuming twice the power of a larger unit. Therefore, MIAQ requested that DOE develop a new set of baseline efficiency levels for portable dehumidifiers that create more parity in the MPCs and baseline efficiencies for the product sizes. (MIAQ, No. 20 at pp. 3–4)

As noted, DOE analyzes the changes due to potential energy conservation standards against the baseline for each product class. DOE determined in the June 2016 Final Rule that the current standards were technologically feasible and economically justified for each of the five dehumidifier product classes (81 FR 38338, 38385–38388), and models exist on the market at or above the current standard level in each class. Therefore, DOE has evaluated baseline efficiency levels for this NOPR analysis that correspond to the current energy conservation standards for dehumidifiers. DOE notes that units with capacities larger than 50 pints/day have inherent differences in design from those with smaller capacities related to the different consumer utility they provide. The larger dehumidifiers in Product Class 3 provide dehumidification for large spaces, are more robustly constructed, and are more efficient due to their greater size and capacity. The smaller dehumidifiers are intended to dehumidify smaller spaces and provide consumers with an affordable, lighter-weight, and more compact option to dehumidify a targeted area. The current energy conservation standards on which the baseline efficiency levels are based reflect that consumers derive utility from the greater capacity, efficiency, and robust construction of larger dehumidifiers and that smaller dehumidifiers offer utility in the form of their smaller size and lower cost. These differences in utility are borne out in the design differences observed between these classes of dehumidifiers, with larger dehumidifiers implementing more durable materials and larger heat exchangers. These design differences lead to the cost differential observed by manufacturers and consumers between larger and smaller dehumidifiers. DOE developed the higher efficiency levels in each product class based on the units currently on the market, external efficiency criteria such as ENERGY STAR, and technological feasibility of design options to improve dehumidifier efficiency. DOE then evaluated the economic impacts of potential standards at each of these efficiency levels, including incremental impacts on MPCs and MSPs in each product class, as part of the NOPR analysis. DOE is not aware of and lacks sufficient consumer usage data showing that consumers install multiple smaller dehumidifiers in the same room instead of purchasing one larger, more efficient dehumidifier as part of an average period of use, and therefore did not model any product class switching as a result of evaluated potential standards.

DOE requests comment regarding consumer's dehumidifier usage patterns and whether consumers typically purchase multiple smaller dehumidifiers to meet dehumidification requirements as opposed to a single, higher capacity dehumidifier.

b. Higher Efficiency Levels

As discussed above, DOE modeled several efficiency levels above the baseline for dehumidifiers in each product class, using a combination of design options that varied by product class (for detailed discussion of the design options used to model each efficiency level, see chapter 5 of the NOPR TSD). As part of DOE's analysis, the maximum available efficiency level is the highest efficiency unit currently available on the market. DOE also defines a ''max-tech'' efficiency level to represent the maximum possible efficiency for a given product. At all of these levels, DOE considered incremental compressor efficiency improvements as a design option. In the June 2022 Preliminary Analysis, DOE reviewed compressor manufacturer product catalogues to identify the maximum technologically feasible R–32 compressor efficiency. However, based on additional research and input from

manufacturer interviews, DOE understands that the most efficient compressors listed in catalogues may not be widely available to all dehumidifier manufacturers or available at the scale necessary to serve the dehumidifier market at the anticipated date of compliance of any new standards. This is especially true for the relatively small manufacturers that produce dehumidifiers in Product Class 4 and Product Class 5, given the specialized applications for these products and the corresponding lower production volumes. To address this concern in the NOPR analysis, DOE considered incremental compressor efficiency increases for each product class only up to the highest R–32 single-speed compressor efficiency observed in the teardown sample in that class. This change ensures that the higher-efficiency compressors considered as design options are widely available and technologically feasible for all dehumidifier manufacturers to implement. As discussed in chapter 5 of the NOPR TSD, DOE modeled replacing permanent split capacitor (''PSC'') fan motors with more efficient ECMs, replacing baseline single-speed compressors with the most efficient single-speed compressors already available on the market, reducing standby power using more efficient controls, and increasing the cabinet and heat exchanger to the largest sizes feasible without impacting consumer utility to improve efficiency. For all product classes, the max-tech level identified exceeds any other regulatory or voluntary efficiency criteria currently in effect.

DOE received the following comments related to the higher efficiency levels modeled in the preliminary engineering analysis.

AHAM requested that DOE account for additional controls, specifically variable-frequency drives that are required for ECMs in the improved fan and fan motor efficiency technology option. According to AHAM, in addition to the significant cost increase associated with ECMs being a significant obstacle to widespread adoption in dehumidifiers, additional controls would only further increase the cost and require additional space within the product case, potentially affecting the size and weight of the product. (AHAM, No. 22 at p. 5)

DOE is aware that ECMs require specialized control boards and additional space within dehumidifier chassis to locate them and considered this issue as part of the engineering analysis. DOE found that there is a variable-speed dehumidifier on the market that implements a variable-speed compressor, and this model has the same chassis size as another comparable dehumidifier from the same manufacturer that does not implement the variable-speed components and functionality. DOE expects that a variable-speed dehumidifier would have similar control requirements to one that implements ECMs. Therefore, DOE tentatively finds that the implementation of ECMs for fan blowers in dehumidifiers does not inherently necessitate a change in chassis size.

According to AHAM and a survey of its members, employing the technology options that DOE suggested in the preliminary TSD to meet the analyzed efficiency levels for Product Classes 1, 2, and 3 would require significant increases in both model weight and model dimensions. For Product Classes 1 and 2, AHAM stated that an increase of up to 30 percent in model weight and up to 59 percent in model dimensions is required to meet EL 3, and an increase of up to 38 percent in model weight and up to 68 percent in model dimensions is required to meet EL 4. For Product Class 3, AHAM stated that EL 2 would require a product redesign and likely an increase in both weight and dimension by unknown quantities. AHAM also stated that increased product size and weight associated with implementing the technology options specified in the preliminary TSD will affect the consumer utility of dehumidifiers, specifically regarding portability. According to AHAM, consumers must move or lift dehumidifiers when purchased and when used in different spaces in their homes. Additionally, manufacturers design models to meet a 51-pound weight threshold for a one-person lift, a design parameter that not only reflects consumer utility but also is a requirement under worker safety standards, parcel delivery service fee structures, and other distribution requirements that AHAM stated DOE should consider for all product classes. AHAM urged DOE to assess impacts on product weight associated with increased heat exchanger area and added tube rows in the improved condenser and evaporator performance technology option. According to AHAM, an increase in weight of the coil section could severely impact consumer use in existing dehumidifier designs that require lifting the coil section in order to access the water collection bucket. Additionally, AHAM stated that its members specifically identified weight increases associated with this technology option in meeting EL 3 for all product classes. AHAM requested that DOE assess all potential cost increases associated with the technology options that increase product size and/or weight and noted its recommendation for a standard that does not go beyond EL 2 for Product Class 1, a gap-fill analysis for Product Class 2, and no change in the standard for Product Class 3 to avoid these negative impacts. (AHAM, No. 22 at pp. 2–5)

In the June 2022 Preliminary Analysis, DOE modeled the efficiency levels below max-tech mentioned by AHAM by implementing more efficient compressors without any additional design options. In DOE's assessment, these higher-efficiency compressors would result in a slight weight increase but would require no changes to the dehumidifier's chassis size or any substantive change in overall weight. Additionally, based on teardowns of other space conditioning products, DOE does not expect that ECMs are heavier than the PSC motors currently used in dehumidifiers. However, as AHAM suggested, DOE does expect weight changes at the max-tech level associated with increasing the heat exchanger size. DOE accounted for the effect of these weight changes and changes to chassis size in its analysis of shipping costs, and limited the maximum increase in heat exchanger size for portable dehumidifiers in Product Classes 1 and 2 to dimensions already observed on the market in these product classes to ensure the units analyzed retained their consumer utility as smaller, portable units. Because product weight changes due to heat exchanger size increases are correlated with product dimensions, DOE does not expect that these weight increases will result in units that are significantly heavier than those currently on the market, such that any weight increases will not adversely affect consumer utility. For Product Class 3, DOE's market analysis suggests that most models in Product Class 3, even at baseline efficiency, typically weigh roughly between 55 and 70 pounds, already surpassing the 51-pound weight limit for a single-person lift mentioned by AHAM. Therefore, Product Class 3 units already require two people to lift and install, a requirement that would not be altered by minor increases in chassis size and thus weight. However, a significantly larger chassis size might become more unwieldy for two people to lift. Accordingly, DOE limited the heat exchanger dimension increases considered for Product Class 3 to 5 percent greater than those observed in product teardowns in order to preclude any adverse effects on consumer utility.

DOE further notes that portable dehumidifiers are typically equipped with wheels that allow consumers to move them from room to room within the home. While DOE is aware of a dehumidifier design that requires consumers to lift the coil section to access the water bucket, the design is not efficiency-related and is proprietary, and therefore DOE did not consider this design in its analysis. In sum, DOE expects that the NOPR analysis and any subsequent amended energy conservation standards would not impact the design, weight, or dimensions of any dehumidifier significantly, as the required chassis dimensions are within the scope of those previously observed in dehumidifiers. For these reasons, in the NOPR analysis DOE continued to consider design options that increase the weight of dehumidifiers, limited to the extent discussed by restrictions on the allowable chassis size increases.

DOE requests comment on whether limiting needed chassis size increases is sufficient to preserve consumer utility at the max-tech level.

AHAM stated that while improved compressor efficiency can achieve higher overall efficiency, changes in compressor technology may require product redesigns in the form of additional safety components, particularly with the transition to R–32 refrigerant. According to AHAM, these additional safety components would make it more difficult to implement other technology options that will require room within the product casing. (AHAM, No. 22 at p. 5)

DOE is aware that the EPA's Significant New Alternatives Policy (''SNAP'') regulations now allow the use of R–32 in new dehumidifiers, provided that they comply with the relevant industry safety standard [19] to ensure new dehumidifiers are designed with the flammability of R–32 in mind. *See* 88 FR 26382. However, DOE does not have information regarding the sorts of design changes necessary to comply with this standard. See section V.B.2.e of this document for discussion of how DOE accounts for refrigerant transition costs in its cumulative regulatory burden analysis.

ASAP and the Joint Commenters encouraged DOE to evaluate at least one intermediate efficiency level between EL 3 and EL 4 for Product Classes 1 and 2 to address the large gap in efficiencies due to the introduction of multiple design options at EL 4. The Joint Commenters added that DOE could evaluate an intermediate level based on the highest-efficiency compressors, or one reflecting all design options except for increases in heat exchanger size. According to the Joint Commenters, DOE may refer to the April 2022 NOPR for room air conditioners in which the most efficient single-speed compressors were associated with an increase in efficiency of 19 to 25 percent relative to baseline units and an incremental cost of less than $15. (ASAP, Public Meeting Transcript, No. 19 at pp. 19–20; Joint Commenters, No. 21 at p. 2)

In the June 2022 Preliminary Analysis for Product Classes 1 and 2, DOE analyzed two efficiency levels above the ENERGY STAR level: the maximum available efficiency on the market and the max-tech efficiency. For Product Class 3 and for whole-home dehumidifiers, DOE analyzed the max-tech efficiency level above the ENERGY STAR level and no other intermediate levels, because there were no units on the market above the ENERGY STAR efficiency. While conducting the analysis for this NOPR, DOE noted the potential to add an efficiency level for all product classes beyond the maximum available efficiency but below max tech by using more efficient single-speed compressors and implementing ECM technology. DOE used these design options to model a new intermediate efficiency level, EL 4, for all product classes. The new EL 4 level improves the efficiency by 35 to 63 percent relative to baseline units with incremental costs between $83 and $119, depending on product class. See chapter 5 of the NOPR TSD for additional discussion of the new efficiency levels and incremental costs.

2. Cost Analysis

The cost analysis portion of the engineering analysis is conducted using one or a combination of cost approaches. The selection of cost approach depends on a suite of factors, including the availability and reliability of public information, characteristics of the regulated product, and the availability and timeliness of purchasing the product on the market. The cost approaches are summarized as follows:

□ *Physical teardowns:* Under this approach, DOE physically dismantles a commercially available product, component by component, to develop a detailed bill of materials for the product.

□ *Catalog teardowns:* In lieu of physically deconstructing a product, DOE identifies each component using parts diagrams (*e.g.,* available from manufacturer websites or appliance repair websites) to develop the bill of materials for the product.

□ *Price surveys:* If neither a physical nor catalog teardown is feasible (*e.g.,* for tightly integrated products such as fluorescent lamps, which are infeasible to disassemble and for which parts diagrams are unavailable) or is cost-prohibitive and otherwise impractical (*e.g.,* for large commercial boilers), DOE conducts price surveys using publicly available pricing data published on major online retailer websites and/or by soliciting prices from distributors and other commercial channels.

In the present case, DOE conducted the analysis using physical teardowns. The resulting bill of materials provides the basis for the MPC estimates.

To account for manufacturers' non-production costs and profit margin, DOE applies a multiplier (the manufacturer markup) to the MPC. The resulting manufacturer selling price (''MSP'') is the price at which the manufacturer distributes a unit into commerce. DOE developed an average manufacturer markup by examining corporate annual reports filed by publicly traded manufacturers primarily engaged in appliance manufacturing and whose combined product range includes dehumidifiers. See section IV.J.2.d of this document or chapter 12 of the NOPR TSD for additional information on the manufacturer markup.

In response to June 2022 Preliminary Analysis, MIAQ stated that although the manufacturer markup of 1.45 used in the preliminary analysis was historically accurate, it now overstates the current market situation which is decreasing as costs continue to increase and are unable to be passed onto the consumer. MIAQ also stated it would be willing to share information on their current markup for dehumidifiers. (MIAQ, No. 20 at p. 5)

For this NOPR analysis, DOE adjusted the estimated industry average manufacturer markup from the 1.45 estimate published in the June 2022 Preliminary Analysis. DOE used market share weights to adjust the manufacturer markup based on confidential feedback provided in manufacturer interviews and a review of recent corporate annual reports by public companies engaged in manufacturing dehumidifiers. DOE estimates that the industry average manufacturer markup is 1.40 for all product classes. See section IV.J.2.d of this document and chapter 12 of the NOPR TSD for additional information on the manufacturer markup.

[19] 3rd edition, dated November 1, 2019, of Underwriters Laboratories (''UL'') Standard 60335–2–40, ''Household and Similar Electrical Appliances—Safety—Part 2–40: Particular Requirements for Electrical Heat Pumps, Air Conditioners and Dehumidifiers''.

AHAM stated that implementation of technology options that both increase product efficiency and product size and/or weight runs counter to manufacturer efforts to decrease product size and maximize shipping container space in order to deliver products to consumers in a timely manner while minimizing added costs due to ongoing supply chain and logistics issues. AHAM requested that DOE avoid design options that require increases in size and/or weight for these reasons and requested that DOE account for these added costs in its analysis. (AHAM, No. 22 at p. 3)

In this NOPR, DOE's analysis includes the impact of changes in dimensions on overseas container and domestic shipping rates. For efficiency levels below max-tech, DOE does not find increases in shipping costs, because chassis size and weight of the units are not expected to change from the baseline at these efficiency levels. At max-tech, there are increases in shipping costs due to the expected increase in chassis size. Additional information about shipping costs is available in section IV.F.1 of this document and chapter 8 of the NOPR TSD.

3. Cost-Efficiency Results

The results of the engineering analysis are presented as cost-efficiency data for each of the efficiency levels for each of the product classes. DOE developed estimates of MPCs for each unit in the teardown sample, and also performed additional modeling for each of the teardown samples, to develop a comprehensive set of MPCs at each efficiency level. DOE then consolidated the resulting MPCs for each of DOE's teardown units and modeled units using a weighted average for product classes in which DOE analyzed units from multiple manufacturers. DOE's weighting factors were based on a market penetration analysis for each of the manufacturers within each product class. The resulting weighted-average incremental MPCs (*i.e.,* the additional costs manufacturers would likely incur by producing dehumidifiers at each efficiency level compared to the baseline) are provided in Tables 5.5.12 and 5.5.13 in chapter 5 of the NOPR TSD. *See* chapter 5 of the NOPR TSD for additional detail on the engineering analysis.

DOE requests comment on the incremental MPCs from the NOPR engineering analysis.

D. Markups Analysis

The markups analysis develops appropriate markups (*e.g.,* retailer markups, distributor markups, contractor markups) in the distribution chain and sales taxes to convert the MSP estimates derived in the engineering analysis to consumer prices, which are then used in the LCC and PBP analysis. At each step in the distribution channel, companies mark up the price of the product to cover business costs and profit margin.

DOE developed baseline and incremental markups for each actor in the distribution chain. Baseline markups are applied to the price of products with baseline efficiency, while incremental markups are applied to the difference in price between baseline and higher-efficiency models (the incremental cost increase). The incremental markup is typically less than the baseline markup and is designed to maintain similar per-unit operating profit before and after new or amended standards.[20]

For portable dehumidifiers with capacities less than or equal to 50.0 pints/day, DOE assumed all sales were through the retail channel. DOE developed baseline and incremental retail markups using data from the 2017 Annual Retail Trade Survey for the ''electronics and appliance stores'' sector.[21] The whole-home dehumidifier distribution channel reflects two additional markups to include wholesalers and contractors used in the purchase of the larger dehumidifiers. DOE developed wholesaler and contractor markups using U.S. Census Bureau data from the 2017 Annual Wholesale Trade Report [22] and the 2017 U.S. Economic Census,[23] respectively. For portable dehumidifiers with capacities greater than 50.00 pints/day, DOE assumed 60 percent of shipments were through the retail channel, and 40 percent of shipments were through the whole-home dehumidifier distribution channel based on feedback from manufacturer interviews.

Chapter 6 of the NOPR TSD provides details on DOE's development of markups for dehumidifiers.

E. Energy Use Analysis

The purpose of the energy use analysis is to determine the annual energy consumption of dehumidifiers at different efficiencies in representative U.S. single-family homes and multi-family residences, and to assess the energy savings potential of increased dehumidifier efficiency. The energy use analysis estimates the range of energy use of dehumidifiers in the field (*i.e.,* as they are actually used by consumers). The energy use analysis provides the basis for other analyses DOE performed, particularly assessments of the energy savings and the savings in consumer operating costs that could result from adoption of amended or new standards.

DOE used data from the EIA's 2020 Residential Energy Consumption Survey (''*RECS* 2020'') [24] to determine dehumidifier ownership and usage across the United States. *RECS* 2020 represents the largest nationally available dataset of installed residential appliance stock of dehumidifiers in households (either portable or whole home) as well as the number of portable units in each household. *RECS* also provides dehumidifier usage information in the form of broad categories of annual usage frequency as reported by the households. DOE estimated monthly vapor density data for each household that reported owning a portable dehumidifier by using corresponding outdoor temperature and humidity information for the year 2020 provided by the National Oceanic and Atmospheric Administration (NOAA).[25] DOE used this vapor density data in conjunction with the annual usage information to estimate the respective annual operating hours of portable dehumidifiers for each consumer sample as applicable.

DOE determined that portable dehumidifiers operated in active (dehumidification) mode, fan-only mode, and standby mode while whole-home dehumidifiers operated in active and standby modes only. To estimate the annual dehumidifier energy consumption, DOE first calculated the number of operating hours in each mode. For portable dehumidifiers, DOE used available dehumidifier field

[20] Because the projected prices of standards-compliant products are typically higher than the price of baseline products, using the same markup for the incremental cost and the baseline cost would result in higher per-unit operating profit. While such an outcome is possible in the short term, DOE maintains that in markets that are reasonably competitive, it is unlikely that standards would lead to a sustainable increase in profitability in the long run.

[21] US Census Bureau, Annual Retail Trade Survey. 2017. *www.census.gov/programs-surveys/arts.html.*

[22] US Census Bureau, Annual Retail Trade Survey. 2017. *www.census.gov/programs-surveys/arts.html.*

[23] US Census Bureau, 2017 Economic Census. *www.census.gov/programs-surveys/economic-census/year/2017/economic-census-2017/data.html.*

[24] U.S. Department of Energy–Energy Information Administration. Residential Energy Consumption Survey. 2020. *www.eia.gov/consumption/residential/data/2020/.*

[25] Available at *https://www.ncdc.noaa.gov/cdo-web/datatools/lcd.*

studies [26] [27] that provided a relationship between vapor density and daily operating hours. DOE estimated that portable dehumidifiers operated in active mode for an average of 1,337 hours annually. For whole-home dehumidifiers, based on data from the field study, DOE estimated that, on average, 28 percent of the daily operating hours were spent in active or dehumidification mode and the remaining in standby mode. DOE paired these data with estimates of the number of months that dehumidifiers may be used based on usage behavior as reported in RECS 2020. DOE estimated that consumers leave the dehumidifier to cycle on and off for the entire month or months of the dehumidification season.

MIAQ stated that although dehumidifiers use the same vapor compression refrigeration cycle as air conditioners, their operation is much different and the latent load or run time is affected by many variables. According to MIAQ, consumers typically do not manually change the mode of operation or settings once a dehumidifier is installed. (MIAQ, No. 20 at p. 4)

DOE agrees that there are differences in operation between dehumidifiers and air conditioners. DOE's energy use analysis is based on dehumidifier field studies that capture real world dehumidifier operation in a variety of different operating conditions. The studies used by DOE support MIAQ's assertion that consumers do not manually change the mode of operation or settings once the dehumidifier is installed.

MIAQ stated that more than 10 percent of households have more than one dehumidifier, which indicates that consumers understand they can purchase two smaller capacity units rather than one large capacity unit. (MIAQ, No. 20 at p. 4)

Using RECS 2020, DOE estimates that 10.6 percent of portable dehumidifier-owning households own multiple units, similar to the estimate provided by MIAQ. DOE adjusted the consumer sample to account for households with multiple units using the household weights derived by RECS 2020 and the reported number of portable dehumidifiers in each household.

[26] Willem, H., T. Burke, C. Dunham, B. Beraki, J. Lutz, M. Melody, M. Nagaraju, C. Ni, S. Pratt, S. Price, and V. Tavares. *Using Field-Metered Data to Quantify Annual Energy Use of Residential Portable Unit Dehumidifiers.* 2013. Report No. LBNL–6469e.

[27] Burke, T. A., H. Willem, C. C. Ni, H. Stratton, C. Dunham Whitehead, and R. Johnson. *Whole-Home Dehumidifiers: Field-Monitoring Study.* 2014. Report No. LBNL–1003950E.

Chapter 7 of the NOPR TSD provides details on DOE's energy use analysis for dehumidifiers.

F. Life-Cycle Cost and Payback Period Analysis

DOE conducted LCC and PBP analyses to evaluate the economic impacts on individual consumers of potential energy conservation standards for dehumidifiers. The effect of new or amended energy conservation standards on individual consumers usually involves a reduction in operating cost and an increase in purchase cost. DOE used the following two metrics to measure consumer impacts:

□ The LCC is the total consumer expense of an appliance or product over the life of that product, consisting of total installed cost (manufacturer selling price, distribution chain markups, sales tax, and installation costs) plus operating costs (expenses for energy use, maintenance, and repair). To compute the operating costs, DOE discounts future operating costs to the time of purchase and sums them over the lifetime of the product.

□ The PBP is the estimated amount of time (in years) it takes consumers to recover the increased purchase cost (including installation) of a more efficient product through lower operating costs. DOE calculates the PBP by dividing the change in purchase cost at higher efficiency levels by the change in annual operating cost for the year that amended or new standards are assumed to take effect.

For any given efficiency level, DOE measures the change in LCC relative to the LCC in the no-new-standards case, which reflects the estimated efficiency distribution of dehumidifiers in the absence of new or amended energy conservation standards. In contrast, the PBP for a given efficiency level is measured relative to the baseline product.

For each considered efficiency level in each product class, DOE calculated the LCC and PBP for a nationally representative set of U.S. households. As stated previously, DOE developed household samples from RECS 2020. For each sample household, DOE determined the energy consumption for the dehumidifiers and the appropriate energy price. By developing a representative sample of households, the analysis captured the variability in energy consumption and energy prices associated with the use of dehumidifiers.

Inputs to the calculation of total installed cost include the cost of the product—which includes MPCs, manufacturer markups, retailer and distributor markups, and sales taxes—and installation costs. Inputs to the calculation of operating expenses include annual energy consumption, energy prices and price projections, repair and maintenance costs, product lifetimes, and discount rates. DOE created distributions of values for product lifetime, discount rates, and sales taxes, with probabilities attached to each value, to account for their uncertainty and variability.

The computer model DOE uses to calculate the LCC relies on a Monte Carlo simulation to incorporate uncertainty and variability into the analysis. The Monte Carlo simulations randomly sample input values from the probability distributions and dehumidifier user samples. The model calculated the LCC for products at each efficiency level for 10,000 households per simulation run. The analytical results include a distribution of 10,000 data points showing the range of LCC savings for a given efficiency level relative to the no-new-standards case efficiency distribution. In performing an iteration of the Monte Carlo simulation for a given consumer, product efficiency is chosen based on its probability. If the chosen product efficiency is greater than or equal to the efficiency of the standard level under consideration, the LCC calculation reveals that a consumer is not impacted by the standard level. By accounting for consumers who already purchase more efficient products, DOE avoids overstating the potential benefits from increasing product efficiency.

DOE calculated the LCC and PBP for consumers of dehumidifiers as if each were to purchase a new product in the expected year of required compliance with new or amended standards. New and amended standards would apply to dehumidifiers manufactured 3 years after the date on which any new or amended standard is published. (42 U.S.C. 6295 (m)(4)(A)) At this time, DOE estimates publication of a final rule in 2025. Therefore, for purposes of its analysis, DOE used 2028 as the first year of compliance with any amended standards for dehumidifiers.

Table IV.3 summarizes the approach and data DOE used to derive inputs to the LCC and PBP calculations. The subsections that follow provide further discussion. Details of the spreadsheet model, and of all the inputs to the LCC and PBP analyses, are contained in

chapter 8 of the NOPR TSD and its appendices.

TABLE IV.4—SUMMARY OF INPUTS AND METHODS FOR THE LCC ANALYSIS *

Inputs	Source/method
Product Costs	Derived by multiplying MPCs by manufacturer, retailer, and contractor markups and sales tax, as appropriate. Used historical data to derive a price scaling index to project product costs. Applied price trend to electronic controls used on products with variable-speed blower motors.
Installation Costs	Baseline installation cost determined with data from RSMeans. Assumed no change with efficiency level.
Annual Energy Use	The total annual energy use derived from power demand of each mode multiplied by the hours per year in that mode. Average number of hours based on field data. Variability: Based on RECS 2020.
Energy Prices	Electricity: Based on Edison Electric Institute data for 2022. Variability: Regional energy prices determined for each census division.
Energy Price Trends	Based on *AEO2023* electricity price projections from 2022–2050; constant value based on average of price for 2046–2050 thereafter.
Repair and Maintenance Costs	Assumed no change with efficiency level.
Product Lifetime	Weibull probability distribution based on averages provided from manufacturer interviews: 10 years for portable dehumidifiers and 12 years for whole-home dehumidifiers.
Discount Rates	Approach involves identifying all possible debt or asset classes that might be used to purchase the considered appliances or that might be affected indirectly. Primary data source was the Federal Reserve Board's Survey of Consumer Finances.
Compliance Date	2028.

* Not used for PBP calculation. References for the data sources mentioned in this table are provided in the following sections and in chapter 8 of the NOPR TSD.

1. Product Cost

To calculate consumer product costs, DOE multiplied the MPCs developed in the engineering analysis by the markups described previously (along with sales taxes). DOE used different markups for baseline products and higher-efficiency products, because DOE applies an incremental markup to the increase in MSP associated with higher-efficiency products.

Economic literature and historical data suggest that the real costs of many products may trend downward over time according to ''learning'' or ''experience'' curves. Experience curve analysis implicitly includes factors such as efficiencies in labor, capital investment, automation, materials prices, distribution, and economies of scale at an industry-wide level. DOE developed two types of experience curves to project the future dehumidifier prices. One is an overall price trend applied to the cost of dehumidifier units excluding the cost of electronic controls used for variable-speed blower fans, and the other is a separate learning rate associated with the electronic controls used in units with variable-speed blower fans. To derive the first type of experience curve for portable dehumidifiers, DOE used historical Producer Price Index (''PPI'') data between 1983 and 2014 for ''small electric household appliances, except fans'' and data from the Bureau of Labor Statistics (''BLS'') [28] between 2014 and 2022 for ''small electric household appliances manufacturing'' to construct a combined price index that is most representative of portable dehumidifiers. Inflation-adjusted price indices were calculated by dividing the PPI series by the implicit gross domestic product (''GDP'') price deflator for the same years. DOE assembled a time series of annual shipments of portable dehumidifiers from AHAM and *Appliance Magazine*.[29] For efficiency levels that include variable-speed blowers, DOE applied a different price trend to the controls portion of the variable-speed blowers that contributes to the price increments moving from single-speed blower to variable-speed blower. DOE used PPI data between 1967 and 2022 on ''semiconductors and related device manufacturing'' to estimate the historic price trend of electronic components in the controls. The regression performed as an exponential trend line fit results in an R-square of 0.99, with an annual price decline rate of 6.3 percent. DOE applied the same learning parameters for whole-home dehumidifiers. See chapter 8 of the NOPR TSD for further details on this topic.

DOE included the cost to internationally ship and domestically transport dehumidifier units to the United States. DOE calculated shipping costs for the baseline and for higher efficiency levels that have larger product dimensions that increase shipping costs.

2. Installation Cost

Installation cost includes labor, overhead, and any miscellaneous materials and parts needed to install the product. In the June 2022 Preliminary Analysis, DOE assumed that there were no installation costs for portable dehumidifiers given that consumers were directed by manufacturer instructions to simply plug them in to a wall outlet for operation. For whole-home dehumidifiers, DOE used data from RSMeans' 2022 Residential Cost Data to estimate installation costs for baseline and more efficient units.

For this NOPR, DOE assumed that whole-home dehumidifier installation costs do not increase with efficiency based on feedback from manufacturer interviews. DOE used the baseline installation cost for all efficiency levels for whole-home dehumidifiers. DOE maintained the assumption of no installation costs for portable dehumidifiers.

DOE seeks available data on installation costs for baseline and more efficient units.

3. Annual Energy Consumption

For each sampled household, DOE determined the energy consumption for dehumidifiers at different efficiency levels using the approach described

[28] Product series IDs: PCU33521033521014 and PCU335210335210. More information at *www.bls.gov/ppi/*.

[29] Appliance Magazine. *Appliance Historical Statistical Review: 1954–2012*. 2014. UBM Canon.

previously in section IV.E of this document.

4. Energy Prices

Because marginal electricity price more accurately captures the incremental savings associated with a change in energy use from higher efficiency, it provides a better representation of incremental change in consumer costs than average electricity prices. Therefore, DOE applied average electricity prices for the energy use of the product purchased in the no-new-standards case, and marginal electricity prices for the incremental change in energy use associated with the other efficiency levels considered.

DOE derived electricity prices in 2022 using data from Edison Electric Institute (''EEI'') Typical Bills and Average Rates reports. Based upon comprehensive, industry-wide surveys, this semi-annual report presents typical monthly electric bills and average kilowatt-hour costs to the customer as charged by investor-owned utilities. For the residential sector, DOE calculated electricity prices using the methodology described in Coughlin and Beraki (2018).[30] DOE used the EEI data to define a marginal price as the ratio of the change in the bill to the change in energy consumption.

To estimate energy prices in future years, DOE multiplied the 2022 energy prices by the projection of annual average price changes for each of the nine census divisions from the Reference case in AEO2023, which has an end year of 2050.[31] To estimate energy prices after 2050, DOE assumed a constant 2050 value for all years.

5. Maintenance and Repair Costs

Repair costs are associated with repairing or replacing product components that have failed in an appliance; maintenance costs are associated with maintaining the operation of the product. Typically, small incremental increases in product efficiency produce no, or only minor, changes in repair and maintenance costs compared to baseline efficiency products.

In the June 2022 Preliminary Analysis, DOE assumed that maintenance and repair costs would not vary by efficiency level and did not include them in the LCC analysis.

MIAQ stated that, in general, more efficient dehumidifiers are typically made with more complex components which potentially increases the failure probability and the skill level of the technician required to conduct any repairs. (MIAQ, No. 20 at p. 5)

Feedback from manufacturer interviews (*see* section IV.J.3 of this document) indicated that portable dehumidifiers do not require maintenance costs that would change with efficiency and whole-home dehumidifier consumers are more likely to replace rather than repair their units. Based on this feedback, DOE assumed that portable dehumidifier consumers are also more likely to replace a unit rather than repair it, similar to whole-home units. For this NOPR analysis, DOE did not include maintenance or repair costs for portable or whole-home dehumidifiers. DOE assumes that filter change frequency and cost would not change with efficiency for each product class. DOE notes that higher failure rates for units with more complex technology could potentially indicate a different lifetime for those units. However, DOE is unaware of any data indicating differences in failure rates based on the components used in more efficient dehumidifiers.

DOE seeks comment on the assumption that dehumidifier consumers are most likely to replace a broken unit rather than repair it. DOE also seeks available data on the filter change and repair frequency and costs.

6. Product Lifetime

In the June 2022 Preliminary Analysis, DOE assumed a lifetime distribution with an average age of 11 years for portable dehumidifiers, based on the June 2016 Final Rule. 81 FR 38338, 38359. In the absence of data specific to whole-home dehumidifiers, DOE assumed that whole-home dehumidifiers would have a lifetime distribution similar to residential packaged central air conditioners that operate in humid climates. For whole-home dehumidifiers, DOE used the lifetime distribution with an average lifetime of 18 years from the Residential Central Air and Heat Pumps Direct Final Rule, published on January 6, 2017. 82 FR 1786.

MIAQ stated that since dehumidifiers operate under different conditions than air conditioning equipment, dehumidifiers may have a shorter average lifetime due to increased freeze/thaw cycling, corrosion from increased water saturation time, and component failure from extreme intake air temperatures. MIAQ suggested a shorter 8- to 12-year lifetime as more applicable for dehumidifiers due to these different conditions. (MIAQ, No. 20 at p. 2)

For this NOPR analysis, DOE has included the estimates from MIAQ and other feedback from manufacturers in its lifetime distributions. For portable dehumidifiers, DOE incorporated additional average lifetime estimates from manufacturers indicating an average lifetime of 10 years. A previous estimate of an average lifetime of 12 years from the Northeast Energy Star Lighting and Appliance is no longer available online and thus not included in the lifetime estimates. For whole-home units, as described by MIAQ, dehumidifiers are subject to different operating conditions relative to other air conditioning equipment that could lead to a different average lifetime. For whole-home dehumidifiers, DOE used an average value of 12 years whole-home dehumidifiers based on MIAQ's comments.

7. Discount Rates

In the calculation of LCC, DOE applies discount rates appropriate to households to estimate the present value of future operating cost savings. DOE estimated a distribution of discount rates for dehumidifiers based on the opportunity cost of consumer funds.

DOE applies weighted average discount rates calculated from consumer debt and asset data, rather than marginal or implicit discount rates.[32] The LCC analysis estimates net present value over the lifetime of the product, so the appropriate discount rate will reflect the general opportunity cost of household funds, taking this time scale into account. Given the long time horizon modeled in the LCC analysis, the application of a marginal interest rate associated with an initial source of funds is inaccurate. Regardless of the method of purchase, consumers are expected to continue to rebalance their debt and asset holdings over the LCC analysis period, based on the restrictions consumers face in their debt payment requirements and the relative size of the interest rates available on debts and assets. DOE estimates the

[30] Coughlin, K. and B. Beraki. 2018. Residential Electricity Prices: A Review of Data Sources and Estimation Methods. Lawrence Berkeley National Laboratory. Berkeley, CA. Report No. LBNL–2001169. *ees.lbl.gov/publications/residential-electricity-prices-review.*

[31] EIA. *Annual Energy Outlook 2023.* Washington, DC. Available at *www.eia.gov/forecasts/aeo/* (accessed August 21, 2023).

[32] The implicit discount rate is inferred from a consumer purchase decision between two otherwise identical goods with different first cost and operating cost. It is the interest rate that equates the increment of first cost to the difference in net present value of lifetime operating cost, incorporating the influence of several factors: transaction costs; risk premiums and response to uncertainty; time preferences; and interest rates at which a consumer is able to borrow or lend. The implicit discount rate is not appropriate for the LCC analysis because it reflects a range of factors that influence consumer purchase decisions, rather than the opportunity cost of the funds that are used in purchases.

aggregate impact of this rebalancing using the historical distribution of debts and assets.

To establish residential discount rates for the LCC analysis, DOE identified all relevant household debt or asset classes in order to approximate a consumer's opportunity cost of funds related to appliance energy cost savings. It estimated the average percentage shares of the various types of debt and equity by household income group using data from the Federal Reserve Board's triennial Survey of Consumer Finances [33] (''SCF'') starting in 1995 and ending in 2019. Using the SCF and other sources, DOE developed a distribution of rates for each type of debt and asset by income group to represent the rates that may apply in the year in which amended standards would take effect. DOE assigned each sample household a specific discount rate drawn from one of the distributions. The average rate across all types of household debt and equity and income groups, weighted by the shares of each type, is 4.3 percent. See chapter 8 of the NOPR TSD for further details on the development of consumer discount rates.

8. Energy Efficiency Distribution in the No-New-Standards Case

To accurately estimate the share of consumers that would be affected by a potential energy conservation standard at a particular efficiency level, DOE's LCC analysis considered the projected distribution (market shares) of product efficiencies under the no-new-standards case (*i.e.,* the case without amended or new energy conservation standards).

In the June 2022 Preliminary Analysis, DOE used shipments-weighted efficiency data submitted by AHAM to estimate the efficiency distribution for portable dehumidifiers. DOE used these data in conjunction with the model counts from the Compliance Certification Database (''CCD'') database to assign market share to efficiency levels defined in the June 2022 Preliminary Analysis. DOE assumed an annual efficiency improvement of 0.25 percent to develop the efficiency distribution in the first year of compliance.

AHAM stated that model counts based on the CCD database are not an accurate proxy to estimate the efficiency distribution for portable dehumidifiers. AHAM suggested DOE use shipment-weighted data gathered from AHAM members. AHAM also noted that data from AHAM members indicated that 100 percent of shipments for Product Class 3 are at the baseline efficiency level and the one model in CCD meeting EL 2 is a whole-home dehumidifier. (AHAM, No. 22 at p. 7)

DOE thanks AHAM for providing shipments-weighted distributions and has included the data for establishing the efficiency distribution of portable dehumidifiers in 2022. DOE notes in response to AHAM's note on current market efficiency distribution that the no-new-standards case efficiency distribution used in the LCC is the projected efficiency distribution in the compliance year (2028) and includes the impact of market efficiency trends. For dehumidifiers, the efficiency trend employed by DOE is based on historical market trends towards more efficient products in response to ENERGY STAR criterion updates. The current ENERGY STAR specification 5.0 criterion were adopted in 2019. As indicated by ENERGY STAR shipments data, 94 percent of the dehumidifier market met ENERGY STAR levels in 2021, compared to 88 percent in 2020 and 80 percent in 2019. On October 10, 2023, EPA released the final recognition criteria for ENERGY STAR Most Efficient 2024, which meet or exceed the proposed standards in all product classes.[34] The expected publication of ENERGY STAR specification 6.0 for dehumidifiers in 2024 will likely continue to shift the dehumidifier market toward more efficient products in the absence of a standard. To account for this observed historical trend towards a higher average market efficiency in the absence of a new standard, DOE included an annual improvement of 0.25 percent in the average shipment-weighted IEF, based on trends observed for room air conditioners [35] and also used in the June 2016 Final Rule for dehumidifiers. For whole-home dehumidifiers, in the absence of shipments-weighted data, DOE has maintained the approach of using model counts from the CCD database for the estimation of efficiency distributions and included an annual improvement of 0.25 percent in average shipment-weighted IEF for the no-new-standards case.

DOE seeks data and comment on its efficiency distribution estimate and the assumption of an annual efficiency improvement of 0.25 percent and the expected market respond to updated ENERGY STAR 6.0 specifications.

The estimated market shares for the no-new-standards case for dehumidifiers in 2028 are shown in Tables IV.4 and IV.5. See chapter 8 of the NOPR TSD for further information on the derivation of the efficiency distributions.

TABLE IV.5—MARKET SHARE OF EACH EFFICIENCY LEVEL FOR PORTABLE DEHUMIDIFIERS FOR THE NO-NEW-STANDARDS CASE IN 2028

Product class	≤25.00 pints/day		25.01–50.00 pints/day		≥50.01 pints/day	
Product class market share	19.5%		77.9%		1.1%	
EL	Integrated energy factor (L/kWh)	Market share (%)	Integrated energy factor (L/kWh)	Market share (%)	Integrated energy factor (L/kWh)	Market share (%)
0	1.30	0	1.60	0	2.80	86
1	1.40	25	1.70	0	3.10	14
2	1.57	66	1.80	87	3.30	0
3	1.70	9	2.01	13	3.51	0
4	1.94	0	2.07	0	3.67	0
5	2.32	0	2.38	0	.....	.....

[33] U.S. Board of Governors of the Federal Reserve System. Survey of Consumer Finances. 1995, 1998, 2001, 2004, 2007, 2010, 2013, 2016, and 2019. Available at *www.federalreserve.gov/econresdata/scf/scfindex.htm* (last accessed February 22, 2023).

[34] Available at *https://www.energystar.gov/sites/default/files/asset/document/Dehumidifiers%20ENERGY%20STAR%20Most%20Efficient%202024%20Final%20Criteria.pdf.*

[35] Ganeshalingam, M., Ni, C., and Yang, H–C. 2021. A Retrospective Analysis of the 2011 Direct Final Rule for Room Air Conditioners. Lawrence Berkeley National Laboratory. LBNL-2001413.

TABLE IV.6—MARKET SHARE OF EACH EFFICIENCY LEVEL FOR WHOLE-HOME DEHUMIDIFIERS FOR THE NO-NEW-STANDARDS CASE IN 2028

Product class	≤8.0 cu ft case volume		>8.0 cu ft case volume	
Product class market share	1.2%		0.3%	
EL	Integrated energy factor (L/kWh)	Market share (%)	Integrated energy factor (L/kWh)	Market share (%)
0	1.77	8	2.41	54
1	2.09	14	2.70	46
2	2.22	74	3.30	0
3	2.39	4	3.81	0
4	.....	.....	4.17	0

The LCC Monte Carlo simulations draw from the efficiency distributions and randomly assign an efficiency to the dehumidifiers purchased by each sample household in the no-new-standards case. The resulting percent shares within the sample match the market shares in the efficiency distributions.

9. Payback Period Analysis

The payback period is the amount of time (expressed in years) it takes the consumer to recover the additional installed cost of more efficient products, compared to baseline products, through energy cost savings. Payback periods that exceed the life of the product mean that the increased total installed cost is not recovered in reduced operating expenses.

The inputs to the PBP calculation for each efficiency level are the change in total installed cost of the product and the change in the first-year annual operating expenditures relative to the baseline. DOE refers to this as a ''simple PBP'' because it does not consider changes over time in operating cost savings. The PBP calculation uses the same inputs as the LCC analysis when deriving first-year operating costs.

As noted previously, EPCA establishes a rebuttable presumption that a standard is economically justified if the Secretary finds that the additional cost to the consumer of purchasing a product complying with an energy conservation standard level will be less than three times the value of the first year's energy savings resulting from the standard, as calculated under the applicable test procedure. (42 U.S.C. 6295(o)(2)(B)(iii)) For each considered efficiency level, DOE determined the value of the first year's energy savings by calculating the energy savings in accordance with the applicable DOE test procedure, and multiplying those savings by the average energy price projection for the year in which compliance with the amended standards would be required.

G. Shipments Analysis

DOE uses projections of annual product shipments to calculate the national impacts of potential amended or new energy conservation standards on energy use, NPV, and future manufacturer cash flows.[36] The shipments model takes an accounting approach, tracking market shares of each product class and the vintage of units in the stock. Stock accounting uses product shipments as inputs to estimate the age distribution of in-service product stocks for all years. The age distribution of in-service product stocks is a key input to calculations of both the NES and NPV, because operating costs for any year depend on the age distribution of the stock.

DOE's stock accounting model is calibrated based on historical shipments for portable and whole-home dehumidifiers. In the June 2022 Preliminary Analysis, DOE used historical shipments provided by AHAM for portable dehumidifiers and assumed that whole-home dehumidifiers accounted for 1 percent of total dehumidifier shipments. In this NOPR analysis, DOE included 2022 shipments estimates for whole-home dehumidifiers based on feedback from manufacturers indicating whole-home dehumidifiers shipments account for 1.6 percent of the total dehumidifier market.

DOE's shipments model for dehumidifiers considers shipments to replace existing units and to first-time owners. To determine replacement shipments, DOE used survival probability distributions based on average lifetime estimates of 10 years for portable dehumidifiers and 12 years for whole-home dehumidifiers provided by manufacturers. To estimate shipments to first-time owners, DOE used projections of AEO2023 housing stock coupled with the historical shipments data. DOE's shipments projections include shipments reductions due to consumers that do not replace a failed unit.

DOE considers the impacts on shipments from changes in product purchase price associated with higher energy efficiency levels using a price elasticity. As in the June 2022 Preliminary Analysis, DOE employs a price elasticity of −0.45 in its shipments model. These values are based on analysis of aggregated data for five residential appliances.[37] The market impact is defined as the difference between the product of price elasticity of demand and the change in price due to a standard level.

When comparing the first cost of the efficiency level selected for PC1 and PC2 at each TSL, DOE considers that the difference of installed cost in standards case is not significant enough to warrant a product switching scenario that would result in a different market share distribution from the no-new-standards case. Given the small overall market share of PC3, DOE did not include a product switching scenario in the analysis. DOE assumed that consumers are unlikely to purchase multiple lower capacity units in place of a larger capacity unit as a result of a standard.

DOE seeks comment on the assumption that dehumidifier consumers' purchase decision are unlikely to change as a result of a standard.

H. National Impact Analysis

The NIA assesses the national energy savings (''NES'') and the NPV from a national perspective of total consumer costs and savings that would be expected to result from new or amended

[36] DOE uses data on manufacturer shipments as a proxy for national sales, as aggregate data on sales are lacking. In general, one would expect a close correspondence between shipments and sales.

[37] Fujita, K. (2015) Estimating Price Elasticity using Market-Level Appliance Data. Lawrence Berkeley National Laboratory, LBNL–188289.

standards at specific efficiency levels.[38] (''Consumer'' in this context refers to consumers of the product being regulated.) DOE calculates the NES and NPV for the potential standard levels considered based on projections of annual product shipments, along with the annual energy consumption and total installed cost data from the energy use and LCC analyses. For the present analysis, DOE projected the energy savings, operating cost savings, product costs, and NPV of consumer benefits over the lifetime of dehumidifiers sold from 2028 through 2057.

DOE evaluates the impacts of new or amended standards by comparing a case without such standards with standards-case projections. The no-new-standards case characterizes energy use and consumer costs for each product class in the absence of new or amended energy conservation standards. For this projection, DOE considers historical trends in efficiency and various forces that are likely to affect the mix of efficiencies over time. DOE compares the no-new-standards case with projections characterizing the market for each product class if DOE adopted new or amended standards at specific energy efficiency levels (*i.e.,* the TSLs or standards cases) for that class. For the standards cases, DOE considers how a given standard would likely affect the market shares of products with efficiencies greater than the standard.

DOE uses a spreadsheet model to calculate the energy savings and the national consumer costs and savings from each TSL. Interested parties can review DOE's analyses by changing various input quantities within the spreadsheet. The NIA spreadsheet model uses typical values (as opposed to probability distributions) as inputs.

Table IV.6 summarizes the inputs and methods DOE used for the NIA analysis for the NOPR. Discussion of these inputs and methods follows the table. See chapter 10 of the NOPR TSD for further details.

TABLE IV.7—SUMMARY OF INPUTS AND METHODS FOR THE NATIONAL IMPACT ANALYSIS

Inputs	Method
Shipments	Annual shipments from shipments model.
Compliance Date of Standard	2028.
Efficiency Trends	No-new-standards case: 0.25 percent annual increase in efficiency. Standards cases: Roll-up in compliance year to meet potential efficiency level.
Annual Energy Consumption per Unit	Annual weighted-average values are a function of energy use at each TSL.
Total Installed Cost per Unit	Annual weighted-average values are a function of cost at each TSL. Incorporates projection of future product prices based on historical data.
Annual Energy Cost per Unit	Annual weighted-average values as a function of the annual energy consumption per unit and energy prices.
Repair and Maintenance Cost per Unit	Annual values do not change with efficiency level.
Energy Price Trends	AEO2023 projections to 2050 and constant 2050 value thereafter.
Energy Site-to-Primary and FFC Conversion	A time-series conversion factor based on AEO2023.
Discount Rate	3 percent and 7 percent.
Present Year	2023.

1. Product Efficiency Trends

A key component of the NIA is the trend in energy efficiency projected for the no-new-standards case and each of the standards cases. DOE developed an energy efficiency distribution for the no-new-standards case (which yields a shipment-weighted average efficiency) for each of the considered product classes for the year of anticipated compliance with an amended or new standard. As described in section IV.F.8 of this document, the efficiency trend used in the no-new-standards case is based on historical market trends towards more efficient product in response to ENERGY STAR specifications. To account for the historical movement towards more efficient products in the market in the absence of a standard, DOE included an annual improvement of 0.25 percent in the average shipment-weighted IEF in each year of the analysis period shipments projection in the no-new-standards case. The approach is further described in chapter 10 of the NOPR TSD

For the standards cases, DOE used a ''roll-up'' scenario to establish the shipment-weighted efficiency for the year that standards are assumed to become effective (2028). In this scenario, the market shares of products in the no-new-standards case that do not meet the standard under consideration would ''roll up'' to meet the new standard level, and the market share of products above the standard would remain unchanged.

2. National Energy Savings

The national energy savings analysis involves a comparison of national energy consumption of the considered products between each TSL and the case with no new or amended energy conservation standards. DOE calculated the national energy consumption by multiplying the number of units (stock) of each product (by vintage or age) by the unit energy consumption (also by vintage). DOE calculated annual NES based on the difference in national energy consumption for the no-new standards case and for each higher efficiency standard case. DOE estimated energy consumption and savings based on site energy and converted the electricity consumption and savings to primary energy (*i.e.,* the energy consumed by power plants to generate site electricity) using annual conversion factors derived from AEO 2023. Cumulative energy savings are the sum of the NES for each year over the timeframe of the analysis.

Use of higher-efficiency products is sometimes associated with a direct rebound effect, which refers to an increase in utilization of the product due to the increase in efficiency. DOE did not find any data on the rebound effect specific to dehumidifiers and assumed no rebound in the NOPR analysis.

[38] The NIA accounts for impacts in the 50 states and U.S. territories.

In 2011, in response to the recommendations of a committee on ''Point-of-Use and Full-Fuel-Cycle Measurement Approaches to Energy Efficiency Standards'' appointed by the National Academy of Sciences, DOE announced its intention to use FFC measures of energy use and greenhouse gas and other emissions in the national impact analyses and emissions analyses included in future energy conservation standards rulemakings. 76 FR 51281 (Aug. 18, 2011). After evaluating the approaches discussed in the August 18, 2011, notice, DOE published a statement of amended policy in which DOE explained its determination that EIA's National Energy Modeling System (''NEMS'') is the most appropriate tool for its FFC analysis and its intention to use NEMS for that purpose. 77 FR 49701 (Aug. 17, 2012). NEMS is a public domain, multi-sector, partial equilibrium model of the U.S. energy sector [39] that EIA uses to prepare its *Annual Energy Outlook.* The FFC factors incorporate losses in production and delivery in the case of natural gas (including fugitive emissions) and additional energy used to produce and deliver the various fuels used by power plants. The approach used for deriving FFC measures of energy use and emissions is described in appendix 10B of the NOPR TSD.

3. Net Present Value Analysis

The inputs for determining the NPV of the total costs and benefits experienced by consumers are (1) total annual installed cost, (2) total annual operating costs (energy costs and repair and maintenance costs), and (3) a discount factor to calculate the present value of costs and savings. DOE calculates net savings each year as the difference between the no-new-standards case and each standards case in terms of total savings in operating costs versus total increases in installed costs. DOE calculates operating cost savings over the lifetime of each product shipped during the projection period.

As discussed in section IV.F.1 of this document, DOE developed dehumidifier price trends based on historical PPI data. DOE applied the same trends to project prices for each product class at each considered efficiency level. By 2057, which is the end date of the projection period, the average dehumidifier price is projected to drop 25 percent relative to 2028. DOE's projection of product prices is described in appendix 10C of the NOPR TSD.

To evaluate the effect of uncertainty regarding the price trend estimates, DOE investigated the impact of different product price projections on the consumer NPV for the considered TSLs for dehumidifiers. In addition to the default price trend, DOE considered two product price sensitivity cases: (1) a high price decline case and (2) a low price decline case. In the high price decline case, DOE used a faster price decline for the non-controls portion of the price derived from the same combined price index PPI data for dehumidifiers between 2005 and 2022. In the low price decline case, DOE used the same combined price index PPI data for dehumidifiers between 1983 and 1998. For both high and low price decline cases, DOE used the default price decline for variable-speed blower controls. The derivation of these price trends and the results of these sensitivity cases are described in appendix 10C of the NOPR TSD.

The energy cost savings are calculated using the estimated energy savings in each year and the projected price of the appropriate form of energy. To estimate energy prices in future years, DOE multiplied the average regional energy prices by the projection of annual national-average residential energy price changes in the Reference case from AEO2023, which has an end year of 2050. To estimate price trends after 2050, the 2050 value was used for all years. As part of the NIA, DOE also analyzed scenarios that used inputs from variants of the AEO2023 Reference case that have lower and higher economic growth. Those cases have lower and higher energy price trends compared to the Reference case. NIA results based on these cases are presented in appendix 10C of the NOPR TSD.

In calculating the NPV, DOE multiplies the net savings in future years by a discount factor to determine their present value. For this NOPR, DOE estimated the NPV of consumer benefits using both a 3-percent and a 7-percent real discount rate. DOE uses these discount rates in accordance with guidance provided by the Office of Management and Budget (''OMB'') to Federal agencies on the development of regulatory analysis.[40] The discount rates for the determination of NPV are in contrast to the discount rates used in the LCC analysis, which are designed to reflect a consumer's perspective. The 7-percent real value is an estimate of the average before-tax rate of return to private capital in the U.S. economy. The 3-percent real value represents the ''social rate of time preference,'' which is the rate at which society discounts future consumption flows to their present value.

I. Consumer Subgroup Analysis

In analyzing the potential impact of new or amended energy conservation standards on consumers, DOE evaluates the impact on identifiable subgroups of consumers that may be disproportionately affected by a new or amended national standard. The purpose of a subgroup analysis is to determine the extent of any such disproportional impacts. DOE evaluates impacts on particular subgroups of consumers by analyzing the LCC impacts and PBP for those particular consumers from alternative standard levels. For this NOPR, DOE analyzed the impacts of the considered standard levels on two subgroups: (1) low-income households and (2) senior-only households. The analysis used subsets of the RECS 2020 sample composed of households that meet the criteria for the two subgroups. DOE used the LCC and PBP spreadsheet model to estimate the impacts of the considered efficiency levels on these subgroups. Chapter 11 in the NOPR TSD describes the consumer subgroup analysis.

J. Manufacturer Impact Analysis

1. Overview

DOE performed an MIA to estimate the financial impacts of amended energy conservation standards on manufacturers of dehumidifiers and to estimate the potential impacts of such standards on employment and manufacturing capacity. The MIA has both quantitative and qualitative aspects and includes analyses of projected industry cash flows, the INPV, investments in research and development (R&D) and manufacturing capital, and domestic manufacturing employment. Additionally, the MIA seeks to determine how amended energy conservation standards might affect manufacturing employment, capacity, and competition, as well as how standards contribute to overall regulatory burden. Finally, the MIA serves to identify any disproportionate impacts on manufacturer subgroups, including small business manufacturers.

The quantitative part of the MIA primarily relies on the GRIM, an industry cash flow model with inputs specific to this proposed rulemaking.

[39] For more information on NEMS, refer to *The National Energy Modeling System: An Overview 2018,* DOE/EIA–0581(2018), April 2019. Available at *https://www.eia.gov/outlooks/aeo/nems/overview/pdf/0581(2018).pdf* (last accessed February 22, 2023).

[40] United States Office of Management and Budget. *Circular A–4: Regulatory Analysis.* September 17, 2003. Section E. Available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf.*

The key GRIM inputs include data on the industry cost structure, unit production costs, product shipments, manufacturer markups, and investments in R&D and manufacturing capital required to produce compliant products. The key GRIM outputs are the INPV, which is the sum of industry annual cash flows over the analysis period, discounted using the industry-weighted average cost of capital, and the impact to domestic manufacturing employment. The model uses standard accounting principles to estimate the impacts of more-stringent energy conservation standards on a given industry by comparing changes in INPV and domestic manufacturing employment between a no-new-standards case and the various standards cases (*i.e.,* TSLs). To capture the uncertainty relating to manufacturer pricing strategies following amended standards, the GRIM estimates a range of possible impacts under different manufacturer markup scenarios.

The qualitative part of the MIA addresses manufacturer characteristics and market trends. Specifically, the MIA considers such factors as a potential standard's impact on manufacturing capacity, competition within the industry, the cumulative impact of other DOE and non-DOE regulations, and impacts on manufacturer subgroups. The complete MIA is outlined in chapter 12 of the NOPR TSD.

DOE conducted the MIA for this rulemaking in three phases. In Phase 1 of the MIA, DOE prepared a profile of the dehumidifier manufacturing industry based on the market and technology assessment, preliminary manufacturer interviews, and publicly available information. This included a top-down analysis of dehumidifier manufacturers that DOE used to derive preliminary financial inputs for the GRIM (*e.g.,* revenues; materials, labor, overhead, and depreciation expenses; selling, general, and administrative expenses (SG&A); and R&D expenses). DOE also used public sources of information to further calibrate its initial characterization of the dehumidifier manufacturing industry, including corporate annual reports, the U.S. Census Bureau's *Annual Survey of Manufactures* (*ASM*),[41] and reports from Dun & Bradstreet.[42]

In Phase 2 of the MIA, DOE prepared a framework industry cash-flow analysis to quantify the potential impacts of amended energy conservation standards. The GRIM uses several factors to determine a series of annual cash flows starting with the announcement of the standard and extending over a 30-year period following the compliance date of the standard. These factors include annual expected revenues, costs of sales, SG&A and R&D expenses, taxes, and capital expenditures. In general, energy conservation standards can affect manufacturer cash flow in three distinct ways: (1) creating a need for increased investment, (2) raising production costs per unit, and (3) altering revenue due to higher per-unit prices and changes in sales volumes.

In addition, during Phase 2, DOE developed interview guides to distribute to manufacturers of dehumidifiers in order to develop other key GRIM inputs, including product and capital conversion costs, and to gather additional information on the anticipated effects of energy conservation standards on revenues, direct employment, capital assets, industry competitiveness, and subgroup impacts.

In Phase 3 of the MIA, DOE conducted structured, detailed interviews with representative manufacturers. During these interviews, DOE discussed engineering, manufacturing, procurement, and financial topics to validate assumptions used in the GRIM and to identify key issues or concerns. See section IV.J.3 of this document for a description of the key issues raised by manufacturers during the interviews. As part of Phase 3, DOE also evaluated subgroups of manufacturers that may be disproportionately impacted by amended standards or that may not be accurately represented by the average cost assumptions used to develop the industry cash flow analysis. Such manufacturer subgroups may include small business manufacturers, low-volume manufacturers, niche players, and/or manufacturers exhibiting a cost structure that largely differs from the industry average. DOE identified one subgroup for a separate impact analysis: small business manufacturers. The small business subgroup is discussed in section VI.B of this document, ''Review under the Regulatory Flexibility Act'' and in chapter 12 of the NOPR TSD.

2. Government Regulatory Impact Model and Key Inputs

DOE uses the GRIM to quantify the changes in cash flow due to amended standards that result in a higher or lower industry value. The GRIM uses a standard, annual discounted cash-flow analysis that incorporates manufacturer costs, markups, shipments, and industry financial information as inputs. The GRIM models changes in costs, distribution of shipments, investments, and manufacturer margins that could result from an amended energy conservation standard. The GRIM spreadsheet uses the inputs to arrive at a series of annual cash flows, beginning in 2023 (the base year of the analysis) and continuing to 2057. DOE calculated INPVs by summing the stream of annual discounted cash flows during this period. For manufacturers of dehumidifiers, DOE used a real discount rate of 8.4 percent, which was derived from industry financials and then modified according to feedback received during manufacturer interviews.

The GRIM calculates cash flows using standard accounting principles and compares changes in INPV between the no-new-standards case and each standards case. The difference in INPV between the no-new-standards case and a standards case represents the financial impact of the amended energy conservation standard on manufacturers. As discussed previously, DOE developed critical GRIM inputs using a number of sources, including publicly available data, results of the engineering analysis, and information gathered from industry stakeholders during the course of manufacturer interviews. The GRIM results are presented in section V.B.2 of this document. Additional details about the GRIM, the discount rate, and other financial parameters can be found in chapter 12 of the NOPR TSD.

a. Manufacturer Production Costs

Manufacturing more efficient equipment is typically more expensive than manufacturing baseline equipment due to the use of more complex components, which are typically more costly than baseline components. The changes in the MPCs of covered products can affect the revenues, gross margins, and cash flow of the industry.

DOE typically uses one of two approaches to develop energy efficiency levels for the engineering analysis: (1) relying on observed efficiency levels in the market (*i.e.,* the efficiency-level approach), or (2) determining the incremental efficiency improvements associated with incorporating specific design options to a baseline model (*i.e.,* the design-option approach). In this proposed rulemaking, DOE relied on a combination of the efficiency-level approach and the design-option

[41] U.S. Census Bureau, *Annual Survey of Manufactures.* ''Summary Statistics for Industry Groups and Industries in the U.S (2021).'' Available at: *www.census.gov/data/tables/time-series/econ/asm/2018-2021-asm.html* (last accessed March 3, 2023).

[42] The Dun & Bradstreet Hoovers login is available at: *app.dnbhoovers.com* (last accessed March 3, 2023).

approach to develop cost estimates at each efficiency level for dehumidifiers, structured around the reverse engineering approach. The analysis involved reviewing publicly available cost and performance information, physically disassembling commercially available products and modeling equipment cost while removing costs associated with non-efficiency related components or features. DOE then considered the incremental steps manufacturers may take to reach higher efficiency levels. In its modeling, DOE started with the baseline MPC and added the expected design options at each higher efficiency level to estimate incremental MPCs. For a complete description of the MPCs, see section IV.C of this document or chapter 5 of the NOPR TSD.

b. Shipments Projections

The GRIM estimates manufacturer revenues based on total unit shipment projections and the distribution of those shipments by efficiency level. Changes in sales volumes and efficiency distributions over time can significantly affect manufacturer finances. For this analysis, the GRIM uses the NIA's annual shipment projections derived from the shipments analysis from 2023 (the base year) to 2057 (the end year of the analysis period). The shipments model takes an accounting approach, tracking market shares of each product class and the vintage of units in the stock. Stock accounting uses product shipments as inputs to estimate the age distribution of in-service product stocks for all years. DOE's stock accounting model is calibrated based on historical shipments for portable and whole-home dehumidifiers. See section IV.G of this document or chapter 9 of the NOPR TSD for additional details.

c. Capital and Product Conversion Costs

Amended energy conservation standards could cause manufacturers to incur conversion costs to bring their production facilities and equipment designs into compliance. DOE evaluated the level of conversion-related expenditures that would be needed to comply with each considered efficiency level in each product class. For the MIA, DOE classified these conversion costs into two major groups: (1) capital conversion costs; and (2) product conversion costs. Capital conversion costs are investments in property, plant, and equipment necessary to adapt or change existing production facilities such that new compliant product designs can be fabricated and assembled. Product conversion costs are investments in research, development, testing, marketing, and other non-capitalized costs necessary to make product designs comply with amended energy conservation standards.

DOE relied on feedback from manufacturer interviews and information from the product teardown and engineering analyses to estimate the capital investment required at each analyzed efficiency level. DOE asked manufacturers to estimate the capital conversion costs (*e.g.,* changes in production processes, equipment, and tooling) to implement the various design options. The data generated from the product teardown and engineering analyses were used to estimate the capital investment in equipment and tooling required of OEMs at each efficiency level, considering such factors as product design, raw materials, purchased components, and fabrication method. Changes in equipment and tooling were used to estimate capital conversion costs.

DOE relied on feedback from manufacturer interviews, the engineering analysis, and model counts from DOE's Compliance Certification Database (CCD) to evaluate the product conversion costs industry would likely incur at the considered standard levels. In interviews, DOE asked manufacturers to estimate the redesign effort and engineering resources required at various efficiency levels to quantify the product conversion costs. DOE integrated feedback from manufacturers on redesign effort and staffing to estimate product conversion cost. Manufacturer numbers were aggregated to protect confidential information. DOE used model counts to scale the feedback gathered in interviews to the overall dehumidifier industry.

In general, DOE assumes all conversion-related investments occur between the year of publication of the final rule and the year by which manufacturers must comply with the new standard. The conversion cost figures used in the GRIM can be found in section V.B.2 of this document. For additional information on the estimated capital and product conversion costs, see chapter 12 of the NOPR TSD.

d. Manufacturer Markup Scenarios

MSPs include direct manufacturing production costs (*i.e.,* labor, materials, and overhead estimated in DOE's MPCs) and all non-production costs (*i.e.,* SG&A, R&D, and interest), along with profit. To calculate the MSPs in the GRIM, DOE applied manufacturer markups to the MPCs estimated in the engineering analysis for each product class and efficiency level. Modifying these manufacturer markups in the standards case yields different sets of impacts on manufacturers. For the MIA, DOE modeled two standards-case scenarios to represent uncertainty regarding the potential impacts on prices and profitability for manufacturers following the implementation of amended energy conservation standards: (1) a preservation of gross margin percentage scenario; and (2) a preservation of operating profit scenario. These scenarios lead to different manufacturer markup values that, when applied to the MPCs, result in varying revenue and cash flow impacts.

Under the preservation of gross margin percentage scenario, DOE applied a single uniform ''gross margin percentage'' markup across all efficiency levels, which assumes that manufacturers would be able to maintain the same amount of profit as a percentage of revenues at all efficiency levels within a product class. As manufacturer production costs increase with efficiency, this scenario implies that the per-unit dollar profit will increase. DOE assumed a gross margin percentage of 29 percent for all product classes.[43] Manufacturers tend to believe it is optimistic to assume that they would be able to maintain the same gross margin percentage as their production costs increase, particularly for minimally efficient products. Therefore, this scenario represents an upper bound of industry profitability under an amended energy conservation standard.

In the preservation of operating profit scenario, as the cost of production goes up under a standards case, manufacturers are generally required to reduce their manufacturer markups to a level that maintains base-case operating profit. DOE implemented this scenario in the GRIM by lowering the manufacturer markups at each TSL to yield approximately the same earnings before interest and taxes in the standards case as in the no-new-standards case in the year after the expected compliance date of the amended standards. The implicit assumption behind this scenario is that the industry can only maintain its operating profit in absolute dollars after the standard takes effect.

A comparison of industry financial impacts under the two markup scenarios is presented in section V.B.2.a of this document.

[43] The gross margin percentage of 29 percent is based on a manufacturer markup of 1.40.

3. Manufacturer Interviews

DOE interviewed manufacturers representing approximately 52 percent of industry shipments. Participants included both foreign and domestic OEMs with varying market shares and product class offerings.

In interviews, DOE asked manufacturers to describe their major concerns regarding potential more stringent energy conservation standards for dehumidifiers. The following section highlights manufacturer concerns that helped inform the projected potential impacts of an amended standard on the industry. Manufacturer interviews are conducted under non-disclosure agreements (NDAs), so DOE does not document these discussions in the same way that it does public comments in the comment summaries and DOE's responses throughout the rest of this document.

a. Increases in Chassis Size

In interviews, manufacturers expressed concern about efficiency levels that would necessitate increasing the chassis size to accommodate larger heat exchangers. First, these manufacturers stated that increasing the chassis size would require significant capital investment and engineering time to fully redesign their portfolio of dehumidifier models. Second, manufacturers stated that increasing the chassis size would add significant product costs, which would likely lead to lower sales volumes if consumers are not willing to pay for the higher upfront cost. Third, manufacturers of portable dehumidifiers with overseas production facilities expressed concern that increasing the chassis or cabinet size would negatively impact the loading capacity of the shipping container and increase shipping costs. Finally, some portable dehumidifier manufacturers expressed concern that the 3-year compliance period would be insufficient to develop cost-optimized models with new chassis designs to accommodate larger heat exchangers across their entire product portfolio.

b. Refrigerant Regulation

In interviews, manufacturers noted that new refrigerant regulations restrict the use of high-global warming potential (GWP) refrigerants in dehumidifiers, which increases cumulative regulatory burden. Specifically, during interviews, manufacturers discussed State regulations, such as CARB's rulemaking prohibiting the use of refrigerants with a GWP of 750 or greater starting January 1, 2023 for self-contained, residential dehumidifiers and starting January 1, 2025 for whole-home dehumidifiers.[44] [45] Most manufacturers of portable dehumidifiers noted that they would likely transition to R–32, which is a classified as a flammable refrigerant.[46] A whole-home manufacturer expressed uncertainty about the choice of low-GWP refrigerants but noted that the various alternative refrigerant options being considered are also classified as flammable refrigerants. All manufacturers interviewed stated that transitioning to a low-GWP refrigerant requires notable engineering time and capital investment to update production facilities to accommodate flammable refrigerants. Some portable dehumidifier manufacturers with experience transitioning other products (*e.g.,* portable air conditioners) to make use of R–32 stated that the dehumidifier transition would be relatively straightforward given their prior experience with R–32. In interviews, manufacturers indicated that they had already started the development process but were waiting on EPA to finalize its SNAP proposed rule before starting production of dehumidifiers with low-GWP refrigerants. EPA has since finalized the SNAP rule allowing for the use of R–32. *See* 88 FR 26382.

4. Discussion of MIA Comments

In response to the June 2022 Preliminary Analysis, AHAM requested that DOE consider the impacts of tariffs on manufacturers, noting that manufacturers currently pay an additional 25 percent tariff under the China Section 301 tariffs for importing dehumidifiers on top of existing excise taxes and tariffs. According to AHAM, shipping costs are also impacted due to the shortage in shipping containers and lack of availability of transport to deliver manufactured products. (AHAM, No. 22 at pp. 3–4)

Based on information from manufacturer interviews and a review of model listings from DOE's CCD, DOE assumes nearly all portable units with 25.00 pints/day or less (Product Class 1) and portable units with 25.01 to 50.00 pints/day (Product Class 2) are manufactured in Asia. DOE also assumes that 50 percent of portable units greater than 50.00 pints/day (Product Class 3) and 20 percent of whole-home units (Product Classes 4 and 5) are manufactured in Asia. Regarding U.S. tariffs on Chinese imports, DOE is aware that the Section 301 tariffs on dehumidifiers increased to 10 percent in September 2018 and to 25 percent in May 2019. As result of tariffs, DOE expects that manufactures will begin to shift production of these products to countries in East Asia and Southeast Asia not subject to Section 301 tariffs. However, due to uncertainty about the exact countries of origin, DOE's engineering analysis continues to rely on data based on a Chinese point of origin. To revise MPCs to account for points of origin outside of China, DOE would require information on the countries of manufacture and 5-year averages for key inputs used to develop manufacturer production costs, such as fully-burdened production labor wage rates and local raw material prices.

To better model the impact of Section 301 tariffs on dehumidifiers that continue to be manufactured in China, DOE requires additional information about the portion of products still manufactured there and how the tariffs are absorbed by the entities along the room AC value chain, such as the foreign OEMs, U.S. importers, retailers, and consumers. Increases in retail price may affect consumer purchasing decisions, as captured by the price sensitivity modeled in the shipments analysis. Furthermore, DOE considers the costs of overseas and domestic shipping in its calculation of consumer price used in the LCC and PBP analyses.

AHAM stated that manufacturers will face significant retooling and redesign costs if existing chassis sizes are insufficient to implement the technology options specified in the June 2022 Preliminary Analysis. (AHAM, No. 22 at p. 3)

DOE used results of the product teardown and engineering analyses as well as feedback from confidential manufacturer interviews to estimate the capital and product conversion costs required to reach each analyzed efficiency level, which included design options that would require a change in chassis size. See section IV.J.2.c of this document for a discussion on the conversion cost methodology and

[44] State of California Air Resource Board, ''Prohibitions on Use of Certain Hydrofluorocarbons in Stationary Refrigeration, Chillers, Aerosols-Propellants, and Foam End-Uses Regulation.'' Amendments effective January 1, 2022. *ww2.arb.ca.gov/sites/default/files/barcu/regact/2020/hfc2020/frorevised.pdf* (last accessed March 4, 2023).

[45] In a public hearing to consider the proposed amendments to the Prohibitions on the Use of Certain Hydrofluorocarbons in Stationary Refrigeration, Chillers, Aerosols-Propellants, and Foam End-Uses regulation, CARB stated that a whole home dehumidifier would be regulated as ''Other Air-Conditioning Equipment'' with a regulation effective date of January 1, 2025, and not as a ''Residential Dehumidifier,'' which is both self-contained and portable. Public hearing date December 10, 2020. Agenda item number: 20–13–4. *ww2.arb.ca.gov/sites/default/files/barcu/regact/2020/hfc2020/fsorrevised.pdf* (last accessed March 4, 2023).

[46] R–32 is classified as an A2L refrigerant. The A2L class defines refrigerants that are nontoxic, but mildly flammable.

section V.B.2.a of this document for a description of conversion costs by TSL.

MIAQ stated that in addition to small business manufacturers, refrigerant desiccant dehumidifier manufacturers could also be disproportionally affected by amended energy conservation standards for dehumidifiers. (MIAQ, No. 20 at pp. 5–6)

At the time of this NOPR analysis, DOE is not aware of any consumer refrigerant desiccant dehumidifiers currently available on the market. However, DOE tentatively expects that manufacturers of refrigerant desiccant dehumidifiers would follow a similar design path as pure refrigerant-based whole-home dehumidifiers if they were to introduce new models of consumer refrigerant desiccant dehumidifiers to the market. Thus, DOE tentatively determined that the industry analysis reasonably represents the potential impacts to refrigerant desiccant dehumidifier manufacturers.

DOE requests comment on its tentative conclusion that refrigerant desiccant dehumidifier manufacturers would be similarly impacted by potential amended standards and therefore would not warrant a separate subgroup analysis.

K. Emissions Analysis

The emissions analysis consists of two components. The first component estimates the effect of potential energy conservation standards on power sector and site (where applicable) combustion emissions of CO_2, NO_X, SO_2, and Hg. The second component estimates the impacts of potential standards on emissions of two additional greenhouse gases, CH_4 and N_2O, as well as the reductions to emissions of other gases due to ''upstream'' activities in the fuel production chain. These upstream activities comprise extraction, processing, and transporting fuels to the site of combustion.

The analysis of electric power sector emissions of CO_2, NO_X, SO_2, and Hg uses emissions factors intended to represent the marginal impacts of the change in electricity consumption associated with amended or new standards. The methodology is based on results published for the AEO, including a set of side cases that implement a variety of efficiency-related policies. The methodology is described in appendix 13A in the NOPR TSD. The analysis presented in this document uses projections from AEO2023. Power sector emissions of CH_4 and N_2O from fuel combustion are estimated using Emission Factors for Greenhouse Gas Inventories published by the Environmental Protection Agency (EPA).[47] FFC upstream emissions, which include emissions from fuel combustion during extraction, processing, and transportation of fuels, and ''fugitive'' emissions (direct leakage to the atmosphere) of CH_4 and CO_2, are estimated based on the methodology described in chapter 15 of the NOPR TSD.

The emissions intensity factors are expressed in terms of physical units per megawatt hour (MWh) or metric million British thermal unit MMBtu of site energy savings. For power sector emissions, specific emissions intensity factors are calculated by sector and end use. Total emissions reductions are estimated using the energy savings calculated in the national impact analysis.

1. Air Quality Regulations Incorporated in DOE's Analysis

DOE's no-new-standards case for the electric power sector reflects the AEO, which incorporates the projected impacts of existing air quality regulations on emissions. AEO2023 reflects, to the extent possible, laws and regulations adopted through mid-November 2022, including the emissions control programs discussed in the following paragraphs and the Inflation Reduction Act.[48]

SO_2 emissions from affected electric generating units (''EGUs'') are subject to nationwide and regional emissions cap-and-trade programs. Title IV of the Clean Air Act sets an annual emissions cap on SO_2 for affected EGUs in the 48 contiguous States and the District of Columbia (''DC''). (42 U.S.C. 7651 *et seq.*) SO_2 emissions from numerous States in the eastern half of the United States are also limited under the Cross-State Air Pollution Rule (''CSAPR''). 76 FR 48208 (Aug. 8, 2011). CSAPR requires these States to reduce certain emissions, including annual SO_2 emissions, and went into effect as of January 1, 2015.[49] The AEO incorporates implementation of CSAPR, including the update to the CSAPR ozone season program emission budgets and target dates issued in 2016. 81 FR 74504 (Oct. 26, 2016). Compliance with CSAPR is flexible among EGUs and is enforced through the use of tradable emissions allowances. Under existing EPA regulations, any excess SO_2 emissions allowances resulting from the lower electricity demand caused by the adoption of an efficiency standard could be used to permit offsetting increases in SO_2 emissions by another regulated EGU.

However, beginning in 2016, SO_2 emissions began to fall as a result of the Mercury and Air Toxics Standards (''MATS'') for power plants. 77 FR 9304 (Feb. 16, 2012). Because of the emissions reductions under the MATS, it is unlikely that excess SO_2 emissions allowances resulting from the lower electricity demand would be needed or used to permit offsetting increases in SO_2 emissions by another regulated EGU. Therefore, energy conservation standards that decrease electricity generation would generally reduce SO_2 emissions. DOE estimated SO_2 emissions reduction using emissions factors based on AEO2023.

CSAPR also established limits on NO_X emissions for numerous States in the eastern half of the United States. Energy conservation standards would have little effect on NO_X emissions in those States covered by CSAPR emissions limits if excess NO_X emissions allowances resulting from the lower electricity demand could be used to permit offsetting increases in NO_X emissions from other EGUs. In such case, NO_X emissions would remain near the limit even if electricity generation goes down. A different case could possibly result, depending on the configuration of the power sector in the different regions and the need for allowances, such that NO_X emissions might not remain at the limit in the case of lower electricity demand. In this case, energy conservation standards might reduce NO_X emissions in covered States. Despite this possibility, DOE has chosen to be conservative in its analysis and has maintained the assumption that standards will not reduce NO_X emissions in States covered by CSAPR. Energy conservation standards would be expected to reduce NO_X emissions in the States not covered by CSAPR. DOE used AEO2023 data to derive NO_X

[47] Available at *www.epa.gov/sites/production/files/2021-04/documents/emission-factors_apr2021.pdf* (last accessed July 12, 2021).

[48] For further information, see the *Assumptions to AEO2023* report that sets forth the major assumptions used to generate the projections in the *Annual Energy Outlook 2023.* Available at *www.eia.gov/outlooks/aeo/assumptions/* (last accessed August 21, 2023).

[49] CSAPR requires states to address annual emissions of SO_2 and NO_X, precursors to the formation of fine particulate matter ($PM_{2.5}$) pollution, in order to address the interstate transport of pollution with respect to the 1997 and 2006 $PM_{2.5}$ National Ambient Air Quality Standards (''NAAQS''). CSAPR also requires certain states to address the ozone season (May–September) emissions of NO_X, a precursor to the formation of ozone pollution, in order to address the interstate transport of ozone pollution with respect to the 1997 ozone NAAQS. 76 FR 48208 (Aug. 8, 2011). EPA subsequently issued a supplemental rule that included an additional five states in the CSAPR ozone season program. 76 FR 80760 (Dec. 27, 2011) (Supplemental Rule).

emissions factors for the group of States not covered by CSAPR.

The MATS limit mercury emissions from power plants, but they do not include emissions caps and, as such, DOE's energy conservation standards would be expected to slightly reduce Hg emissions. DOE estimated mercury emissions reduction using emissions factors based on AEO2023, which incorporates the MATS.

L. Monetizing Emissions Impacts

As part of the development of this proposed rule, for the purpose of complying with the requirements of Executive Order (''E.O.'') 12866, DOE considered the estimated monetary benefits from the reduced emissions of CO_2, CH_4, N_2O, NO_X, and SO_2 that are expected to result from each of the TSLs considered. In order to make this calculation analogous to the calculation of the NPV of consumer benefit, DOE considered the reduced emissions expected to result over the lifetime of products shipped in the projection period for each TSL. This section summarizes the basis for the values used for monetizing the emissions benefits and presents the values considered in this NOPR.

To monetize the benefits of reducing GHG emissions this analysis uses the interim estimates presented in the Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates Under Executive Order 13990 published in February 2021 by the Interagency Working Group on the Social Cost of Greenhouse Gases (IWG).

DOE requests comment on how to address the climate benefits and other effects of the proposal.

1. Monetization of Greenhouse Gas Emissions

DOE estimates the monetized benefits of the reductions in emissions of CO_2, CH_4, and N_2O by using a measure of the social cost (''SC'') of each pollutant *(e.g.,* SC–CO_2). These estimates represent the monetary value of the net harm to society associated with a marginal increase in emissions of these pollutants in a given year, or the benefit of avoiding that increase. These estimates are intended to include (but are not limited to) climate change-related changes in net agricultural productivity, human health, property damages from increased flood risk, disruption of energy systems, risk of conflict, environmental migration, and the value of ecosystem services.

DOE exercises its own judgment in presenting monetized climate benefits as recommended by applicable executive orders, and DOE would reach the same conclusion presented in this proposed rulemaking in the absence of the social cost of greenhouse gases. That is, the social costs of greenhouse gases, whether measured using the February 2021 interim estimates presented by the Interagency Working Group on the Social Cost of Greenhouse Gases or by another means, did not affect the rule ultimately proposed by DOE.

DOE estimated the global social benefits of CO_2, CH_4, and N_2O reductions *(i.e.,* SC–GHGs) using the estimates presented in the Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates under E.O. 13990, published in February 2021 by the IWG (''February 2021 SC–GHG TSD''). The SC–GHGs is the monetary value of the net harm to society associated with a marginal increase in emissions in a given year, or the benefit of avoiding that increase. In principle, SC–GHGs includes the value of all climate change impacts, including (but not limited to) changes in net agricultural productivity, human health effects, property damage from increased flood risk and natural disasters, disruption of energy systems, risk of conflict, environmental migration, and the value of ecosystem services. The SC–GHGs therefore reflects the societal value of reducing emissions of the gas in question by one metric ton. The SC–GHGs is the theoretically appropriate value to use in conducting benefit-cost analyses of policies that affect CO_2, N_2O, and CH_4 emissions. As a member of the IWG involved in the development of the February 2021 SC–GHG TSD, DOE agrees that the interim SC–GHG estimates represent the most appropriate estimate of the SC–GHG until revised estimates have been developed reflecting the latest peer-reviewed science.

The SC–GHG estimates presented in this NOPR were developed over many years using a transparent process, the best science available at the time of that process, peer-reviewed methodologies, and input from the public. Specifically, in 2009, the IWG—which included the DOE and other executive branch agencies and offices—was established to ensure that agencies were using the best available science and to promote consistency in the social cost of carbon (''SC–CO_2'') values used across agencies. The IWG published SC–CO_2 estimates in 2010 that were developed from an ensemble of three widely cited integrated assessment models (''IAMs'') that estimate global climate damages using highly aggregated representations of climate processes and the global economy combined into a single modeling framework. The three IAMs were run using a common set of input assumptions in each model for future population, economic, and CO_2 emissions growth, as well as equilibrium climate sensitivity—a measure of the globally averaged temperature response to increased atmospheric CO_2 concentrations. These estimates were updated in 2013 based on new versions of each IAM. In August 2016, the IWG published estimates of the social cost of methane (''SC–CH_4'') and nitrous oxide (''SC–N_2O'') using methodologies that are consistent with the methodology underlying the SC–CO_2 estimates. The modeling approach that extends the IWG SC–CO_2 methodology to non-CO_2 GHGs has undergone multiple stages of peer review. The SC–CH_4 and SC–N_2O estimates were developed by Marten *et al.*[50] and underwent a standard double-blind peer review process prior to journal publication. In 2015, as part of the response to public comments received to a 2013 solicitation for comments on the SC–CO_2 estimates, the IWG announced a National Academies of Sciences, Engineering, and Medicine (''National Academies'') review of the SC–CO_2 estimates to offer advice on how to approach future updates to ensure that the estimates continue to reflect the best available science and methodologies. In January 2017, the National Academies released their final report, Valuing Climate Damages: Updating Estimation of the Social Cost of Carbon Dioxide, and recommended specific criteria for future updates to the SC–CO_2 estimates, a modeling framework to satisfy the specified criteria, and both near-term updates and longer-term research needs pertaining to various components of the estimation process.[51] Shortly thereafter, in March 2017, President Trump issued E.O. 13783, which disbanded the IWG, withdrew the previous TSDs, and directed agencies to ensure SC–CO_2 estimates used in regulatory analyses are consistent with the guidance contained in OMB's Circular A–4, ''including with respect to the consideration of domestic versus international impacts and the consideration of appropriate discount

[50] Marten, A.L., E.A. Kopits, C.W. Griffiths, S.C. Newbold, and A. Wolverton. Incremental CH_4 and N_2O mitigation benefits consistent with the US Government's SC–CO_2 estimates. *Climate Policy.* 2015. 15(2): pp. 272–298.

[51] National Academies of Sciences, Engineering, and Medicine. *Valuing Climate Damages: Updating Estimation of the Social Cost of Carbon Dioxide.* 2017. The National Academies Press: Washington, DC.

rates'' (E.O. 13783, Section 5(c)). Benefit-cost analyses following E.O. 13783 used SC–GHG estimates that attempted to focus on the U.S.-specific share of climate change damages as estimated by the models and were calculated using two discount rates recommended by Circular A–4: 3-percent and 7-percent. All other methodological decisions and model versions used in SC–GHG calculations remained the same as those used by the IWG in 2010 and 2013, respectively.

On January 20, 2021, President Biden issued E.O. 13990, which re-established the IWG and directed it to ensure that the U.S. Government's estimates of the social cost of carbon and other greenhouse gases reflect the best available science and the recommendations in the National Academies 2017 report. The IWG was tasked with first reviewing the SC–GHG estimates currently used in Federal analyses and publishing interim estimates within 30 days of the E.O. that reflect the full impact of GHG emissions, including by taking global damages into account. The interim SC–GHG estimates published in February 2021 are used here to estimate the climate benefits for this proposed rulemaking. The E.O. instructs the IWG to undertake a fuller update of the SC–GHG estimates that takes into consideration the advice of the National Academies 2017 report and other recent scientific literature. The February 2021 SC–GHG TSD provides a complete discussion of the IWG's initial review conducted under E.O. 13990. In particular, the IWG found that the SC–GHG estimates used under E.O. 13783 fail to reflect the full impact of GHG emissions in multiple ways.

First, the IWG found that the SC–GHG estimates used under E.O. 13783 fail to fully capture many climate impacts that affect the welfare of U.S. citizens and residents, and those impacts are better reflected by global measures of the SC–GHG. Examples of omitted effects from the E.O. 13783 estimates include direct effects on U.S. citizens, assets, and investments located abroad, supply chains, U.S. military assets and interests abroad, and tourism, and spillover pathways such as economic and political destabilization and global migration that can lead to adverse impacts on U.S. national security, public health, and humanitarian concerns. In addition, assessing the benefits of U.S. GHG mitigation activities requires consideration of how those actions may affect mitigation activities by other countries, as those international mitigation actions will provide a benefit to U.S. citizens and residents by mitigating climate impacts that affect U.S. citizens and residents. A wide range of scientific and economic experts have emphasized the issue of reciprocity as support for considering global damages of GHG emissions. If the United States does not consider impacts on other countries, it is difficult to convince other countries to consider the impacts of their emissions on the United States. The only way to achieve efficient allocation of resources for emissions reduction on a global basis—and so benefit the U.S. and its citizens—is for all countries to base their policies on global estimates of damages. As a member of the IWG involved in the development of the February 2021 SC–GHG TSD, DOE agrees with this assessment and, therefore, in this proposed rule DOE centers attention on a global measure of SC–GHG. This approach is the same as that taken in DOE regulatory analyses from 2012 through 2016. A robust estimate of climate damages that accrue only to U.S. citizens and residents does not currently exist in the literature. As explained in the February 2021 TSD, existing estimates are both incomplete and an underestimation of total damages that accrue to the citizens and residents of the U.S. because they do not fully capture the regional interactions and spillovers discussed above, nor do they include all of the important physical, ecological, and economic impacts of climate change recognized in the climate change literature. As noted in the February 2021 SC–GHG TSD, the IWG will continue to review developments in the literature, including more robust methodologies for estimating a U.S.-specific SC–GHG value, and explore ways to better inform the public of the full range of carbon impacts. As a member of the IWG, DOE will continue to follow developments in the literature pertaining to this issue.

Second, the IWG found that the use of the social rate of return on capital (7 percent under current OMB Circular A–4 guidance) to discount the future benefits of reducing GHG emissions inappropriately underestimates the impacts of climate change for the purposes of estimating the SC–GHG. Consistent with the findings of the National Academies and the economic literature, the IWG continued to conclude that the consumption rate of interest is the theoretically appropriate discount rate in an intergenerational context,[52] and recommended that discount rate uncertainty and relevant aspects of intergenerational ethical considerations be accounted for in selecting future discount rates.

Furthermore, the damage estimates developed for use in the SC–GHG are estimated in consumption-equivalent terms, and so an application of OMB Circular A–4's guidance for regulatory analysis would then use the consumption discount rate to calculate the SC–GHG. DOE agrees with this assessment and will continue to follow developments in the literature pertaining to this issue. DOE also notes that while OMB Circular A–4, as published in 2003, recommends using 3-percent and 7-percent discount rates as ''default'' values, Circular A–4 also reminds agencies that ''different regulations may call for different emphases in the analysis, depending on the nature and complexity of the regulatory issues and the sensitivity of the benefit and cost estimates to the key assumptions.'' On discounting, Circular A–4 recognizes that ''special ethical considerations arise when comparing benefits and costs across generations,'' and Circular A–4 acknowledges that analyses may appropriately ''discount future costs and consumption benefits . . . at a lower rate than for intragenerational analysis.'' In the 2015 Response to Comments on the Social Cost of Carbon for Regulatory Impact Analysis, OMB, DOE, and the other IWG members recognized that ''Circular A–4 is a living document'' and ''the use of 7 percent is not considered appropriate for intergenerational discounting. There is wide support for this view in the academic literature, and it is recognized in Circular A–4 itself.'' Thus, DOE

[52] Interagency Working Group on Social Cost of Carbon, United States Government. Technical Support Document: Social Cost of Carbon for Regulatory Impact Analysis Under Executive Order 12866. 2010. Available at *www.epa.gov/sites/default/files/2016-12/documents/scc_tsd_2010.pdf* (last accessed April 15, 2022); Interagency Working Group on Social Cost of Carbon, United States Government. Technical Support Document: Technical Update of the Social Cost of Carbon for Regulatory Impact Analysis Under Executive Order No. 12866. 2013. Available at *www.federalregister.gov/documents/2013/11/26/2013-28242/technical-support-document-technical-update-of-the-social-cost-of-carbon-for-regulatory-impact* (last accessed April 15, 2022); Interagency Working Group on Social Cost of Greenhouse Gases, United States Government. Technical Support Document: Technical Update on the Social Cost of Carbon for Regulatory Impact Analysis Under Executive Order 12866. August 2016. Available at *www.epa.gov/sites/default/files/2016-12/documents/sc_co2_tsd_august_2016.pdf* (last accessed January 18, 2022); Interagency Working Group on Social Cost of Greenhouse Gases, United States Government. Addendum to Technical Support Document on Social Cost of Carbon for Regulatory Impact Analysis Under Executive Order 12866: Application of the Methodology to Estimate the Social Cost of Methane and the Social Cost of Nitrous Oxide. August 2016. *www.epa.gov/sites/default/files/2016-12/documents/addendum_to_sc-ghg_tsd_august_2016.pdf* (last accessed January 18, 2022).

concludes that a 7-percent discount rate is not appropriate to apply to value the social cost of greenhouse gases in the analysis presented in this analysis.

To calculate the present and annualized values of climate benefits, DOE uses the same discount rate as the rate used to discount the value of damages from future GHG emissions, for internal consistency. That approach to discounting follows the same approach that the February 2021 TSD recommends ''to ensure internal consistency—*i.e.,* future damages from climate change using the SC–GHG at 2.5 percent should be discounted to the base year of the analysis using the same 2.5 percent rate.'' DOE has also consulted the National Academies' 2017 recommendations on how SC–GHG estimates can ''be combined in RIAs with other cost and benefits estimates that may use different discount rates.'' The National Academies reviewed several options, including ''presenting all discount rate combinations of other costs and benefits with [SC–GHG] estimates.''

As a member of the IWG involved in the development of the February 2021 SC–GHG TSD, DOE agrees with the above assessment and will continue to follow developments in the literature pertaining to this issue. While the IWG works to assess how best to incorporate the latest peer-reviewed science to develop an updated set of SC–GHG estimates, it set the interim estimates to be the most recent ones developed by the IWG prior to the group being disbanded in 2017. The estimates rely on the same models and harmonized inputs and are calculated using a range of discount rates. As explained in the February 2021 SC–GHG TSD, the IWG has recommended that agencies revert to the same set of four values drawn from the SC–GHG distributions based on three discount rates as were used in regulatory analyses between 2010 and 2016 and were subject to public comment. For each discount rate, the IWG combined the distributions across models and socioeconomic emissions scenarios (applying equal weight to each) and then selected a set of four values recommended for use in benefit-cost analyses: an average value resulting from the model runs for each of three discount rates (2.5-percent, 3-percent, and 5-percent), plus a fourth value, selected as the 95th percentile of estimates based on a 3-percent discount rate. The fourth value was included to provide information on potentially higher-than-expected economic impacts from climate change. As explained in the February 2021 SC–GHG TSD, and DOE agrees, this update reflects the immediate need to have an operational SC–GHG for use in regulatory benefit-cost analyses and other applications developed using a transparent process, the science available at the time of that process, and peer-reviewed methodologies. Those estimates were subject to public comment in the context of dozens of proposed rulemakings as well as in a dedicated public comment period in 2013.

There are a number of limitations and uncertainties associated with the SC–GHG estimates. First, the current scientific and economic understanding of discounting approaches suggests discount rates appropriate for intergenerational analysis in the context of climate change are likely to be less than 3 percent, near 2 percent, or lower.[53] Second, the IAMs used to produce these interim estimates do not include all of the important physical, ecological, and economic impacts of climate change recognized in the climate change literature and the science underlying their ''damage functions'' (*i.e.,* the core parts of the IAMs that map global mean temperature changes and other physical impacts of climate change into economic (both market and nonmarket) damages) lags behind the most recent research. For example, limitations include the incomplete treatment of catastrophic and non-catastrophic impacts in the integrated assessment models, their incomplete treatment of adaptation and technological change, the incomplete way in which inter-regional and intersectoral linkages are modeled, uncertainty in the extrapolation of damages to high temperatures, and inadequate representation of the relationship between the discount rate and uncertainty in economic growth over long time horizons. Likewise, the socioeconomic and emissions scenarios used as inputs to the models do not reflect new information from the last decade of scenario generation or the full range of projections. The modeling limitations do not all work in the same direction in terms of their influence on the SC–CO_2 estimates. However, as discussed in the February 2021 TSD, the IWG has recommended that, taken together, the limitations suggest that the interim SC–GHG estimates used in this proposed rule likely underestimate the damages from GHG emissions. DOE concurs with this assessment.

DOE's derivations of the SC–CO_2, SC–N_2O, and SC–CH_4 values used for this NOPR are discussed in the following sections, and the results of DOE's analyses estimating the benefits of the reductions in emissions of these GHGs are presented in section V.B.6 of this document.

a. Social Cost of Carbon

The SC–CO_2 values used for this final rule were based on the values developed for the IWG's February 2021 TSD, which are shown in Table IV.7 in five-year increments from 2020 to 2050. The set of annual values that DOE used, which was adapted from estimates published by EPA,[54] is presented in appendix 14A of the NOPR TSD. These estimates are based on methods, assumptions, and parameters identical to the estimates published by the IWG (which were based on EPA modeling), and include values for 2051 to 2070. DOE expects additional climate benefits to accrue for products still operating after 2070, but a lack of available SC–CO_2 estimates for emissions years beyond 2070 prevents DOE from monetizing these potential benefits in this analysis.

[53] Interagency Working Group on Social Cost of Greenhouse Gases (IWG). 2021. Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates under Executive Order 13990. February. United States Government. Available at *https://www.whitehouse.gov/wp-content/uploads/2021/02/TechnicalSupportDocument_SocialCostofCarbonMethaneNitrousOxide.pdf.*

[54] *See* EPA, Revised 2023 and Later Model Year Light-Duty Vehicle GHG Emissions Standards: Regulatory Impact Analysis, Washington, DC, December 2021. Available at *nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P1013ORN.pdf* (last accessed February 21, 2023).

TABLE IV.8—ANNUAL SC–CO_2 VALUES FROM 2021 INTERAGENCY UPDATE, 2020–2050

[2020$ per metric ton CO_2]

Year	Discount rate and statistic			
	5%	3%	2.5%	3%
	Average	Average	Average	95th percentile
2020	14	51	76	152
2025	17	56	83	169
2030	19	62	89	187
2035	22	67	96	206
2040	25	73	103	225
2045	28	79	110	242
2050	32	85	116	260

DOE multiplied the CO_2 emissions reduction estimated for each year by the SC–CO_2 value for that year in each of the four cases. DOE adjusted the values to 2022$ using the implicit price deflator for GDP from the Bureau of Economic Analysis. To calculate a present value of the stream of monetary values, DOE discounted the values in each of the four cases using the specific discount rate that had been used to obtain the SC–CO_2 values in each case.

b. Social Cost of Methane and Nitrous Oxide

The SC–CH_4 and SC–N_2O values used for this NOPR were based on the values developed for the February 2021 TSD. Table IV.8 shows the updated sets of SC–CH_4 and SC–N_2O estimates from the latest interagency update in 5-year increments from 2020 to 2050. The full set of annual values used is presented in appendix 14A of the NOPR TSD. To capture the uncertainties involved in regulatory impact analysis, DOE has determined it is appropriate to include all four sets of SC–CH_4 and SC–N_2O values, as recommended by the IWG. DOE derived values after 2050 using the approach described above for the SC–CO_2 values.

TABLE IV.9—ANNUAL SC–CH_4 AND SC–N_2O VALUES FROM 2021 INTERAGENCY UPDATE, 2020–2050

[2020$ per metric ton]

Year	SC–CH_4				SC–N_2O			
	Discount rate and statistic				Discount rate and statistic			
	5%	3%	2.5%	3%	5%	3%	2.5%	3%
	Average	Average	Average	95th percentile	Average	Average	Average	95th percentile
2020	670	1,500	2,000	3,900	5,800	18,000	27,000	48,000
2025	800	1,700	2,200	4,500	6,800	21,000	30,000	54,000
2030	940	2,000	2,500	5,200	7,800	23,000	33,000	60,000
2035	1,100	2,200	2,800	6,000	9,000	25,000	36,000	67,000
2040	1,300	2,500	3,100	6,700	10,000	28,000	39,000	74,000
2045	1,500	2,800	3,500	7,500	12,000	30,000	42,000	81,000
2050	1,700	3,100	3,800	8,200	13,000	33,000	45,000	88,000

DOE multiplied the CH_4 and N_2O emissions reduction estimated for each year by the SC–CH_4 and SC–N_2O estimates for that year in each of the cases. DOE adjusted the values to 2022$ using the implicit price deflator for GDP from the Bureau of Economic Analysis. To calculate a present value of the stream of monetary values, DOE discounted the values in each of the cases using the specific discount rate that had been used to obtain the SC–CH_4 and SC–N_2O estimates in each case.

2. Monetization of Other Emissions Impacts

For the NOPR, DOE estimated the monetized value of NO_X and SO_2 emissions reductions from electricity generation using the latest benefit per ton estimates for that sector from the EPA's Benefits Mapping and Analysis Program.[55] DOE used EPA's values for $PM_{2.5}$-related benefits associated with NO_X and SO_2 and for ozone-related benefits associated with NO_X for 2025, 2030, and 2040, calculated with discount rates of 3-percent and 7-percent. DOE used linear interpolation to define values for the years not given in the 2025 to 2040 period; for years beyond 2040, the values are held constant. DOE combined the EPA regional benefit-per-ton estimates with regional information on electricity consumption and emissions from *AEO2023* to define weighted-average national values for NO_X and SO_2 (see appendix 14B of the NOPR TSD).

[55] U.S. Environmental Protection Agency. Estimating the Benefit per Ton of Reducing Directly-Emitted $PM_{2.5}$,$PM_{2.5}$ Precursors and Ozone Precursors from 21 Sectors. *www.epa.gov/benmap/estimating-benefit-ton-reducing-directly-emitted-pm25-pm25-precursors-and-ozone-precursors.*

M. Utility Impact Analysis

The utility impact analysis estimates the changes in installed electrical capacity and generation projected to result for each considered TSL. The analysis is based on published output from the NEMS associated with AEO2023. NEMS produces the *AEO* Reference case, as well as a number of side cases that estimate the economy-wide impacts of changes to energy supply and demand. For the current analysis, impacts are quantified by comparing the levels of electricity sector generation, installed capacity, fuel consumption and emissions in the AEO2023 Reference case and various side cases. Details of the methodology are provided in the appendices to chapters 13 and 15 of the NOPR TSD.

The output of this analysis is a set of time-dependent coefficients that capture the change in electricity generation,

primary fuel consumption, installed capacity and power sector emissions due to a unit reduction in demand for a given end use. These coefficients are multiplied by the stream of electricity savings calculated in the NIA to provide estimates of selected utility impacts of potential new or amended energy conservation standards.

N. Employment Impact Analysis

DOE considers employment impacts in the domestic economy as one factor in selecting a proposed standard. Employment impacts from new or amended energy conservation standards include both direct and indirect impacts. Direct employment impacts are any changes in the number of employees of manufacturers of the products subject to standards, their suppliers, and related service firms. The MIA addresses those impacts. Indirect employment impacts are changes in national employment that occur due to the shift in expenditures and capital investment caused by the purchase and operation of more-efficient appliances. Indirect employment impacts from standards consist of the net jobs created or eliminated in the national economy, other than in the manufacturing sector being regulated, caused by (1) reduced spending by consumers on energy, (2) reduced spending on new energy supply by the utility industry, (3) increased consumer spending on the products to which the new standards apply and other goods and services, and (4) the effects of those three factors throughout the economy.

One method for assessing the possible effects on the demand for labor of such shifts in economic activity is to compare sector employment statistics developed by the Labor Department's Bureau of Labor Statistics (''BLS''). BLS regularly publishes its estimates of the number of jobs per million dollars of economic activity in different sectors of the economy, as well as the jobs created elsewhere in the economy by this same economic activity. Data from BLS indicate that expenditures in the utility sector generally create fewer jobs (both directly and indirectly) than expenditures in other sectors of the economy.[56] There are many reasons for these differences, including wage differences and the fact that the utility sector is more capital-intensive and less labor-intensive than other sectors. Energy conservation standards have the effect of reducing consumer utility bills. Because reduced consumer expenditures for energy likely lead to increased expenditures in other sectors of the economy, the general effect of efficiency standards is to shift economic activity from a less labor-intensive sector (*i.e.,* the utility sector) to more labor-intensive sectors (*e.g.,* the retail and service sectors). Thus, the BLS data suggest that net national employment may increase due to shifts in economic activity resulting from energy conservation standards.

DOE estimated indirect national employment impacts for the standard levels considered in this NOPR using an input/output model of the U.S. economy called Impact of Sector Energy Technologies version 4 (''ImSET'').[57] ImSET is a special-purpose version of the ''U.S. Benchmark National Input-Output'' (''I–O'') model, which was designed to estimate the national employment and income effects of energy-saving technologies. The ImSET software includes a computer-based I–O model having structural coefficients that characterize economic flows among 187 sectors most relevant to industrial, commercial, and residential building energy use.

DOE notes that ImSET is not a general equilibrium forecasting model, and that the uncertainties involved in projecting employment impacts, especially changes in the later years of the analysis. Because ImSET does not incorporate price changes, the employment effects predicted by ImSET may overestimate actual job impacts over the long run for this rule. Therefore, DOE used ImSET only to generate results for near-term timeframes (2028–2032), where these uncertainties are reduced. For more details on the employment impact analysis, see chapter 16 of the NOPR TSD.

V. Analytical Results and Conclusions

The following section addresses the results from DOE's analyses with respect to the considered energy conservation standards for dehumidifiers. It addresses the TSLs examined by DOE, the projected impacts of each of these levels if adopted as energy conservation standards for dehumidifiers, and the standards levels that DOE is proposing to adopt in this NOPR. Additional details regarding DOE's analyses are contained in the NOPR TSD supporting this document.

A. Trial Standard Levels

In general, DOE typically evaluates new or potential amended standards for products and equipment by grouping individual efficiency levels for each class into TSLs. Use of TSLs allows DOE to identify and consider manufacturer cost interactions between the product classes, to the extent that there are such interactions, and price elasticity of consumer purchasing decisions that may change when different standard levels are set.

In the analysis conducted for this NOPR, DOE analyzed the benefits and burdens of four TSLs for dehumidifiers. DOE developed TSLs that combine efficiency levels for each analyzed product class. TSL 1 represents the smallest incremental increase in analyzed efficiency level above the baseline for each analyzed product class. TSL 2 corresponds to current ENERGY STAR® requirements for all product classes. TSL 3 is an intermediate TSL that maintains positive average LCC savings for all product classes while increasing stringency for Product Classes 1, 2, 4, and 5. TSL 4 represents max-tech. DOE presents the results for the TSLs in this document, while the results for all efficiency levels that DOE analyzed are in the NOPR TSD.

In response to the June 2022 Preliminary Analysis, AHAM raised concerns about the technological feasibility and the economic impact of setting the amended energy conservation standard at EL 3 for all portable product classes. AHAM also questioned whether DOE can justify proposing a standard where a majority of energy savings come from one product class. (AHAM, No. 22 at p. 8)

To clarify, DOE does not propose adopting standard levels at the Preliminary Analysis stage. The current NOPR analysis has been updated based on stakeholder feedback received in response to the June 2022 Preliminary Analysis, additional tear down of units to support the engineering analysis, and manufacturer interviews. For this NOPR analysis, DOE analyzed four trial standard levels and proposes a TSL that DOE considers technologically feasible and economically justified based on a multitude of factors (see section V.C.1 for discussion of the benefits and burdens of TSLs considered in this NOPR).

Table V.1 presents the TSLs and the corresponding efficiency levels that DOE has identified for potential

[56] See U.S. Department of Commerce—Bureau of Economic Analysis. *Regional Multipliers: A User Handbook for the Regional Input-Output Modeling System (RIMS II).* 1997. U.S. Government Printing Office: Washington, DC. Available at *https://www.bea.gov/sites/default/files/methodologies/RIMSII_User_Guide.pdf* (last accessed February 22, 2023).

[57] Livingston, O.V., S.R. Bender, M.J. Scott, and R.W. Schultz. *ImSET 4.0: Impact of Sector Energy Technologies Model Description and User Guide.* 2015. Pacific Northwest National Laboratory: Richland, WA. PNNL–24563.

amended energy conservation standards for dehumidifiers.

TABLE V.1—TRIAL STANDARD LEVELS FOR DEHUMIDIFIERS

TSL	Portable						Whole-home			
	PC1: ≤25.00 pints/day		PC2: 25.01–50.00 pints/day		PC3: >50.00 pints/day		PC4: ≤8.0 cu. ft.		PC5: >8.0 cu. ft.	
	EL	IEF (L/kWh)	EL	IEF (L/kWh)	EL	IEF (L/kWh)	EL	IEF (L/kWh)	EL	IEF (L/kWh)
1	1	1.40	1	1.70	1	3.10	1	2.09	1	2.70
2	2	1.57	2	1.80	2	3.30	1	2.09	2	3.30
3	3	1.70	3	2.01	1	3.10	2	2.22	3	3.81
4	5	2.32	5	2.38	4	3.67	3	2.39	4	4.17

For Product Class 3, DOE found that EL 3 results in the largest average LCC loss and the highest percent of consumers negatively impacted consumers among considered efficiency levels. Similarly, for Product Classes 1 and 2, EL 4 results in the smallest average LCC savings and the highest percent of consumers negatively impacted among considered efficiency levels. Therefore, DOE did not include these ELs in the construction of TSLs.

B. Economic Justification and Energy Savings

1. Economic Impacts on Individual Consumers

DOE analyzed the economic impacts on dehumidifier consumers by looking at the effects that potential amended standards at each TSL would have on the LCC and PBP. DOE also examined the impacts of potential standards on selected consumer subgroups. These analyses are discussed in the following sections.

a. Life-Cycle Cost and Payback Period

In general, higher-efficiency products affect consumers in two ways: (1) purchase price increases and (2) annual operating costs decreases. Inputs used for calculating the LCC and PBP include total installed costs (*i.e.,* product price plus installation costs), and operating costs (*i.e.,* annual energy use, energy prices, energy price trends, repair costs, and maintenance costs). The LCC calculation also uses product lifetime and a discount rate. Chapter [8] of the NOPR TSD provides detailed information on the LCC and PBP analyses.

Table V.2 through Table V.11 show the LCC and PBP results for the TSLs considered for each product class. In the first of each pair of tables, the simple payback is measured relative to the baseline product. In the second table, impacts are measured relative to the efficiency distribution in the no-new-standards case in the compliance year (see section IV.F.8 of this document). Because some consumers purchase products with higher efficiency in the no-new-standards case, the average savings are less than the difference between the average LCC of the baseline product and the average LCC at each TSL. The savings refer only to consumers who are affected by a standard at a given TSL. Those who already purchase a product with efficiency at or above a given TSL are not affected. Consumers for whom the LCC increases at a given TSL experience a net cost.

TABLE V.2—AVERAGE LCC AND PBP RESULTS FOR PRODUCT CLASS 1: PORTABLE DEHUMIDIFIERS

[≤25.00 pints/day]

TSL	Efficiency level	IEF (L/kWh)	Average costs (2022$)				Simple payback (years)	Average lifetime (years)
			Installed cost	First year's operating cost	Lifetime operating cost	LCC		
	Baseline	1.30	$279	$66	$569	$848	.....	10.0
1	1	1.40	283	61	531	814	1.0	10.0
2	2	1.57	288	55	479	767	0.9	10.0
3	3	1.70	293	51	444	737	0.9	10.0
	4	1.94	397	46	396	793	5.9	10.0
4	5	2.32	447	39	337	784	6.3	10.0

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

TABLE V.3—AVERAGE LCC SAVINGS RELATIVE TO THE NO-NEW-STANDARDS CASE FOR PRODUCT CLASS 1: PORTABLE DEHUMIDIFIERS

[≤25.00 pints/day]

TSL	Efficiency level	Life-cycle cost savings	
		Average LCC savings*+ (2022$)	Percentage of consumers that experience net cost (%)
1	1	$0	0
2	2	46	1
3	3	42	3
	4	(17)	70
4	5	(9)	65

*The savings represent the average LCC for affected consumers.
+Parentheses denote negative (−) values.

TABLE V.4—AVERAGE LCC AND PBP RESULTS FOR PRODUCT CLASS 2: PORTABLE DEHUMIDIFIERS

[25.01–50.00 pints/day]

TSL	Efficiency level	IEF (L/kWh)	Average costs (2022$)				Simple payback (years)	Average lifetime (years)
			Installed cost	First year's operating cost	Lifetime operating cost	LCC		
	Baseline	1.60	$315	$112	$968	$1,283	.....	10.0
1	1	1.70	319	106	915	1,234	0.7	10.0
2	2	1.80	324	100	869	1,193	0.8	10.0
3	3	2.01	327	91	784	1,112	0.6	10.0
	4	2.07	429	89	767	1,196	4.9	10.0
4	5	2.38	493	78	676	1,169	5.3	10.0

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

TABLE V.5—AVERAGE LCC SAVINGS RELATIVE TO THE NO-NEW-STANDARDS CASE FOR PRODUCT CLASS 2: PORTABLE DEHUMIDIFIERS

[25.01–50.00 pints/day]

TSL	Efficiency level	Life-cycle cost savings	
		Average LCC savings* (2022$)	Percentage of consumers that experience net cost (%)
1	1	$0	0
2	2	0	0
3	3	81	0
	4	(13)	68
4	5	14	60

*The savings represent the average LCC for affected consumers.

TABLE V.6—AVERAGE LCC AND PBP RESULTS FOR PRODUCT CLASS 3: PORTABLE DEHUMIDIFIERS

[>50.00 pints/day]

TSL	Efficiency level	IEF (L/kWh)	Average costs (2022$)				Simple payback (years)	Average lifetime (years)
			Installed cost	First year's operating cost	Lifetime operating cost	LCC		
	Baseline	2.80	$1,043	$88	$765	$1,807	.....	10.0
1,3	1	3.10	1,080	80	696	1,776	4.8	10.0
2	2	3.30	1,149	76	657	1,807	8.7	10.0
	3	3.51	1,248	72	622	1,870	12.5	10.0

TABLE V.6—AVERAGE LCC AND PBP RESULTS FOR PRODUCT CLASS 3: PORTABLE DEHUMIDIFIERS—Continued

[>50.00 pints/day]

TSL	Efficiency level	IEF (L/kWh)	Average costs (2022$)				Simple payback (years)	Average lifetime (years)
			Installed cost	First year's operating cost	Lifetime operating cost	LCC		
4	4	3.67	1,257	69	597	1,854	11.2	10.0

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

TABLE V.7—AVERAGE LCC SAVINGS RELATIVE TO THE NO-NEW-STANDARDS CASE FOR PRODUCT CLASS 3: PORTABLE DEHUMIDIFIERS

[>50.00 pints/day]

TSL	Efficiency level	Life-cycle cost savings	
		Average LCC savings *+ (2022$)	Percentage of consumers that experience net cost (%)
1,3	1	$31	33
2	2	(4)	65
	3	(67)	79
4	4	(52)	74

*The savings represent the average LCC for affected consumers.
+Parentheses denote negative (−) values.

TABLE V.8—AVERAGE LCC AND PBP RESULTS FOR PRODUCT CLASS 4: WHOLE-HOME DEHUMIDIFIERS

[≤8.0 cu ft case volume]

TSL	Efficiency level	IEF (L/kWh)	Average costs (2022$)				Simple payback (years)	Average lifetime (years)
			Installed cost	First year's operating cost	Lifetime operating cost	LCC		
	Baseline	1.77	$2,733	$144	$1,441	$4,174	.....	12.0
1,2	1	2.09	2,876	123	1,235	4,110	6.9	12.0
3	2	2.22	2,907	117	1,170	4,077	6.4	12.0
4	3	2.39	2,978	110	1,099	4,077	7.2	12.0

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

TABLE V.9—AVERAGE LCC SAVINGS RELATIVE TO THE NO-NEW-STANDARDS CASE FOR PRODUCT CLASS 4: WHOLE-HOME DEHUMIDIFIERS

[≤8.0 cu ft case volume]

TSL	Efficiency level	Life-cycle cost savings	
		Average LCC savings * (2022$)	Percentage of consumers that experience net cost (%)
1,2	1	$63	4
3	2	56	8
4	3	12	56

*The savings represent the average LCC for affected consumers.

TABLE V.10—AVERAGE LCC AND PBP RESULTS FOR PRODUCT CLASS 5: WHOLE-HOME DEHUMIDIFIERS

[>8.0 cu ft case volume]

TSL	Efficiency level	IEF (L/kWh)	Average costs (2022$)				Simple payback (years)	Average lifetime (years)
			Installed cost	First year's operating cost	Lifetime operating cost	LCC		
	Baseline	2.41	$2,734	$115	$1,166	$3,901	.....	12.0
1	1	2.70	2,797	104	1,053	3,850	5.6	12.0
2	2	3.30	2,816	87	882	3,698	2.9	12.0
3	3	3.81	2,954	77	778	3,731	5.7	12.0
4	4	4.17	3,077	71	720	3,796	7.8	12.0

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

TABLE V.11—AVERAGE LCC SAVINGS RELATIVE TO THE NO-NEW-STANDARDS CASE FOR PRODUCT CLASS 5: WHOLE-HOME DEHUMIDIFIERS

[>8.0 cu ft case volume]

TSL	Efficiency level	Life-cycle cost savings	
		Average LCC savings* (2022$)	Percentage of consumers that experience net cost (%)
1	1	$53	19
2	2	179	7
3	3	146	38
4	4	81	53

* The savings represent the average LCC for affected consumers.

b. Consumer Subgroup Analysis

In the consumer subgroup analysis, DOE estimated the impact of the considered TSLs on low-income households and senior-only households. Table V.12 through Table V.16 compares the average LCC savings and PBP at each efficiency level for the consumer subgroups with similar metrics for the entire consumer sample for each product class. In most cases, the average LCC savings and PBP for low-income households and senior-only households at the considered efficiency levels are not substantially different from the average for all households. Chapter 11 of the NOPR TSD presents the complete LCC and PBP results for the subgroups.

TABLE V.12—COMPARISON OF LCC SAVINGS AND PBP FOR CONSUMER SUBGROUPS AND ALL HOUSEHOLDS; PRODUCT CLASS 1: PORTABLE DEHUMIDIFIERS

[≤25.00 pints/day]

	Low-income households	Senior-only households	All households
Average LCC Savings (2022$):*			
TSL 1	$0	$0	$0
TSL 2	$38	$43	$46
TSL 3	$34	$39	$42
TSL 4	($37)	($22)	($9)
Payback Period (years):			
TSL 1	1.2	1.1	1.0
TSL 2	1.1	1.0	0.9
TSL 3	1.1	1.0	0.9
TSL 4	7.6	6.9	6.3
Consumers with Net Benefit (%):			
TSL 1	0%	0%	0%
TSL 2	23%	24%	24%
TSL 3	83%	89%	88%
TSL 4	27%	30%	35%
Consumers with Net Cost (%):			
TSL 1	0%	0%	0%
TSL 2	1%	0%	1%
TSL 3	7%	2%	3%
TSL 4	73%	70%	65%

* Parentheses denote negative (−) values.

TABLE V.13—COMPARISON OF LCC SAVINGS AND PBP FOR CONSUMER SUBGROUPS AND ALL HOUSEHOLDS; PRODUCT CLASS 2: PORTABLE DEHUMIDIFIERS

[25.01–50.00 pints/day]

	Low-income households	Senior-only households	All households
Average LCC Savings (2022$): *			
TSL 1	$0	$0	$0
TSL 2	$0	$0	$0
TSL 3	$65	$74	$81
TSL 4	($21)	($2)	$14
Payback Period (years):			
TSL 1	0.9	0.8	0.7
TSL 2	1.0	0.9	0.8
TSL 3	0.7	0.7	0.6
TSL 4	6.4	5.8	5.3
Consumers with Net Benefit (%):			
TSL 1	0%	0%	0%
TSL 2	0%	0%	0%
TSL 3	87%	87%	87%
TSL 4	32%	35%	40%
Consumers with Net Cost (%):			
TSL 1	0%	0%	0%
TSL 2	0%	0%	0%
TSL 3	0%	0%	0%
TSL 4	68%	65%	60%

* Parentheses denote negative (−) values.

TABLE V.14—COMPARISON OF LCC SAVINGS AND PBP FOR CONSUMER SUBGROUPS AND ALL HOUSEHOLDS; PRODUCT CLASS 3: PORTABLE DEHUMIDIFIERS

[>50.00 pints/day]

	Low-income households	Senior-only households	All households
Average LCC Savings (2022$): *			
TSL 1	$21	$25	$31
TSL 2	($19)	($13)	($4)
TSL 3	$21	$25	$31
TSL 4	($76)	($66)	($52)
Payback Period (years):			
TSL 1	5.6	5.3	4.8
TSL 2	10.0	9.5	8.7
TSL 3	5.6	5.3	4.8
TSL 4	12.9	12.3	11.2
Consumers with Net Benefit (%):			
TSL 1	53%	51%	53%
TSL 2	29%	29%	35%
TSL 3	53%	51%	53%
TSL 4	17%	20%	26%
Consumers with Net Cost (%):			
TSL 1	33%	34%	33%
TSL 2	71%	71%	65%
TSL 3	33%	34%	33%
TSL 4	83%	80%	74%

* Parentheses denote negative (−) values.

TABLE V.15—COMPARISON OF LCC SAVINGS AND PBP FOR CONSUMER SUBGROUPS AND ALL HOUSEHOLDS; PRODUCT CLASS 4: WHOLE-HOME DEHUMIDIFIERS

[≤8.0 cu ft case volume]

	Low-income households	Senior-only households	All households
Average LCC Savings (2022$): *			
TSL 1	$99	$70	$63
TSL 2	$99	$70	$63
TSL 3	$76	$60	$56
TSL 4	$37	$14	$12
Payback Period (years):			
TSL 1	4.8	6.8	6.9
TSL 2	4.8	6.8	6.9

TABLE V.15—COMPARISON OF LCC SAVINGS AND PBP FOR CONSUMER SUBGROUPS AND ALL HOUSEHOLDS; PRODUCT CLASS 4: WHOLE-HOME DEHUMIDIFIERS—Continued

[≤8.0 cu ft case volume]

	Low-income households	Senior-only households	All households
TSL 3	4.4	6.3	6.4
TSL 4	4.9	7.1	7.2
Consumers with Net Benefit (%):			
TSL 1	5%	4%	4%
TSL 2	5%	4%	4%
TSL 3	15%	14%	14%
TSL 4	48%	39%	40%
Consumers with Net Cost (%):			
TSL 1	3%	4%	4%
TSL 2	3%	4%	4%
TSL 3	5%	8%	8%
TSL 4	40%	58%	56%

* Parentheses denote negative (−) values.

TABLE V.16—COMPARISON OF LCC SAVINGS AND PBP FOR CONSUMER SUBGROUPS AND ALL HOUSEHOLDS; PRODUCT CLASS 5: WHOLE-HOME DEHUMIDIFIERS

[>8.0 cu ft case volume]

	Low-income households	Senior-only households	All households
Average LCC Savings (2022$): *			
TSL 1	$64	$51	$53
TSL 2	$178	$179	$179
TSL 3	$187	$147	$146
TSL 4	$163	$82	$81
Payback Period (years):			
TSL 1	3.8	5.5	5.6
TSL 2	2.0	2.9	2.9
TSL 3	3.9	5.6	5.7
TSL 4	5.3	7.6	7.8
Consumers with Net Benefit (%):			
TSL 1	36%	33%	34%
TSL 2	89%	95%	93%
TSL 3	66%	62%	62%
TSL 4	55%	47%	47%
Consumers with Net Cost (%):			
TSL 1	13%	20%	19%
TSL 2	3%	5%	7%
TSL 3	26%	38%	38%
TSL 4	37%	53%	53%

* Parentheses denote negative (−) values.

c. Rebuttable Presumption Payback

As discussed in section III.E.2 EPCA establishes a rebuttable presumption that an energy conservation standard is economically justified if the increased purchase cost for a product that meets the standard is less than three times the value of the first-year energy savings resulting from the standard. In calculating a rebuttable presumption payback period for each of the considered TSLs, DOE used discrete values, and, as required by EPCA, based the energy use calculation on the DOE test procedure for dehumidifiers. In contrast, the PBPs presented in section V.B.1.a were calculated using average values derived from distributions that reflect the range of energy use in the field.

Table V.17 presents the rebuttable-presumption payback periods for the considered TSLs for dehumidifiers. While DOE examined the rebuttable-presumption criterion, it considered whether the standard levels considered for the NOPR are economically justified through a more detailed analysis of the economic impacts of those levels, pursuant to 42 U.S.C. 6295(o)(2)(B)(i), that considers the full range of impacts to the consumer, manufacturer, Nation, and environment. The results of that analysis serve as the basis for DOE to definitively evaluate the economic justification for a potential standard level, thereby supporting or rebutting the results of any preliminary determination of economic justification.

TABLE V.17—REBUTTABLE-PRESUMPTION PAYBACK PERIODS

Product class	Efficiency level				
	1	2	3	4	5
	years				
Product Class 1: Portable Dehumidifiers ≤25.00 Pints/Day	1.2	1.1	1.2	6.6	7.3
Product Class 2: Portable Dehumidifiers 25.01–50.00 Pints/Day	0.9	1.0	0.8	5.4	6.1
Product Class 3: Portable Dehumidifiers >50.00 Pints/Day	5.9	10.7	11.5	10.7	
Product Class 4: Whole-Home Dehumidifiers ≤8.0 cu ft Case Volume	4.8	4.8	5.6		
Product Class 5: Whole-Home Dehumidifiers >8.0 cu ft Case Volume	5.2	2.7	4.7	6.5	

2. Economic Impacts on Manufacturers

DOE performed an MIA to estimate the impact of amended energy conservation standards on manufacturers of dehumidifiers. The following section describes the expected impacts on manufacturers at each considered TSL. Chapter 12 of the NOPR TSD explains the analysis in further detail.

a. Industry Cash Flow Analysis Results

In this section, DOE provides GRIM results from the analysis, which examines changes in the industry that would result from a standard. The following tables summarize the estimated financial impacts (represented by changes in INPV) of potential amended energy conservation standards on manufacturers of dehumidifiers, as well as the conversion costs that DOE estimates manufacturers of dehumidifiers would incur at each TSL.

The impact of potential amended energy conservation standards were analyzed under two scenarios: (1) the preservation of gross margin percentage; and (2) the preservation of operating profit, as discussed in section IV.J.2.d of this document. The preservation of gross margin percentages applies a ''gross margin percentage'' of 29 percent for all product classes across all efficiency levels.[58] This scenario assumes that a manufacturer's per-unit dollar profit would increase as MPCs increase in the standards cases and represents the upper-bound to industry profitability under potential amended energy conservation standards.

The preservation of operating profit scenario reflects manufacturers' concerns about their inability to maintain margins as MPCs increase to reach more-stringent efficiency levels. In this scenario, while manufacturers make the necessary investments required to convert their facilities to produce compliant equipment, operating profit does not change in absolute dollars and decreases as a percentage of revenue. The preservation of operating profit scenario results in the lower bound to impacts of potential amended standards on industry.

Each of the modeled scenarios results in a unique set of cash flows and corresponding INPV for each TSL. INPV is the sum of the discounted cash flows to the industry from the base year through the end of the analysis period (2023–2057). The ''change in INPV'' results refer to the difference in industry value between the no-new-standards case and standards case at each TSL. To provide perspective on the short-run cash flow impact, DOE includes a comparison of free cash flow between the no-new-standards case and the standards case at each TSL in the year before amended standards would take effect. This figure provides an understanding of the magnitude of the required conversion costs relative to the cash flow generated by the industry in the no-new-standards case.

Conversion costs are one-time investments for manufacturers to bring their manufacturing facilities and product designs into compliance with potential amended standards. As described in section IV.J.2.c of this document, conversion cost investments occur between the year of publication of the final rule and the year by which manufacturers must comply with the new standard. The conversion costs can have a significant impact on the short-term cash flow on the industry and generally result in lower free cash flow in the period between the publication of the final rule and the compliance date of potential amended standards. Conversion costs are independent of the manufacturer markup scenarios and are not presented as a range in this analysis.

TABLE V.18—MANUFACTURER IMPACT ANALYSIS DEHUMIDIFIER INDUSTRY RESULTS

	Unit	No-new-standards case	TSL 1	TSL 2	TSL 3	TSL 4
INPV	*2022$ Million*	158.3	157.8 to 158.0	157.4 to 158.1	153.1 to 155.0	73.0 to 121.6
Change in INPV	%		(0.3) to (0.2)	(0.6) to (0.2)	(3.3) to (2.1)	(53.9) to (23.2)
Free Cash Flow (2027)	*2022$ Million*	12.6	12.4	12.4	10.3	(18.2)
Change in Free Cash Flow (2027)	%		(1.5)	(2.2)	(18.4)	(244.3)
Product Conversion Costs	*2022$ Million*		0.6	0.8	6.9	20.9
Capital Conversion Costs	*2022$ Million*		0.0	0.0	0.0	53.1
Conversion Costs	*2022$ Million*	-	0.6	0.8	6.9	73.9

At TSL 4, the standard represents the max-tech efficiency levels for all product classes. The change in INPV is expected to range from −53.9 to −23.2 percent. At this level, free cash flow is estimated to decrease by 244.3 percent compared to the no-new-standards case value of $12.6 million in the year 2027, the year before the standards year. Currently, less than 1 percent of domestic dehumidifier shipments meet the efficiencies required at TSL 4.

At max-tech, all product classes would require the most efficient compressor observed in teardown

[58] The gross margin percentage of 29 percent is based on a manufacturer markup of 1.40.

models, ECM blower fan with associated variable-speed driver, controls with less inactive mode power consumption and the largest heat exchangers observed in teardown models in each product class. Increasing heat exchanger surface area would necessitate notable changes to the chassis size of both portable and whole-home units as most dehumidifier designs cannot accommodate a larger heat exchanger within the existing cabinet structure. For the portable dehumidifier classes, which together account for approximately 98 percent of industry shipments, almost all manufacturers would need to make significant investments to adjust equipment, molding, and tooling to accommodate new dimensions across their entire product portfolio. None of the 15 portable dehumidifier OEMs currently offer any models that meet the max-tech efficiencies required. Product conversion costs at this level are significant as manufacturers work to completely redesign all existing models and develop new chassis designs to incorporate larger heat exchangers and more efficient components. DOE estimates capital conversion costs of $53.1 million and product conversion costs of $20.9 million. Conversion costs total $73.9 million.

Compared to the market for portable dehumidifiers, the whole-home dehumidifier market is low-volume and relatively concentrated. Whole-home dehumidifiers account for approximately 2 percent of total industry shipments. DOE identified three OEMs producing whole-home dehumidifiers for the U.S. market. Of the two whole-home product classes, whole-home dehumidifiers ≤8.0 cu. ft. (Product Class 4) account for approximately 85 percent of whole-home dehumidifier shipments. Of the three whole-home OEMs identified, only one OEM currently offers a Product Class 4 model that meets the max-tech level. The remaining two OEMs would need to dedicate significant engineering resources to redesign their entire product portfolio to include larger heat exchangers, which would necessitate a change in dimensions and new chassis design. One of the OEMs without any models that meet max-tech is a small, domestic business with a significant market share of Product Class 4 shipments. For the other whole-home product class, only one OEM currently offers whole-home dehumidifiers >8.0 cu. ft. (Product Class 5). This OEM does not currently offer any models that meet the max-tech efficiency required. Given the limited number of whole-home OEMs, the limited number of models currently available that meet the max-tech efficiency levels, and the extent of the redesign required for the OEMs without any max-tech product offerings, it is possible that the 3-year period between the announcement of the final rule and the compliance date of the amended energy conservation standard might be insufficient to design, test, and manufacture the necessary number of products to meet consumer demand.

At TSL 4, the large conversion costs result in a free cash flow dropping below zero in the years before the standards year. The negative free cash flow calculation indicates manufacturers may need to access cash reserves or outside capital to finance conversion efforts.

At TSL 4, the shipment-weighted average MPC for all dehumidifiers is expected to increase by 52.7 percent relative to the no-new-standards case shipment-weighted average MPC for all dehumidifiers in 2028. Given the projected increase in production costs, DOE expects an estimated 23.5 percent drop in shipments in the year the standard takes effect relative to the no-new-standards case. In the preservation of gross margin percentage scenario, the increase in cashflow from the higher MSP is outweighed by the $73.9 million in conversion costs and drop in annual shipments, causing a significant negative change in INPV at TSL 4 under this scenario. Under the preservation of operating profit scenario, the manufacturer markup decreases in 2029, the year after the analyzed compliance year. This reduction in the manufacturer markup, the $73.9 million in conversion costs incurred by manufacturers, and the drop in annual shipments cause a significant decrease in INPV at TSL 4 under the preservation of operating profit scenario.

At TSL 3, the standard represents an intermediate TSL that maintains positive average LCC savings for all products while increasing stringency for Product Classes 1, 2, 4, and 5. The change in INPV is expected to range from −3.3 to −2.1 percent. At this level, free cash flow is estimated to decrease by 18.4 percent compared to the no-new-standards case value of $12.6 million in the year 2027, the year before the standards year. Currently, approximately 3 percent of domestic dehumidifier shipments meet the efficiencies required at TSL 3.

For the portable dehumidifier classes ≤50.00 pints/day (Product Class 1 and Product Class 2), TSL 3 corresponds to EL3. For portable dehumidifiers >50 pints/day, TSL 3 corresponds to EL1. For whole home dehumidifiers ≤8.0 cu. ft., TSL 3 corresponds to EL2. For whole home dehumidifiers >8.0 cu. ft., TSL 3 corresponds to EL3. At this level, DOE expects that all product classes would incorporate a higher efficiency compressor compared to the current baseline. For the whole-home dehumidifier classes, the analyzed design options also included the addition of an ECM blower and a larger heat exchanger as compared to baseline product offerings but to a lesser extent than what was analyzed at max-tech. At this level, DOE does not expect manufacturers of portable dehumidifiers to adopt new or larger chassis designs. As such, DOE does not expect industry would incur capital conversion costs since portable OEMs can likely achieve TSL 3 efficiencies without changes to the heat exchanger and chassis design. Portable dehumidifiers 25.01–50.00 pints/day (Product Class 2) accounts for approximately 73 percent of industry shipments. Of the 15 portable dehumidifier OEMs, around two OEMs currently offer Product Class 2 models that meet the efficiency required by TSL 3. Product conversion costs may be necessary for developing, qualifying, sourcing, and testing more efficient compressors. For whole-home dehumidifiers, DOE expects some manufacturers would need to adopt new or larger chassis designs to accommodate larger heat exchangers but not to the extent required at max-tech. For whole-home designs, DOE expects that the size differences would not necessitate capital investment since existing machinery could likely still be used. Of the three whole-home OEMs, two OEMs currently offer Product Class 4 models that meet the efficiency required. As with TSL 4, whole-home manufacturers would likely need to completely redesign non-compliant models. However, approximately 60 percent of basic model listings (around 32 unique basic models) already meet the efficiency level required. DOE estimates total conversion costs of $6.9 million, all of which are product conversion costs.

At TSL 3, the shipment-weighted average MPC for all dehumidifiers is expected to increase by 1.6 percent relative to the no-new-standards case shipment-weighted average MPC for all dehumidifiers in 2028. Given the projected increase in production costs, DOE does not expect a notable drop in shipments in the year the standard takes effect relative to the no-new-standards case. In the preservation of gross margin percentage scenario, the slight increase in cashflow from the higher MSP is outweighed by the $6.9 million in conversion costs, causing a slightly

negative change in INPV at TSL 3 under this scenario. Under the preservation of operating profit scenario, the manufacturer markup decreases in 2029, the year after the analyzed compliance year. This reduction in the manufacturer markup and the $6.9 million in conversion costs incurred by manufacturers cause a slightly negative change in INPV at TSL 3 under the preservation of operating profit scenario.

At TSL 2, the standard represents efficiency levels consistent with ENERGY STAR requirements for dehumidifiers. The change in INPV is expected to range from −0.9 to −0.2 percent. At this level, free cash flow is estimated to decrease by 2.2 percent compared to the no-new-standards case value of $12.6 million in the year 2027, the year before the standards year. Currently, approximately 89 percent of domestic dehumidifier shipments meet the efficiencies required at TSL 2.

For all product classes, except for whole-home dehumidifiers ≤8.0 cu. ft. (Product Class 4), TSL 2 corresponds to EL2. For Product Class 4, TSL 2 corresponds to EL1. The design options analyzed for most product classes include incorporating incrementally more efficient compressors, similar to TSL 3. For Product Class 5, DOE also expects that manufacturers would need to increase the heat exchanger beyond what would be required at baseline. At this level, DOE estimates that most manufacturers can achieve TSL 2 efficiencies with relatively simple component changes. For the largest portable dehumidifier class (Product Class 2), all 15 OEMs have models that meet the efficiency level required. For the largest whole-home dehumidifier class (Product Class 4), all three OEMs have models that meet the efficiency level required. Product conversion costs may be necessary for developing, qualifying, sourcing, and testing more efficient compressors. DOE estimates total conversion costs of $0.8 million, all of which are product conversion costs.

At TSL 2, the shipment-weighted average MPC for all dehumidifiers is expected to increase by 0.4 percent relative to the no-new-standards case shipment-weighted average MPC for all dehumidifiers in 2028. Given the projected increase in production costs, DOE does not expect a notable drop in shipments in the year the standard takes effect relative to the no-new-standards case. In the preservation of gross margin percentage scenario, the slight increase in cashflow from the higher MSP is outweighed by the $0.8 million in conversion costs, causing a slightly negative change in INPV at TSL 2 under this scenario. Under the preservation of operating profit scenario, the manufacturer markup decreases in 2029, the year after the analyzed compliance year. This reduction in the manufacturer markup and the $0.8 million in conversion costs incurred by manufacturers cause a slightly negative change in INPV at TSL 2 under the preservation of operating profit scenario.

At TSL 1, the standard represents the lowest analyzed efficiency level above baseline for all product classes (EL1). The change in INPV is expected to range from −0.4 to −0.1 percent. At this level, free cash flow is estimated to decrease by 1.5 percent compared to the no-new-standards case value of $12.6 million in the year 2027, the year before the standards year. Currently, approximately 99 percent of domestic dehumidifier shipments meet the efficiencies required at TSL 1.

For all product classes, TSL 1 corresponds to EL1. At TSL 1, DOE analyzed implementing various design options for the range of directly analyzed product classes. corresponds to EL2. For whole-home dehumidifiers under 8.0 cubic feet, TSL 2 corresponds to EL1. The design options analyzed included implementing incrementally more efficient compressors compared to the current baseline, and, for whole home dehumidifiers >8.0 cu. ft. (Product Class 5), the analyzed design options also included implementing larger heat exchangers as compared to the current baseline. At this level, there are no capital conversion costs since most manufacturers can achieve TSL 1 efficiencies with relatively simple component changes. Product conversion costs may be necessary for developing, qualifying, sourcing, and testing more efficient components. DOE estimates total conversion costs of $0.6 million, all of which is product conversion cost.

At TSL 1, the shipment-weighted average MPC for all dehumidifiers is expected to increase by 0.1 percent relative to the no-new-standards case shipment-weighted average MPC for all dehumidifiers in 2028. Given the relatively small increase in production costs, DOE does not project a notable drop in shipments in the year the standard takes effect. In the preservation of gross margin percentage scenario, the minor increase in cashflow from the higher MSP is slightly outweighed by the $0.6 million in conversion costs, causing a slightly negative change in INPV at TSL 1 under this scenario. Under the preservation of operating profit scenario, manufacturers earn the same per-unit operating profit as would be earned in the no-new-standards case, but manufacturers do not earn additional profit from their investments. In this scenario, the manufacturer markup decreases in 2029, the year after the analyzed compliance year. This reduction in the manufacturer markup and the $0.6 million in conversion costs incurred by manufacturers cause a slightly negative change in INPV at TSL 1 under the preservation of operating profit scenario.

DOE seeks comments, information, and data on the capital conversion costs and product conversion costs estimated for each TSL.

b. Direct Impacts on Employment

To quantitatively assess the potential impacts of amended energy conservation standards on direct employment in the dehumidifier industry, DOE used the GRIM to estimate the domestic labor expenditures and number of direct employees in the no-new-standards case and in each of the standards cases during the analysis period. DOE calculated these values using statistical data from the 2021 *ASM*,[59] BLS employee compensation data,[60] results of the engineering analysis, and manufacturer interviews.

Labor expenditures related to product manufacturing depend on the labor intensity of the product, the sales volume, and an assumption that wages remain fixed in real terms over time. The total labor expenditures in each year are calculated by multiplying the total MPCs by the labor percentage of MPCs. The total labor expenditures in the GRIM were then converted to total production employment levels by dividing production labor expenditures by the average fully burdened wage multiplied by the average number of hours worked per year per production worker. To do this, DOE relied on the *ASM* inputs: Production Workers Annual Wages, Production Workers Annual Hours, Production Workers for Pay Period, and Number of Employees. DOE also relied on the BLS employee compensation data to determine the fully burdened wage ratio. The fully burdened wage ratio factors in paid leave, supplemental pay, insurance,

[59] U.S. Census Bureau, *Annual Survey of Manufactures.* ''Summary Statistics for Industry Groups and Industries in the U.S. (2021).'' Available at *www.census.gov/data/tables/time-series/econ/asm/2018-2021-asm.html* (last accessed March 4, 2023).

[60] U.S. Bureau of Labor Statistics. *Employer Costs for Employee Compensation—September 2022.* December 15, 2022. Available at *www.bls.gov/news.release/pdf/ecec.pdf* (last accessed March 4, 2023).

retirement and savings, and legally required benefits.

The number of production employees is then multiplied by the U.S. labor percentage to convert total production employment to total domestic production employment. The U.S. labor percentage represents the industry fraction of domestic manufacturing production capacity for the covered products. This value is derived from manufacturer interviews, equipment database analysis, and publicly available information. The U.S. labor percentage varies by product class. Nearly all portable units are manufactured outside of the United States. Comparatively, DOE estimates that 80 percent of whole-home units are manufactured in the United States. Overall, DOE estimates that 2 percent of all covered dehumidifiers units are manufactured domestically.

The domestic production employees estimate covers production line workers, including line supervisors, who are directly involved in fabricating and assembling products within the OEM facility. Workers performing services that are closely associated with production operations, such as materials handling tasks using forklifts, are also included as production labor. DOE's estimates only account for production workers who manufacture the specific equipment covered by this proposed rulemaking.

Non-production workers account for the remainder of the direct employment figure. The non-production employees estimate covers domestic workers who are not directly involved in the production process, such as sales, engineering, human resources, and management. Using the amount of domestic production workers calculated above, non-production domestic employees are extrapolated by multiplying the ratio of non-production workers in the industry compared to production employees. DOE assumes that this employee distribution ratio remains constant between the no-new-standards case and standards cases.

Using the GRIM, DOE estimates in the absence of amended energy conservation standards there would be 72 domestic production and non-production workers of dehumidifiers in 2028. Table V.19 shows the range of the impacts of potential amended energy conservation standards on U.S. manufacturing employment in dehumidifier industry.

TABLE V.19—DIRECT EMPLOYMENT IMPACTS FOR DOMESTIC DEHUMIDIFIER MANUFACTURERS IN 2028 *

	No-new-standards case	TSL 1	TSL 2	TSL 3	TSL 4
Direct Employment in 2028 (Production Workers + Non-Production Workers).	72	72	72	72	64.
Potential Changes in Direct Employment in 2028*		(53) to 0	(53) to 0	(53) to 0	(53) to (8).

* DOE presents a range of potential employment impacts. Numbers in parentheses denote negative values.

The direct employment impacts shown in Table V.19 represent the potential domestic employment changes that could result following the compliance date of amended energy conservation standards. The upper bound estimate corresponds to the change in the number of domestic workers that would result from amended energy conservation standards if manufacturers continued to produce the same scope of covered products within the United States after compliance takes effect. To establish a conservative lower bound, DOE assumes all manufacturers would shift production to foreign countries with lower costs of labor. At lower TSLs (*i.e.,* TSL 1 through TSL 3), DOE believes the likelihood of changes in production location due to amended standards are low due to the relatively minor production line updates required. However, as amended standards increase in stringency and both the complexity and cost of production facility updates increases, manufacturers are more likely to revisit their production location decisions and/or their make vs. buy decisions.

Additional detail on the analysis of direct employment can be found in chapter 12 of the NOPR TSD. Additionally, the employment impacts discussed in this section are independent of the employment impacts from the broader U.S. economy, which are documented in chapter 16 of the NOPR TSD.

c. Impacts on Manufacturing Capacity

In interviews, some manufacturers expressed concern about efficiency levels that would require increasing the chassis and heat exchanger. These manufacturers asserted that since manufacturing larger units requires longer production and processing time, increasing chassis size could reduce their manufacturing capacity. Furthermore, manufacturers expressed concern that the 3-year compliance period would be insufficient to develop completely new, cost-optimized models across their entire product portfolio if chassis size changes are required.

DOE notes that there could be technical resource constraints due to overlapping regulations, particularly for whole-home dehumidifier manufacturers. Whole-home dehumidifier manufacturers may face resource constraints should DOE set more stringent standards that necessitate the redesign of the majority of models given State (*e.g.,* CARB) and potential Federal refrigerant regulations requiring low-GWP refrigerants over a similar compliance timeline.

DOE seeks comment on whether manufacturers expect manufacturing capacity constraints or engineering resource constraints would limit product availability to consumers in the timeframe of the amended standard compliance date (2028).

d. Impacts on Subgroups of Manufacturers

Using average cost assumptions to develop industry cash-flow estimates may not capture the differential impacts among subgroups of manufacturers. Small manufacturers, niche players, or manufacturers exhibiting a cost structure that differs substantially from the industry average could be affected disproportionately. DOE investigated small businesses as a manufacturer subgroup that could be disproportionally impacted by energy conservation standards and could merit additional analysis. DOE did not identify any other adversely impacted manufacturer subgroups for this proposed rulemaking based on the results of the industry characterization.

DOE analyzes the impacts on small businesses in a separate analysis in section VI.B of this document as part of the Regulatory Flexibility Analysis. In summary, the Small Business Administration (SBA) defines a ''small business'' as having 1,500 or employees

or less for North American Industry Classification System (NAICS) 335210, ''Small Electrical Appliance Manufacturing'' and 1,250 employees or less for NAICS 333415, ''Air Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing.'' For a discussion of the impacts on the small business manufacturer subgroup, see the Regulatory Flexibility Analysis in section VI.B of this document and chapter 12 of the NOPR TSD.

e. Cumulative Regulatory Burden

One aspect of assessing manufacturer burden involves looking at the cumulative impact of multiple DOE standards and the product-specific regulatory actions of other Federal agencies that affect the manufacturers of a covered product or equipment. While any one regulation may not impose a significant burden on manufacturers, the combined effects of several existing or impending regulations may have serious consequences for some manufacturers, groups of manufacturers, or an entire industry. Assessing the impact of a single regulation may overlook this cumulative regulatory burden. In addition to energy conservation standards, other regulations can significantly affect manufacturers' financial operations. Multiple regulations affecting the same manufacturer can strain profits and lead companies to abandon product lines or markets with lower expected future returns than competing products. For these reasons, DOE conducts an analysis of cumulative regulatory burden as part of its rulemakings pertaining to appliance efficiency.

DOE evaluates product-specific regulations that will take effect approximately three years before or after the estimated 2028 compliance date of any amended energy conservation standards for dehumidifiers. This information is presented in Table V.20.

TABLE V.20—COMPLIANCE DATES AND EXPECTED CONVERSION EXPENSES OF FEDERAL ENERGY CONSERVATION STANDARDS AFFECTING DEHUMIDIFIER ORIGINAL EQUIPMENT MANUFACTURERS

Federal energy conservation standard	Number of OEMs *	Number of OEMs affected by today's rule **	Approx. standards compliance year	Industry conversion costs (millions $)	Industry conversion costs/product revenue *** (%)
Consumer Furnaces † 87 FR 40590 (July 7, 2022).	15	3	2029	$150.6 (2020$)	1.4
Consumer Clothes Dryers,† 87 FR 51734 (August 23, 2022).	15	3	2027	$149.7 (2020$)	1.8
Microwave Ovens 88 FR 39912 (June 20, 2023)	18	1	2026	$46.1 (2021$)	0.7
Consumer Conventional Cooking Products 88 FR 6818 † (February 1, 2023).	34	1	2027	$183.4 (2021$)	1.2
Residential Clothes Washers † 88 FR 13520 (March 3, 2023).	19	3	2027	$690.8 (2021$)	5.2
Refrigerators, Freezers, and Refrigerator-Freezers † 88 FR 12452 (February 27, 2023).	49	3	2027	$1,323.6 (2021$)	3.8
Room Air Conditioners 88 FR 34298 (May 26, 2023).	8	4	2026	$24.8 (2021$)	0.4
Consumer Air Cleaners ‡ 88 FR 21752 (April 11, 2023).	43	2	2024 and 2026 ‡	$57.3 (2021$)	1.3
Miscellaneous Refrigeration Products † 88 FR 19382 (March 31, 2023).	38	3	2029	$126.9 (2021$)	3.1
Dishwashers † 88 FR 32514 (May 19, 2023)	22	3	2027	$125.6 (2021$)	2.1
Consumer Water Heaters † 88 FR 49058 (July 28, 2023).	22	3	2030	$228.1 (2022$)	1.3

* This column presents the total number of OEMs identified in the energy conservation standard rule subject to cumulative regulatory burden.

** This column presents the number of OEMs producing dehumidifiers that are also listed as OEMs in the identified energy conservation standard subject to cumulative regulatory burden.

*** This column presents industry conversion costs as a percentage of product revenue during the conversion period. Industry conversion costs are the upfront investments manufacturers must make to sell compliant products/equipment. The revenue used for this calculation is the revenue from just the covered product/equipment associated with each row. The conversion period is the time frame over which conversion costs are made and lasts from the publication year of the final rule to the compliance year of the energy conservation standard. The conversion period typically ranges from 3 to 5 years, depending on the rulemaking.

† These rulemakings are at the NOPR stage, and all values are subject to change until finalized through publication of a final rule.

‡ The Direct Final Rule for Consumer Air Cleaners adopts an amended standard in 2024 and a higher amended standard in 2026. The conversion costs are spread over a 3-year conversion period ending in 2025, with over 50 percent of the conversion costs occurring between 2024 and 2025.

DOE requests information regarding the impact of cumulative regulatory burden on manufacturers of dehumidifiers associated with multiple DOE standards or product-specific regulatory actions of other Federal agencies.

Refrigerant Regulations

DOE evaluated the potential impacts of State and Federal refrigerant regulations, such as CARB's rulemaking prohibiting the use of refrigerants with a GWP of 750 or greater starting January 1, 2023 for self-contained, residential dehumidifiers and starting January 1, 2025 for whole-home dehumidifiers [61] and EPA's final rule issued on October 5, 2023, which restricts the use of HFCs that have a GWP of 700 or greater for residential dehumidifiers beginning January 1, 2025.[62] Based on market research and information from manufacturer interviews, DOE expects that dehumidifier manufacturers will transition to flammable refrigerants (*e.g.,* R–32) in response to refrigerant GWP restrictions. DOE understands that switching from non-flammable to flammable refrigerants requires time and investment to redesign dehumidifiers and upgrade production facilities to accommodate the additional structural and safety precautions required. DOE tentatively expects manufacturers will need to transition to an A2L refrigerant to comply with upcoming refrigerant regulations, prior to the expected 2028 compliance date of any potential energy conservation standards.

Investments required to transition to flammable refrigerants in response to State regulations or EPA's final rule, necessitates a level of investment beyond typical annual R&D and capital expenditures. DOE considers the cost associated with the refrigerant transition in its GRIM to be independent of DOE actions related to any amended energy conservation standards. DOE accounted for the costs associated with redesigning dehumidifiers to make use of flammable refrigerants and retrofitting production facilities to accommodate flammable refrigerants in the GRIM in the no-new-standards case and standards cases to reflect the cumulative regulatory burden from State and Federal refrigerant regulation.[63] DOE relied on manufacturer feedback in confidential interviews and a report prepared for EPA [64] to estimate the industry refrigerant transition costs. Based on feedback, DOE assumed that the transition to low-GWP refrigerants would require industry to invest approximately $3.6 million in R&D and $7.1 million in capital expenditures (*e.g.,* investments in new charging equipment, leak detection systems, *etc.*).

DOE requests comments on the magnitude of costs associated with transitioning dehumidifier products and production facilities to accommodate low-GWP refrigerants that would be incurred between the publication of this NOPR and the proposed compliance date of amended standards. Quantification and categorization of these costs, such as engineering efforts, testing lab time, certification costs, and capital investments (*e.g.,* new charging equipment), would enable DOE to refine its analysis.

3. National Impact Analysis

This section presents DOE's estimates of the national energy savings and the NPV of consumer benefits that would result from each of the TSLs considered as potential amended standards.

a. Significance of Energy Savings

To estimate the energy savings attributable to potential amended standards for dehumidifiers, DOE compared their energy consumption under the no-new-standards case to their anticipated energy consumption under each TSL. The savings are measured over the entire lifetime of products purchased in the 30-year period that begins in the year of anticipated compliance with amended standards (2028–2057). Table V.21 presents DOE's projections of the national energy savings for each TSL considered for dehumidifiers. The savings were calculated using the approach described in section IV.H of this document.

TABLE V.21—CUMULATIVE NATIONAL ENERGY SAVINGS FOR DEHUMIDIFIERS; 30 YEARS OF SHIPMENTS

[2028–2057]

	Trial standard level			
	1	2	3	4
	quads			
Primary energy	0.00	0.02	0.32	0.97
FFC energy	0.00	0.02	0.33	0.99

OMB Circular A–4 [65] requires agencies to present analytical results, including separate schedules of the monetized benefits and costs that show the type and timing of benefits and costs. Circular A–4 also directs agencies to consider the variability of key elements underlying the estimates of benefits and costs. For this proposed rulemaking, DOE undertook a sensitivity analysis using 9 years, rather than 30 years, of product shipments. The choice of a 9-year period is a proxy for the timeline in EPCA for the review of certain energy conservation standards and potential revision of and compliance with such revised

[61] State of California Air Resource Board, ''Prohibitions on Use of Certain Hydrofluorocarbons in Stationary Refrigeration, Chillers, Aerosols-Propellants, and Foam End-Uses Regulation.'' Amendments effective January 1, 2022. *ww2.arb.ca.gov/sites/default/files/barcu/regact/2020/hfc2020/frorevised.pdf* (last accessed March 4, 2023).

[62] The final rule was issued on October 5, 2023 and is pending publication in the **Federal Register**. A pre-publication version of the EPA final rule is available at: *www.epa.gov/system/files/documents/2023-10/technology-transitions-final-rule-2023-pre-publication.pdf.* Once published, the final rule will be available at: *www.regulations.gov/docket/EPA-HQ-OAR-2021-0643.*

[63] Although State regulations, such as CARB's, required the use low-GWP refrigerants in California starting January 1, 2023, for portable dehumidifiers, DOE assumed the refrigerant transition costs would be incurred over the same time period as whole-home dehumidifiers (2023 to 2024) since manufacturers likely waited for EPA SNAP approval before investing in the transition to low-GWP refrigerants for dehumidifiers. 88 FR 26382.

[64] Report prepared for the U.S. Environmental Protection Agency, prepared by RTI International, ''Global Non-CO2 Greenhouse Gas Emission Projections & Marginal Abatement Cost Analysis: Methodology Documentation'' (2019). Available at *www.epa.gov/sites/default/files/2019-09/documents/nonco2_methodology_report.pdf.*

[65] U.S. Office of Management and Budget. *Circular A–4: Regulatory Analysis.* September 17, 2003. Available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf.*

standards.[66] The review timeframe established in EPCA is generally not synchronized with the product lifetime, product manufacturing cycles, or other factors specific to dehumidifiers. Thus, such results are presented for informational purposes only and are not indicative of any change in DOE's analytical methodology. The NES sensitivity analysis results based on a 9-year analytical period are presented in Table V.22. The impacts are counted over the lifetime of dehumidifiers purchased in 2028–2036.

TABLE V.22—CUMULATIVE NATIONAL ENERGY SAVINGS FOR DEHUMIDIFIERS; 9 YEARS OF SHIPMENTS
[2028–2036]

	Trial standard level			
	1	2	3	4
	quads			
Primary energy	0.00	0.01	0.12	0.28
FFC energy	0.00	0.01	0.12	0.29

b. Net Present Value of Consumer Costs and Benefits

DOE estimated the cumulative NPV of the total costs and savings for consumers that would result from the TSLs considered for dehumidifiers. In accordance with OMB's guidelines on regulatory analysis,[67] DOE calculated NPV using both a 7-percent and a 3-percent real discount rate. Table V.23 shows the consumer NPV results with impacts counted over the lifetime of products purchased in 2028–2057.

TABLE V.23—CUMULATIVE NET PRESENT VALUE OF CONSUMER BENEFITS FOR DEHUMIDIFIERS; 30 YEARS OF SHIPMENTS
[2028–2057]

Discount rate	Trial standard level			
	1	2	3	4
	Billion 2022$			
3 percent	0.02	0.07	2.61	2.21
7 percent	0.01	0.03	1.26	0.50

The NPV results based on the aforementioned 9-year analytical period are presented in Table V.24. The impacts are counted over the lifetime of products purchased in 2028–2036. As mentioned previously, such results are presented for informational purposes only and are not indicative of any change in DOE's analytical methodology or decision criteria.

TABLE V.24—CUMULATIVE NET PRESENT VALUE OF CONSUMER BENEFITS FOR DEHUMIDIFIERS; 9 YEARS OF SHIPMENTS (2028–2036)

Discount rate	Trial standard level			
	1	2	3	4
	Billion 2022$			
3 percent	0.01	0.04	1.16	0.55
7 percent	0.00	0.02	0.71	0.09

The previous results reflect the use of a default trend to estimate the change in price for dehumidifiers over the analysis period (see section IV.F.1 of this document). DOE also conducted a sensitivity analysis that considered one scenario with a lower rate of price decline than the reference case and one scenario with a higher rate of price decline than the reference case. The results of these alternative cases are presented in appendix 10C of the NOPR TSD. In the high-price-decline case, the NPV of consumer benefits is higher than in the default case. In the low-price-decline case, the NPV of consumer benefits is lower than in the default case.

c. Indirect Impacts on Employment

DOE estimates that that amended energy conservation standards for

[66] EPCA requires DOE to review its standards at least once every 6 years, and requires, for certain products, a 3-year period after any new standard is promulgated before compliance is required, except that in no case may any new standards be required within 6 years of the compliance date of the previous standards. (42 U.S.C. 6295(m)) While adding a 6-year review to the 3-year compliance period adds up to 9 years, DOE notes that it may undertake reviews at any time within the 6-year period and that the 3-year compliance date may yield to the 6-year backstop. A 9-year analysis period may not be appropriate given the variability that occurs in the timing of standards reviews and the fact that for some products, the compliance period is 5 years rather than 3 years.

[67] U.S. Office of Management and Budget. *Circular A–4: Regulatory Analysis.* September 17, 2003. Available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf.*

dehumidifiers would reduce energy expenditures for consumers of those products, with the resulting net savings being redirected to other forms of economic activity. These expected shifts in spending and economic activity could affect the demand for labor. As described in section IV.N of this document, DOE used an input/output model of the U.S. economy to estimate indirect employment impacts of the TSLs that DOE considered. There are uncertainties involved in projecting employment impacts, especially changes in the later years of the analysis. Therefore, DOE generated results for near-term timeframes (2028–2032), where these uncertainties are reduced.

The results suggest that the proposed standards would be likely to have a negligible impact on the net demand for labor in the economy. The net change in jobs is so small that it would be imperceptible in national labor statistics and might be offset by other, unanticipated effects on employment. Chapter 16 of the NOPR TSD presents detailed results regarding anticipated indirect employment impacts.

4. Impact on Utility or Performance of Products

As discussed in section IV.C.1.b of this document, DOE has tentatively concluded that the standards proposed in this NOPR would not lessen the utility or performance of the dehumidifiers under consideration in this rulemaking. Manufacturers of these products currently offer units that meet or exceed the proposed standards.

5. Impact of Any Lessening of Competition

DOE considered any lessening of competition that would be likely to result from new or amended standards. As discussed in section III.E.1.e of this document, the Attorney General determines the impact, if any, of any lessening of competition likely to result from a proposed standard, and transmits such determination in writing to the Secretary, together with an analysis of the nature and extent of such impact. To assist the Attorney General in making this determination, DOE has provided DOJ with copies of this NOPR and the accompanying TSD for review. DOE will consider DOJ's comments on the proposed rule in determining whether to proceed to a final rule. DOE will publish and respond to DOJ's comments in that document. DOE invites comment from the public regarding the competitive impacts that are likely to result from this proposed rule. In addition, stakeholders may also provide comments separately to DOJ regarding these potential impacts. See the **ADDRESSES** section for information to send comments to DOJ.

6. Need of the Nation to Conserve Energy

Enhanced energy efficiency, where economically justified, improves the Nation's energy security, strengthens the economy, and reduces the environmental impacts (costs) of energy production. Reduced electricity demand due to energy conservation standards is also likely to reduce the cost of maintaining the reliability of the electricity system, particularly during peak-load periods. Chapter 15 in the NOPR TSD presents the estimated impacts on electricity generating capacity, relative to the no-new-standards case, for the TSLs that DOE considered in this rulemaking.

Energy conservation resulting from potential energy conservation standards for dehumidifiers is expected to yield environmental benefits in the form of reduced emissions of certain air pollutants and greenhouse gases. Table V.25 provides DOE's estimate of cumulative emissions reductions expected to result from the TSLs considered in this rulemaking. The emissions were calculated using the multipliers discussed in section IV.K of this document. DOE reports annual emissions reductions for each TSL in chapter 13 of the NOPR TSD.

TABLE V.25—CUMULATIVE EMISSIONS REDUCTION FOR DEHUMIDIFIERS SHIPPED IN 2028–2057

	Trial standard level			
	1	2	3	4
Power Sector Emissions				
CO_2 (*million metric tons*)	0.07	0.31	6.37	18.68
CH_4 (*thousand tons*)	0.00	0.02	0.41	1.19
N_2O (*thousand tons*)	0.00	0.00	0.06	0.16
NO_X(*thousand tons*)	0.03	0.14	2.97	8.50
SO_2 *(thousand tons*)	0.02	0.08	1.72	5.00
Hg (*tons*)	0.000	0.001	0.011	0.033
Upstream Emissions				
CO_2 (*million metric tons*)	0.01	0.03	0.57	1.69
CH_4 (*thousand tons*)	0.59	2.51	51.53	153.02
N_2O (*thousand tons*)	0.00	0.00	0.00	0.01
NO_X (*thousand tons*)	0.10	0.43	8.84	26.25
SO_2 (*thousand tons*)	0.00	0.00	0.04	0.10
Hg (*tons*)	0.000	0.000	0.000	0.000
Total FFC Emissions				
CO_2 (*million metric tons*)	0.08	0.34	6.94	20.36
CH_4 (*thousand tons*)	0.60	2.53	51.94	154.20
N_2O (*thousand tons*)	0.00	0.00	0.06	0.17
NO_X (*thousand tons*)	0.14	0.57	11.81	34.74
SO_2 (*thousand tons*)	0.02	0.09	1.76	5.10
Hg (*tons*)	0.000	0.001	0.012	0.034

As part of the analysis for this rulemaking, DOE estimated monetary benefits likely to result from the reduced emissions of CO_2 that DOE estimated for each of the considered TSLs for dehumidifiers. Section IV.L of this document discusses the SC–CO_2 values that DOE used. Table V.26 presents the value of CO_2 emissions reduction at each TSL for each of the SC–CO_2 cases. The time-series of annual values is presented for the proposed TSL in chapter 14 of the NOPR TSD.

TABLE V.26—PRESENT VALUE OF CO_2 EMISSIONS REDUCTION FOR DEHUMIDIFIERS SHIPPED IN 2028–2057

TSL	SC–CO_2 case			
	Discount rate and statistics			
	5%	3%	2.5%	3%
	Average	Average	Average	95th percentile
	Billion 2022$			
1	0.00	0.00	0.01	0.01
2	0.00	0.02	0.02	0.05
3	0.08	0.32	0.50	0.98
4	0.22	0.92	1.43	2.79

As discussed in section IV.L.2 of this document, DOE estimated the climate benefits likely to result from the reduced emissions of methane and N_2O that DOE estimated for each of the considered TSLs for dehumidifiers. Table V.27 presents the value of the CH_4 emissions reduction at each TSL, and Table V.28 presents the value of the N_2O emissions reduction at each TSL. The time-series of annual values is presented for the proposed TSL in chapter 14 of the NOPR TSD.

TABLE V.27—PRESENT VALUE OF METHANE EMISSIONS REDUCTION FOR DEHUMIDIFIERS SHIPPED IN 2028–2057

TSL	SC–CH_4 case			
	Discount rate and statistics			
	5%	3%	2.5%	3%
	Average	Average	Average	95th percentile
	Million 2022$			
1	0.31	0.88	1.21	2.33
2	1.28	3.65	5.04	9.66
3	26.43	75.40	104.13	200.00
4	74.88	219.14	304.41	579.67

TABLE V.28—PRESENT VALUE OF NITROUS OXIDE EMISSIONS REDUCTION FOR DEHUMIDIFIERS SHIPPED IN 2028–2057

TSL	SC–N_2O case			
	Discount rate and statistics			
	5%	3%	2.5%	3%
	Average	Average	Average	95th percentile
	Million 2022$			
1	0.00	0.01	0.02	0.03
2	0.01	0.05	0.07	0.12
3	0.25	0.96	1.47	2.56
4	0.69	2.71	4.17	7.20

DOE is well aware that scientific and economic knowledge about the contribution of CO_2 and other GHG emissions to changes in the future global climate and the potential resulting damages to the global and U.S. economy continues to evolve rapidly. DOE, together with other Federal agencies, will continue to review methodologies for estimating the monetary value of reductions in CO_2 and other GHG emissions. This ongoing review will consider the comments on this subject that are part of the public record for this and other rulemakings, as well as other methodological assumptions and issues. DOE notes that the proposed standards would be economically justified even without inclusion of monetized benefits of reduced GHG emissions.

DOE also estimated the monetary value of the health benefits associated with NO_X and SO_2 emissions reductions

anticipated to result from the considered TSLs for dehumidifiers. The dollar-per-ton values that DOE used are discussed in section IV.L of this document. Table V.29 presents the present value for NO_X emissions reduction for each TSL calculated using 7-percent and 3-percent discount rates, and Table V.30 presents similar results for SO_2 emissions reductions. The results in these tables reflect application of EPA's low dollar-per-ton values, which DOE used to be conservative. The time-series of annual values is presented for the proposed TSL in chapter 14 of the NOPR TSD.

TABLE V.29—PRESENT VALUE OF NO_X EMISSIONS REDUCTION FOR DEHUMIDIFIERS SHIPPED IN 2028–2057

TSL	3% Discount rate	7% Discount rate
	Million 2022$	
1	7.26	3.33
2	29.32	13.09
3	610.43	270.11
4	1,716.52	716.08

TABLE V.30—PRESENT VALUE OF SO_2 EMISSIONS REDUCTION FOR DEHUMIDIFIERS SHIPPED IN 2028–2057

TSL	3% Discount rate	7% Discount rate
	Million 2022$	
1	1.51	0.71
2	6.11	2.78
3	126.15	56.92
4	352.00	149.67

Not all the public health and environmental benefits from the reduction of greenhouse gases, NO_X, and SO_2 are captured in the values above, and additional unquantified benefits from the reductions of those pollutants as well as from the reduction of direct PM and other co-pollutants may be significant. DOE has not included monetary benefits of the reduction of Hg emissions because the amount of reduction is very small.

7. Other Factors

The Secretary of Energy, in determining whether a standard is economically justified, may consider any other factors that the Secretary deems to be relevant. (42 U.S.C. 6295(o)(2)(B)(i)(VII)) No other factors were considered in this analysis.

8. Summary of Economic Impacts

Table V.31 presents the NPV values that result from adding the estimates of the potential economic benefits resulting from reduced GHG and NO_X and SO_2 emissions to the NPV of consumer benefits calculated for each TSL considered in this rulemaking. The consumer benefits are domestic U.S. monetary savings that occur as a result of purchasing the covered products, and are measured for the lifetime of products shipped in 2028–2057. The climate benefits associated with reduced GHG emissions resulting from the adopted standards are global benefits, and are also calculated based on the lifetime of dehumidifiers shipped in 2028–2057.

TABLE V.31—CONSUMER NPV COMBINED WITH PRESENT VALUE OF CLIMATE BENEFITS AND HEALTH BENEFITS

Category	TSL 1	TSL 2	TSL 3	TSL 4
Using 3% discount rate for Consumer NPV and Health Benefits (billion 2022$)				
5% Average SC–GHG case	0.03	0.11	3.45	4.57
3% Average SC–GHG case	0.03	0.13	3.75	5.42
2.5% Average SC–GHG case	0.03	0.14	3.95	6.02
3% 95th percentile SC–GHG case	0.04	0.16	4.53	7.65
Using 7% discount rate for Consumer NPV and Health Benefits (billion 2022$)				
5% Average SC–GHG case	0.01	0.05	1.69	1.66
3% Average SC–GHG case	0.02	0.07	1.99	2.50
2.5% Average SC–GHG case	0.02	0.08	2.19	3.10
3% 95th percentile SC–GHG case	0.03	0.10	2.77	4.74

C. Conclusion

When considering new or amended energy conservation standards, the standards that DOE adopts for any type (or class) of covered product must be designed to achieve the maximum improvement in energy efficiency that the Secretary determines is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) In determining whether a standard is economically justified, the Secretary must determine whether the benefits of the standard exceed its burdens by, to the greatest extent

practicable, considering the seven statutory factors discussed previously. (42 U.S.C. 6295(o)(2)(B)(i)) The new or amended standard must also result in significant conservation of energy. (42 U.S.C. 6295(o)(3)(B))

For this NOPR, DOE considered the impacts of amended standards for dehumidifiers at each TSL, beginning with the maximum technologically feasible level, to determine whether that level was economically justified. Where the max-tech level was not justified, DOE then considered the next most efficient level and undertook the same evaluation until it reached the highest efficiency level that is both technologically feasible and economically justified and saves a significant amount of energy.

To aid the reader as DOE discusses the benefits and/or burdens of each TSL, tables in this section present a summary of the results of DOE's quantitative analysis for each TSL. In addition to the quantitative results presented in the tables, DOE also considers other burdens and benefits that affect economic justification. These include the impacts on identifiable subgroups of consumers who may be disproportionately affected by a national standard and impacts on employment.

DOE also notes that the economics literature provides a wide-ranging discussion of how consumers trade off upfront costs and energy savings in the absence of government intervention. Much of this literature attempts to explain why consumers appear to undervalue energy efficiency improvements. There is evidence that consumers undervalue future energy savings as a result of (1) a lack of information, (2) a lack of sufficient salience of the long-term or aggregate benefits, (3) a lack of sufficient savings to warrant delaying or altering purchases, (4) excessive focus on the short term, in the form of inconsistent weighting of future energy cost savings relative to available returns on other investments, (5) computational or other difficulties associated with the evaluation of relevant tradeoffs, and (6) a divergence in incentives (for example, between renters and owners, or builders and purchasers). Having less than perfect foresight and a high degree of uncertainty about the future, consumers may trade off these types of investments at a higher than expected rate between current consumption and uncertain future energy cost savings.

In DOE's current regulatory analysis, potential changes in the benefits and costs of a regulation due to changes in consumer purchase decisions are included in two ways. First, if consumers forgo the purchase of a product in the standards case, this decreases sales for product manufacturers, and the impact on manufacturers attributed to lost revenue is included in the MIA. This approach includes changes to future shipments and INPV but does not include the forgone value to consumers who are no longer expected to purchase a dehumidifier in the standards case. Second, DOE accounts for energy savings attributable only to products actually used by consumers in the standards case; if a standard decreases the number of products purchased by consumers, this decreases the potential energy savings from an energy conservation standard. DOE provides estimates of shipments and changes in the volume of product purchases in chapter 9 of the NOPR TSD. However, DOE's current analysis does not explicitly control for heterogeneity in consumer preferences, preferences across subcategories of products or specific features, or consumer price sensitivity variation according to household income.[68]

While DOE is not prepared at present to provide a fuller quantifiable framework for estimating the benefits and costs of changes in consumer purchase decisions due to an energy conservation standard, DOE is committed to developing a framework that can support empirical quantitative tools for improved assessment of the consumer welfare impacts of appliance standards. DOE has posted a paper that discusses the issue of consumer welfare impacts of appliance energy conservation standards, and potential enhancements to the methodology by which these impacts are defined and estimated in the regulatory process.[69] DOE welcomes comments on how to more fully assess the potential impact of energy conservation standards on consumer choice and how to quantify this impact in its regulatory analysis in future rulemakings.

1. Benefits and Burdens of TSLs Considered for Dehumidifier Standards

Table V.32 and Table V.33 summarize the quantitative impacts estimated for each TSL for dehumidifiers. The national impacts are measured over the lifetime of dehumidifiers purchased in the 30-year period that begins in the anticipated year of compliance with amended standards (2028–2057). The energy savings, emissions reductions, and value of emissions reductions refer to full-fuel-cycle results. The efficiency levels contained in each TSL are described in section V.A of this document.

TABLE V.32—SUMMARY OF ANALYTICAL RESULTS FOR DEHUMIDIFIER TSLS: NATIONAL IMPACTS

Category	TSL 1	TSL 2	TSL 3	TSL 4
Cumulative FFC National Energy Savings				
Quads	0.00	0.02	0.33	0.99
Cumulative FFC Emissions Reduction				
CO_2 (*million metric tons*)	0.08	0.34	6.94	20.36
CH_4 (*thousand tons*)	0.60	2.53	51.94	154.20
N_2O (*thousand tons*)	0.00	0.00	0.06	0.17
NO_X (*thousand tons*)	0.14	0.57	11.81	34.74
SO_2 (*thousand tons*)	0.02	0.09	1.76	5.10
Hg (*tons*)	0.00	0.00	0.01	0.03

[68] P.C. Reiss and M.W. White. Household Electricity Demand, Revisited. *Review of Economic Studies.* 2005. 72(3): pp. 853–883. doi: *10.1111/0034–6527.00354.*

[69] Sanstad, A.H. *Notes on the Economics of Household Energy Consumption and Technology Choice.* 2010. Lawrence Berkeley National Laboratory. Available at *www1.eere.energy.gov/buildings/appliance_standards/pdfs/consumer_ee_theory.pdf* (last accessed February 22, 2023).

TABLE V.32—SUMMARY OF ANALYTICAL RESULTS FOR DEHUMIDIFIER TSLS: NATIONAL IMPACTS—Continued

Category	TSL 1	TSL 2	TSL 3	TSL 4
Present Value of Benefits and Costs (3% discount rate, billion 2022$)				
Consumer Operating Cost Savings	0.03	0.13	2.75	7.80
Climate Benefits*	0.00	0.02	0.40	1.14
Health Benefits**	0.01	0.04	0.74	2.07
Total Benefits†	0.05	0.19	3.89	11.01
Consumer Incremental Product Costs‡	0.02	0.06	0.14	5.59
Consumer Net Benefits	0.02	0.07	2.61	2.21
Total Net Benefits	0.03	0.13	3.75	5.42
Present Value of Benefits and Costs (7% discount rate, billion 2022$)				
Consumer Operating Cost Savings	0.02	0.07	1.34	3.59
Climate Benefits*	0.00	0.02	0.40	1.14
Health Benefits**	0.00	0.02	0.33	0.87
Total Benefits†	0.03	0.10	2.07	5.59
Consumer Incremental Product Costs‡	0.01	0.03	0.08	3.09
Consumer Net Benefits	0.01	0.03	1.26	0.50
Total Net Benefits	0.02	0.07	1.99	2.50

Note: This table presents the costs and benefits associated with dehumidifiers shipped in 2028–2057. These results include benefits to consumers which accrue after 2057 from the products shipped in 2028–2057.

* Climate benefits are calculated using four different estimates of the SC–CO_2, SC–CH_4 and SC–N_2O. Together, these represent the global SC–GHG. For presentational purposes of this table, the climate benefits associated with the average SC–GHG at a 3-percent discount rate are shown, but DOE does not have a single central SC–GHG point estimate. To monetize the benefits of reducing GHG emissions this analysis uses the interim estimates presented in the Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates Under Executive Order 13990 published in February 2021 by the Interagency Working Group on the Social Cost of Greenhouse Gases (IWG).

** Health benefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for NO_X and SO_2) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits, but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions. The health benefits are presented at real discount rates of 3 and 7 percent. See section IV.L of this document for more details.

† Total and net benefits include consumer, climate, and health benefits. For presentation purposes, total and net benefits for both the 3-percent and 7-percent cases are presented using the average SC–GHG with 3-percent discount rate, but DOE does not have a single central SC–GHG point estimate and emphasizes the importance and value of considering the benefits calculated using all four sets of SC–GHG estimates.

‡ Costs include incremental equipment costs as well as installation costs.

TABLE V.33—SUMMARY OF ANALYTICAL RESULTS FOR DEHUMIDIFIER TSLS: MANUFACTURER AND CONSUMER IMPACTS

Category	TSL 1*	TSL 2*	TSL 3*	TSL 4*
Manufacturer Impacts				
Industry NPV (*million 2022$*) (No-new-standards case INPV = $158.3)	157.8 to 158.0	157.4 to 158.1	153.1 to 155.0	73.0 to 121.6
Industry NPV (*% change*)	(0.3) to (0.2)	(0.6) to (0.2)	(3.3) to (2.1)	(53.9) to (23.2)
Consumer Average LCC Savings (*2022$*)				
PC 1: Portable Dehumidifiers ≤25.00 Pints/Day	$0	$46	$42	($9)
PC 2: Portable Dehumidifiers 25.01–50.00 Pints/Day	$0	$0	$81	$14
PC 3: Portable Dehumidifiers >50.00 Pints/Day	$31	($4)	$31	($52)
PC 4: Whole-Home Dehumidifiers ≤8.0 cu. ft. Case Volume	$63	$63	$56	$12
PC 5: Whole-Home Dehumidifiers >8.0 cu. ft. Case Volume	$53	$179	$146	$81
Shipment-Weighted Average*	$1	$13	$71	$7
Consumer Simple PBP (years)				
PC 1: Portable Dehumidifiers ≤25.00 Pints/Day	1.0	0.9	0.9	6.3
PC 2: Portable Dehumidifiers 25.01–50.00 Pints/Day	0.7	0.8	0.6	5.3
PC 3: Portable Dehumidifiers >50.00 Pints/Day	4.8	8.7	4.8	11.2
PC 4: Whole-Home Dehumidifiers ≤8.0 cu. ft. Case Volume	6.9	6.9	6.4	7.2
PC 5: Whole-Home Dehumidifiers >8.0 cu. ft. Case Volume	5.6	2.9	5.7	7.8
Shipment-Weighted Average*	0.9	1.0	0.8	5.6
Percent of Consumers That Experience a Net Cost				
PC 1: Portable Dehumidifiers ≤25.00 Pints/Day	0%	1%	3%	65%
PC 2: Portable Dehumidifiers 25.01–50.00 Pints/Day	0%	0%	0%	60%
PC 3: Portable Dehumidifiers >50.00 Pints/Day	33%	65%	33%	74%
PC 4: Whole-Home Dehumidifiers ≤8.0 cu. ft. Case Volume	4%	4%	8%	56%
PC 5: Whole-Home Dehumidifiers >8.0 cu. ft. Case Volume	19%	7%	38%	53%
Shipment-Weighted Average*	0%	1%	1%	61%

Parentheses indicate negative (−) values.

* Weighted by shares of each product class in total projected shipments in 2022.

DOE first considered TSL 4, which represents the max-tech efficiency levels. At this TSL, all product classes would require the most efficient compressor found in DOE's physical teardowns of commercially available models, an ECM blower fan with associated variable-speed driver, controls with lower inactive mode power consumption, and the largest heat exchangers observed from DOE's physical teardowns of commercially available models in each product class. TSL 4 would save an estimated 0.99 quads of energy, an amount DOE considers significant. Under TSL 4, the NPV of consumer benefit would be $0.50 billion using a discount rate of 7 percent, and $2.21 billion using a discount rate of 3 percent.

The cumulative emissions reductions at TSL 4 are 20.36 Mt of CO_2, 5.10 thousand tons of SO_2, 34.74 thousand tons of NO_X, 0.03 tons of Hg, 154.20 thousand tons of CH_4, and 0.17 thousand tons of N_2O. The estimated monetary value of the climate benefits from reduced GHG emissions (associated with the average SC–GHG at a 3-percent discount rate) at TSL 4 is $1.14 billion. The estimated monetary value of the health benefits from reduced SO_2 and NO_X emissions at TSL 4 is $0.87 billion using a 7-percent discount rate and $2.07 billion using a 3-percent discount rate.

Using a 7-percent discount rate for consumer benefits and costs, health benefits from reduced SO_2 and NO_X emissions, and the 3-percent discount rate case for climate benefits from reduced GHG emissions, the estimated total NPV at TSL 4 is $2.50 billion. Using a 3-percent discount rate for all benefits and costs, the estimated total NPV at TSL 4 is $5.42 billion. The estimated total NPV is provided for additional information, however DOE primarily relies upon the NPV of consumer benefits when determining whether a proposed standard level is economically justified.

Portable dehumidifiers in the CCD range in capacity from 1.7 to 104.3 pints per day and account for 98 percent of the current dehumidifier shipments.[70] Within the portable segment of the market, there are three product classes differentiated by capacity range. Portable dehumidifiers with capacities greater than 25.0 pints per day and less than or equal to 50.0 pints per day (PC 2) have the largest market share accounting for approximately 73 percent of portable dehumidifier shipments. Portable dehumidifiers with capacities less than or equal to 25.0 pints per day (PC 1) account for approximately 26 percent of portable dehumidifier shipments. Portable dehumidifiers with capacities greater than 50.0 pints per day (PC 3) account for the remaining 1 percent of portable dehumidifier shipments. Whole-home dehumidifiers are categorized into two product classes based on case volume and correspond to 2 percent of the total dehumidifier market. Whole-home units range in case volume between 1.7 cu. ft. and 9.5 cu. ft. Whole-home dehumidifiers with case volumes less than or equal to 8.0 cu. ft. (PC 4) account for 85 percent of whole-home dehumidifier shipments in 2022.

For portable dehumidifiers at TSL 4, the average LCC impact is a savings of $14 for PC 2, a net cost of $9 for PC 1 and $52 for PC 3. The simple payback period is 6.3 years for PC 1, 5.3 years for PC 2, and 11.2 years for PC 3. Notably, the simple payback period for PC 3 exceeds the expected average lifetime of 10 years for portable dehumidifiers. The fraction of consumers experiencing a net LCC cost is 65 percent for PC 1, 60 percent for PC 2, and 74 percent for PC 3. For whole-home dehumidifiers, the average LCC impact is a savings of $12 for PC 4 and $81 for PC 5. The simple payback is 7.2 years for PC 4 and 7.8 years for PC 5. The fraction of consumers experiencing a net LCC cost is 56 percent for PC 4 and 53 percent for PC 5. Weighted across the market share for all five product classes, a majority of dehumidifier consumers (61 percent) would experience a net cost.

An analysis of RECS 2020 indicates that 97 percent of low-income households that own a dehumidifier own a portable unit. Assuming the low-income sample has a similar market distribution in portable dehumidifier capacities as the national sample, DOE estimates that approximately 25 percent of low-income dehumidifier consumers purchase units in PC 1 and 71 percent in PC 2. At TSL 4, low-income households experience an average net LCC cost of $37 for PC 1 and $21 for PC 2. The percentage of low-income consumers who experience a net LCC cost is 73 percent for PC 1 and 68 percent for PC 2. Low-income households will experience an installed cost increase of $169 for PC 1 (60 percent price increase relative to baseline unit) and $179 for PC 2 (57 percent price increase relative to baseline unit). The simple payback period for low-income households is 7.6 years for PC 1 and 6.4 years for PC 2.

At TSL 4, the projected change in INPV ranges from a decrease of $85.3 million to a decrease of $36.8 million, which corresponds to decreases of 53.9 percent and 23.2 percent, respectively. DOE estimates that industry must invest $73.9 million to completely redesign nearly all models to accommodate larger heat exchangers and new chassis designs.

Overall, DOE estimates that less than 1 percent of current industry shipments meet the efficiencies required at TSL 4. A max-tech standard would require significant investment. Most manufacturers would need to incorporate larger heat exchangers, which would necessitate increasing chassis dimensions of both portable and whole-home units since most dehumidifiers cannot accommodate a larger heat exchanger within the existing cabinet structure. For the portable dehumidifier classes, which together account for nearly 98 percent of industry shipments, most manufacturers would need to make significant investments to adjust equipment and tooling to accommodate new dimensions across their entire product portfolio. DOE estimates that no portable dehumidifier shipments currently meet the max-tech efficiencies. Of the 15 portable dehumidifier OEMs, none currently offer any models that meet the max-tech efficiencies. Whole-home dehumidifiers account for the remaining 2 percent of industry shipments. DOE estimates that approximately 3 percent of whole-home dehumidifier shipments meet max-tech efficiencies. DOE identified only three OEMs producing whole-home dehumidifiers for the U.S. market. Of those three whole-home OEMs, only one currently offers a PC 4 model that meets the max-tech level. The other two OEMs would therefore need to dedicate significant engineering resources to redesign their entire product portfolio to include larger heat exchangers, which would necessitate a change in dimensions and chassis designs. For product class 5, only one OEM manufacturers whole-home dehumidifiers greater than 8.0 cu. ft. (PC 5). This OEM does not currently offer any models that meet the max-tech efficiency required. Given the limited number of whole-home OEMs, the limited number of models currently available that meet the max-tech efficiency levels, and the extent of the redesign required for the OEMs without any max-tech product offerings, there is uncertainty whether whole-home products would remain sufficiently available to meet consumer demand at

[70] Current shipments estimates refer to the 2022 shipments distribution in the no-new-standards case. See section IV.F.8 of this document for details on the energy efficiency distribution in the no-new-standards case.

the compliance date of amended standards set at TSL 4. At this TSL, DOE expects an estimated 23-percent drop in shipments compared to the no-new-standards case shipments in the year the standard takes effect (2028), as some consumers may forgo or delay purchasing a new dehumidifier due to the increased upfront cost of standards-compliant models.

The Secretary tentatively concludes that at TSL 4 for dehumidifiers, the benefits of energy savings, positive NPV of consumer benefits, emission reductions, and the estimated monetary value of the emissions reductions would be outweighed by the economic burden on a majority of consumers, and the impacts on manufacturers, including the large conversion costs, profit margin impacts that could result in a large reduction in INPV, and the lack of manufacturers currently offering products meeting the efficiency levels required at this TSL. Across all product classes, a majority of dehumidifier consumers (61 percent) would experience a net LCC cost. Additionally, the average LCC savings would be negative for PC 1 and PC 3. DOE's consumer subgroup analysis indicates that both low-income and senior-only households would experience larger economic burdens compared to the national population. All portable dehumidifier product classes, which account for 97 percent of dehumidifiers in low-income households and 98 percent in senior-only households, have a negative average LCC savings and majority of consumers experience a net cost. For PC 2 which accounts for 71 percent of the low-income market share of all dehumidifiers, the average net LCC cost is $21 and 68 percent of the low-income consumers would experience a net cost. Weighted across all product classes, the average low-income consumer would experience a net LCC cost of $23 and 69 percent of low-income consumers would experience a net cost at TSL 4. The average senior-only household would experience a net LCC cost of $8 and 66 percent of consumers experiencing a net cost. The potential reduction in INPV could be as high as 53.9 percent. The drop in industry value and reduction in free cash flow after the compliance year is driven by a range of factors, but most notably the changes are driven by conversion cost investments manufacturers must make to redesign and produce more efficient products. Most manufacturers would need to dedicate significant capital and engineering resources to develop new chassis designs to accommodate larger heat exchangers. Due to the limited amount of engineering resources each manufacturer has, it is unclear if most manufacturers will be able to redesign their entire product offerings of dehumidifiers covered by this rulemaking in the 3-year compliance period. Consequently, the Secretary has tentatively concluded that TSL 4 is not economically justified.

DOE then considered TSL 3, which represents efficiency level 3 for PC 1, PC 2, and PC 5, efficiency level 1 for PC 3, and efficiency level 2 for PC 4. At this level, DOE expects that all product classes would incorporate a higher efficiency compressor. For PC 4 and 5, technology options include the addition of an ECM blower and a larger heat exchanger. TSL 3 would save an estimated 0.33 quads of energy, an amount DOE considers significant. Under TSL 3, the NPV of consumer benefit would be $1.26 billion using a discount rate of 7 percent, and $2.61 billion using a discount rate of 3 percent.

The cumulative emissions reductions at TSL 3 are 6.94 Mt of CO_2, 1.76 thousand tons of SO_2, 11.81 thousand tons of NO_X, 0.01 tons of Hg, 51.94 thousand tons of CH_4, and 0.06 thousand tons of N_2O. The estimated monetary value of the climate benefits from reduced GHG emissions (associated with the average SC–GHG at a 3-percent discount rate) at TSL 3 is $0.40 billion. The estimated monetary value of the health benefits from reduced SO_2 and NO_X emissions at TSL 3 is $0.33 billion using a 7-percent discount rate and $0.74 billion using a 3-percent discount rate.

Using a 7-percent discount rate for consumer benefits and costs, health benefits from reduced SO_2 and NO_X emissions, and the 3-percent discount rate case for climate benefits from reduced GHG emissions, the estimated total NPV at TSL 3 is $1.99 billion. Using a 3-percent discount rate for all benefits and costs, the estimated total NPV at TSL 3 is $3.75 billion. The estimated total NPV is provided for additional information, however DOE primarily relies upon the NPV of consumer benefits when determining whether a proposed standard level is economically justified.

For portable dehumidifiers at TSL 3, the average LCC impact is a savings of $42 for PC 1, $81 for PC 2, and $31 for PC 3. The simple payback period is 0.9 years for PC 1, 0.6 years for PC 2, and 4.8 years for PC 3. The fraction of consumers experiencing a net LCC cost is 3 percent for PC 1, 0 percent for PC 2, and 33 percent for PC 3. For whole-home dehumidifiers, the average LCC savings is $56 for PC 4 and $146 for PC 5. The simple payback period is 6.4 years for PC 4 and 5.7 years for PC 5. The fraction of consumers experiencing a net LCC cost is 8 percent for PC 4 and 38 percent for PC 5. Weighting across all product classes, 1 percent of dehumidifier consumers would experience a net cost. The average LCC savings are positive for all product classes for the national consumer samples as well as for the low-income and senior-only consumer samples. At TSL 3, the percentage of low-income households that experience a net LCC cost is 7 percent for PC 1 and 0 percent for PC 2.

At TSL 3, the projected change in INPV ranges from a decrease of $5.2 million to a decrease of $3.3 million, which correspond to decreases of 3.3 percent and 2.1 percent, respectively. DOE estimates that industry must invest $6.9 million to comply with standards set at TSL 3. DOE estimates that approximately 3 percent of industry shipments currently meet the efficiency levels analyzed at TSL 3.

DOE estimates that approximately 2 percent of portable dehumidifier shipments currently meet the TSL 3 efficiency levels. At this level, manufacturers would likely incur product conversion costs to qualify, source, and test more efficient compressors. However, DOE does not expect portable dehumidifier manufacturers would need to adopt new or larger chassis designs because the proposed levels may be met through component swaps in existing chassis designs. Thus, DOE does not expect manufacturers would incur notable capital conversion costs to meet the efficiencies required. For whole-home dehumidifiers, DOE expects some manufacturers would need to adopt new or larger chassis designs to accommodate larger heat exchangers but not to the extent required at max-tech. For whole-home dehumidifier designs, DOE expects that the size differences would not necessitate capital investment since existing machinery could likely still be used. DOE estimates that 78 percent of PC 4 shipments (which account for 85 percent of whole-home dehumidifier shipments) meet the efficiency level required. Of the three whole-home dehumidifier OEMs, two OEMs currently offer PC 4 models that meet the efficiency required. As with TSL 4, whole-home dehumidifier manufacturers would likely need to completely redesign models that do not meet the required efficiencies. However, approximately 60 percent of PC 4 basic model listings (around 32 unique basic models), representing the full range of

existing sizes of PC 4 models (1.7 to 6.6 cu. ft.), already meet the efficiency level required.

After considering the analysis and weighing the benefits and burdens, the Secretary has tentatively concluded that a standard set at TSL 3 for dehumidifiers would be economically justified. At this TSL, the average LCC savings for all product classes are positive. An estimated 1 percent of portable dehumidifier (PC 1, PC 2, and PC 3) and 13 percent of whole-home dehumidifier (PC 4 and PC 5) consumers experience a net cost. The FFC national energy savings are significant and the NPV of consumer benefits is positive using both a 3-percent and 7-percent discount rate. Notably, the benefits to consumers vastly outweigh the cost to manufacturers. At TSL 3, the NPV of consumer benefits, even measured at the more conservative discount rate of 7 percent, is approximately 242 times higher than the maximum estimated manufacturers' loss in INPV. The standard levels at TSL 3 are economically justified even without weighing the estimated monetary value of emissions reductions. When those emissions reductions are included—representing $0.40 billion in climate benefits (associated with the average SC–GHG at a 7-percent discount rate), and $0.74 billion (using a 3-percent discount rate) or $0.33 billion (using a 7-percent discount rate) in health benefits—the rationale becomes stronger still.

As stated, DOE conducts the walk-down analysis to determine the TSL that represents the maximum improvement in energy efficiency that is technologically feasible and economically justified as required under EPCA. The walk-down is not a comparative analysis, as a comparative analysis would result in the maximization of net benefits instead of energy savings that are technologically feasible and economically justified, which would be contrary to the statute. 86 FR 70892, 70908. Although DOE has not conducted a comparative analysis to select the proposed energy conservation standards, DOE notes that as compared to TSL 4, TSL 3 has shorter payback periods, smaller percentages of consumer experiencing a net cost, higher LCC savings for all product classes, a lower maximum decrease in INPV, and lower manufacturer conversion costs.

Although DOE considered proposed amended standard levels for dehumidifiers by grouping the efficiency levels for each product class into TSLs, DOE evaluates all analyzed efficiency levels in its analysis. For portable dehumidifiers with capacities less than or equal to 50.0 pints per day, which account for 97 percent of the dehumidifier market, TSL 3 represents the maximum energy savings that does not result in a large percentage of consumers experiencing a net LCC cost. Efficiency levels above the proposed standard have lower LCC savings and a significantly larger percentage of consumers that experience a net cost. For portable dehumidifiers with capacities greater than 50.0 pints per day, which accounts for 1.1 percent of the dehumidifier market, TSL 3 corresponds to EL 1, the only efficiency level with positive LCC savings and a majority of consumers either not impacted or positively impacted by the proposed standard. For whole-home dehumidifiers, which represent 1.6 percent of the dehumidifier market, TSL 3 corresponds to efficiency levels one level below the max-tech efficiency level. For PC 4, which accounts for approximately 85 of the whole-home dehumidifier shipments, one OEM (out of the three whole-home OEMs) currently offers one model that meets the max-tech level. Given the limited number of whole-home OEMs, the limited number of models currently available that meet the max-tech efficiency level, and the extent of the redesign required for the OEMs without any max-tech product offerings, there is a risk that the 3-year period between the announcement of the final rule and the compliance date of the amended energy conservation standard might be insufficient to design, test, and manufacture the necessary number of whole-home products to meet consumer demand. For PC 5, a majority of consumers would experience negative LCC savings at the max-tech efficiency level. At the proposed TSL, the LCC savings are higher and the percent negatively impacted consumers are lower compared to the max-tech efficiency level.

Therefore, based on the previous considerations, DOE proposes to adopt the energy conservation standards for dehumidifiers at TSL 3. The proposed amended energy conservation standards for dehumidifiers, which are expressed as IEF, are shown in Table V.34.

TABLE V.34—PROPOSED AMENDED ENERGY CONSERVATION STANDARDS FOR DEHUMIDIFIERS

Product class	Minimum integrated energy factor (L/kWh)
	TSL 3
PC 1: Portable Dehumidifiers ≤25.00 Pints/Day	1.70
PC 2: Portable Dehumidifiers 25.01–50.00 Pints/Day	2.01
PC 3: Portable Dehumidifiers >50.00 Pints/Day	3.10
PC 4: Whole-Home Dehumidifiers ≤8.0 cu. ft. Case Volume	2.22
PC 5: Whole-Home Dehumidifiers >8.0 cu. ft. Case Volume	3.81

2. Annualized Benefits and Costs of the Proposed Standards

The benefits and costs of the proposed standards can also be expressed in terms of annualized values. The annualized net benefit is (1) the annualized national economic value (expressed in 2022$) of the benefits from operating products that meet the proposed standards (consisting primarily of operating cost savings from using less energy, minus increases in product purchase costs), and (2) the annualized monetary value of the climate and health benefits from emission reductions.

Table V.35 shows the annualized values for dehumidifiers under TSL 3, expressed in 2022$. The results under the primary estimate are as follows.

Using a 7-percent discount rate for consumer benefits and costs and NO_X and SO_2 reduction benefits, and a 3-percent discount rate case for GHG social costs, the estimated cost of the proposed standards for dehumidifiers is $8.55 million per year in increased equipment costs, while the estimated annual benefits are $142.04 million from reduced equipment operating

costs, $22.85 million from GHG reductions, and $34.54 million from reduced NO_X and SO_2 emissions. In this case, the net benefit amounts to $190.89 million per year.

Using a 3-percent discount rate for all benefits and costs, the estimated cost of the proposed standards for dehumidifiers is $7.89 million per year in increased equipment costs, while the estimated annual benefits are $157.99 million in reduced operating costs, $22.85 million from GHG reductions, and $42.30 million from reduced NO_X and SO_2 emissions. In this case, the net benefit amounts to $215.24 million per year.

TABLE V.35—ANNUALIZED BENEFITS AND COSTS OF PROPOSED ENERGY CONSERVATION STANDARDS FOR DEHUMIDIFIERS

[TSL 3]

	Million 2022$/year		
	Primary estimate	Low-net-benefits estimate	High-net-benefits estimate
3% discount rate			
Consumer Operating Cost Savings	157.99	153.04	163.15
Climate Benefits *	22.85	22.66	22.93
Health Benefits **	42.30	41.95	42.42
Total Benefits †	223.14	217.65	228.50
Consumer Incremental Product Costs ‡	7.89	7.94	7.77
Net Benefits	215.24	209.71	220.74
Change in Producer Cashflow (INPV ‡‡)	(0.5)–(0.3)	(0.5)–(0.3)	(0.5)–(0.3)
7% discount rate			
Consumer Operating Cost Savings	142.04	138.10	146.50
Climate Benefits * (3% discount rate)	22.85	22.66	22.93
Health Benefits **	34.54	34.31	34.64
Total Benefits †	199.44	195.07	204.06
Consumer Incremental Product Costs ‡	8.55	8.58	8.44
Net Benefits	190.89	186.49	195.62
Change in Producer Cashflow (INPV ‡‡)	(0.5)–(0.3)	(0.5)–(0.3)	(0.5)–(0.3)

Note: This table presents the costs and benefits associated with dehumidifiers shipped in 2028–2057. These results include benefits to consumers which accrue after 2057 from the products shipped in 2028 − 2057. The Primary, Low Net Benefits, and High Net Benefits Estimates utilize projections of energy prices from the AEO2023 Reference case, Low Economic Growth case, and High Economic Growth case, respectively. In addition, incremental equipment costs reflect a medium decline rate in the Primary Estimate, a low decline rate in the Low Net Benefits Estimate, and a high decline rate in the High Net Benefits Estimate. The methods used to derive projected price trends are explained in sections IV.F.1 and IV.H.3 of this document. Note that the Benefits and Costs may not sum to the Net Benefits due to rounding.

* Climate benefits are calculated using four different estimates of the global SC–GHG (see section IV.L of this document). For presentational purposes of this table, the climate benefits associated with the average SC–GHG at a 3-percent discount rate are shown, but DOE does not have a single central SC–GHG point estimate and emphasizes the importance and value of considering the benefits calculated using all four sets of SC–GHG estimates. To monetize the benefits of reducing GHG emissions this analysis uses the interim estimates presented in the Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates Under Executive Order 13990 published in February 2021 by the Interagency Working Group on the Social Cost of Greenhouse Gases (IWG).

** Health benefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits, but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions. See section IV.L of this document for more details.

† Total benefits for both the 3-percent and 7-percent cases are presented using the average SC–GHG with 3-percent discount rate, but DOE does not have a single central SC–GHG point estimate.

‡ Costs include incremental equipment costs as well as installation costs.

‡‡ Operating Cost Savings are calculated based on the life cycle costs analysis and national impact analysis as discussed in detail below. *See* sections IV.F and IV.H of this document. DOE's national impacts analysis includes all impacts (both costs and benefits) along the distribution chain beginning with the increased costs to the manufacturer to manufacture the product and ending with the increase in price experienced by the consumer. DOE also separately conducts a detailed analysis on the impacts on manufacturers (*i.e.,* manufacturer impact analysis, or ''MIA''). *See* section IV.J of this document. In the detailed MIA, DOE models manufacturers' pricing decisions based on assumptions regarding investments, conversion costs, cashflow, and margins. The MIA produces a range of impacts, which is the rule's expected impact on the INPV. The change in INPV is the present value of all changes in industry cash flow, including changes in production costs, capital expenditures, and manufacturer profit margins. The annualized change in INPV is calculated using the industry weighted average cost of capital value of 8.4 percent that is estimated in the manufacturer impact analysis (*see* chapter 12 of the NOPR TSD for a complete description of the industry weighted average cost of capital). For dehumidifiers, the annualized change in INPV ranges from −$0.5 million to −$0.3 million. DOE accounts for that range of likely impacts in analyzing whether a trial standard level is economically justified. *See* section V.C of this document. DOE is presenting the range of impacts to the INPV under two markup scenarios: the Preservation of Gross Margin scenario, which is the manufacturer markup scenario used in the calculation of Consumer Operating Cost Savings in this table; and the Preservation of Operating Profit Markup scenario, where DOE assumed manufacturers would not be able to increase per-unit operating profit in proportion to increases in manufacturer production costs. DOE includes the range of estimated annualized change in INPV in the above table, drawing on the MIA explained further in section IV.J of this document to provide additional context for assessing the estimated impacts of this proposal to society, including potential changes in production and consumption, which is consistent with OMB's Circular A–4 and E.O. 12866. If DOE were to include the INPV into the annualized net benefit calculation for this proposed rule, the annualized net benefits would range from $214.8 million to $214.9 million at 3-percent discount rate and would range from $190.4 million to $190.6 million at 7-percent discount rate.

D. Reporting, Certification, and Sampling Plan

Manufacturers, including importers, must use product-specific certification templates to certify compliance to DOE. For dehumidifiers, the certification template reflects the general certification requirements specified at 10 CFR 429.12. As discussed in the previous paragraphs, DOE is not proposing to amend the product-specific certification requirements for these products.

VI. Procedural Issues and Regulatory Review

A. Review Under Executive Orders 12866, 13563 and 14094

E.O. 12866, ''Regulatory Planning and Review,'' as supplemented and reaffirmed by E.O. 13563, ''Improving Regulation and Regulatory Review,'' 76 FR 3821 (Jan. 21, 2011) and amended by E.O. 14094, ''Modernizing Regulatory Review,'' 88 FR 21879 (April 11, 2023), requires agencies, to the extent permitted by law, to (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public. DOE emphasizes as well that E.O. 13563 requires agencies to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible. In its guidance, the Office of Information and Regulatory Affairs (''OIRA'') in the Office of Management and Budget (''OMB'') has emphasized that such techniques may include identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes. For the reasons stated in the preamble, this proposed regulatory action is consistent with these principles.

Section 6(a) of E.O. 12866 also requires agencies to submit ''significant regulatory actions'' to OIRA for review. OIRA has determined that this proposed regulatory action constitutes a ''significant regulatory action'' within the scope of section 3(f)(1) of E.O. 12866. Accordingly, pursuant to section 6(a)(3)(C) of E.O. 12866, DOE has provided to OIRA an assessment, including the underlying analysis, of benefits and costs anticipated from the proposed regulatory action, together with, to the extent feasible, a quantification of those costs; and an assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, and an explanation why the planned regulatory action is preferable to the identified potential alternatives. These assessments are summarized in this preamble and further detail can be found in the technical support document for this rulemaking.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis (''IRFA'') for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by E.O. 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (Aug. 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's website (*www.energy.gov/gc/office-general-counsel*). DOE has prepared the following IRFA for the products that are the subject of this rulemaking.

For manufacturers of dehumidifiers, the SBA has set a size threshold, which defines those entities classified as ''small businesses'' for the purposes of the statute. DOE used the SBA's small business size standards to determine whether any small entities would be subject to the requirements of the rule. (*See* 13 CFR part 121.) The size standards are listed by North American Industry Classification System (NAICS) code and industry description and are available at *www.sba.gov/document/support--table-size-standards.* Manufacturing of portable dehumidifiers is classified under NAICS 335210, ''Small Electrical Appliance Manufacturing'' and manufacturing of whole-home dehumidifiers is classified under NAICS 333415, ''Air Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing.'' For NAICS 335210, the SBA sets a threshold of 1,500 employees or less and for NAICS 333415, the SBA sets a threshold of 1,250 employees or less, for an entity to be considered as a small business for these categories. For the purpose of this IRFA, DOE used the higher employee limit of 1,500 in order to establish a more inclusive threshold for what determines a ''small business.''

1. Description of Reasons Why Action Is Being Considered

DOE is proposing amended energy conservation standards for dehumidifiers. EPCA authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. Title III, Part B of EPCA established the Energy Conservation Program for Consumer Products Other Than Automobiles. These products include dehumidifiers, the subject of this document. (42 U.S.C. 6295(cc)) In a final rule published on June 13, 2016, DOE prescribed the current energy conservation standards for dehumidifiers manufactured on and after June 13, 2019. 81 FR 38338. EPCA provides that, not later than 6 years after the issuance of any final rule establishing or amending a standard, DOE must publish either a notice of determination that standards for the product do not need to be amended, or a NOPR including new proposed energy conservation standards (proceeding to a final rule, as appropriate). (42 U.S.C. 6295(m)(1)) This propose rulemaking is in accordance with DOE's obligations under EPCA.

2. Objectives of, and Legal Basis for, Rule

EPCA authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. Title III, Part B of EPCA established the Energy Conservation Program for Consumer Products Other Than Automobiles. These products include dehumidifiers, the subject of this document. (42 U.S.C. 6295(cc)) EPCA prescribed energy conservation standards for these products. *Id.* EPCA further provides that, not later than 6 years after the issuance of any final rule establishing or

amending a standard, DOE must publish either a notice of determination that standards for the product do not need to be amended, or a NOPR including new proposed energy conservation standards (proceeding to a final rule, as appropriate). (42 U.S.C. 6295(m)(1))

3. Description on Estimated Number of Small Entities Regulated

DOE conducted a market assessment using public information and subscription-based company reports to identify potential small manufacturers. DOE began its assessment by compiling a product database of dehumidifier models available in the United States. To develop a comprehensive product database of dehumidifier basic models, DOE reviewed its Compliance Certification Database (CCD),[71] supplemented by information from California Energy Commission's Modernized Appliance Efficiency Database System (MAEDbS),[72] EPA's ENERGY STAR Product Finder data set,[73] individual company websites, and prior dehumidifier rulemakings. DOE then reviewed the comprehensive product database to identify the original equipment manufacturers (OEMs) of the dehumidifier models identified. DOE consulted publicly available data, such as manufacturer websites, manufacturer specifications and product literature, import/export logs (*e.g.,* bills of lading from Panjiva[74]), and basic model numbers, to identify OEMs of covered dehumidifiers. DOE further relied on public data and subscription-based market research tools (*e.g.,* Dun & Bradstreet reports[75]) to determine company, location, headcount, and annual revenue. DOE screened out companies that do not offer products covered by this rulemaking, do not meet the SBA's definition of a ''small business,'' or are foreign-owned and operated.

Based on its review, DOE identified 20 OEMs that sell dehumidifiers in the United States. DOE then determined that of the 20 OEMs, 19 were either large OEMs or are foreign owned and operated. Therefore, DOE tentatively determined that one company is a small, domestic manufacturer that meets the SBA's definition of a ''small business'' (*i.e.,* the company has 1,500 employees or less) and manufactures products covered by this rulemaking. This small business manufactures whole-home dehumidifiers ≤8.0 cubic feet (Product Class 4).

DOE reached out to this small business and invited them to participate in voluntary interviews. However, this small business did not consent to participate in the voluntary interviews conducted in support of the NOPR analysis. DOE also requested information about small businesses and potential impacts on small businesses while interviewing larger manufacturers.

4. Description and Estimate of Compliance Requirements Including Differences in Cost, if Any, for Different Groups of Small Entities

DOE reviewed its product database and identified 35 basic models of whole-home dehumidifiers with a capacity of under 8.0 cubic feet (Product Class 4) manufactured by this small, domestic OEM. Of those 35 models, 23 models currently meet the TSL 3 efficiency level. Should this small business choose to redesign the 12 models that do not currently meet the proposed amended standard, DOE estimates that the small business would need to invest $337,000 in product conversion costs to redesign all 12 models to incorporate higher efficiency compressors, ECM blowers, and larger heat exchangers. Product conversion costs are investments in research, development, testing, marketing, and other non-capitalized costs necessary to make product designs comply with amended energy conservation standards. DOE's engineering analysis indicates manufacturers would likely be able to produce compliant products with existing machinery, and, therefore, DOE tentatively does not expect meeting the proposed standard would require new equipment or tooling. DOE's analysis focused on the investments associated with amended standards; investments associated with changes in regulations by other State or Federal agencies (*i.e.,* refrigerant regulations) are not attributed to amended standards. Based on annual revenue estimates from Dun & Bradstreet, DOE estimated the company's annual revenue to be $221 million. The total conversion costs of $337,000 are less than 0.1 percent of company revenue over the 3-year conversion period.

DOE seeks comments, information, and data on the number of small businesses in the industry, the names of those small businesses, and their market shares by product class. DOE also requests comment on the potential impacts of the proposed standards on small manufacturers.

5. Duplication, Overlap, and Conflict With Other Rules and Regulations

DOE is not aware of any rules or regulations that duplicate, overlap, or conflict with the proposed rule.

6. Significant Alternatives to the Rule

The discussion in the previous section analyzes impacts on small businesses that would result from DOE's proposed rule, represented by TSL 3. In reviewing alternatives to the proposed rule, DOE examined energy conservation standards set at lower efficiency levels. While TSL 1 and TSL 2 would reduce the impacts on small business manufacturers, it would come at the expense of a reduction in energy savings. TSL 1 achieves 98 percent lower energy savings compared to the energy savings at TSL 3. TSL 2 achieves 95 percent lower energy savings compared to the energy savings at TSL 3.

Based on the presented discussion, establishing standards at TSL 3 balances the benefits of the energy savings at TSL 3 with the potential burdens placed on dehumidifier manufacturers, including small business manufacturers. Accordingly, DOE does not propose one of the other TSLs considered in the analysis, or the other policy alternatives examined as part of the regulatory impact analysis and included in chapter 17 of the NOPR TSD.

Additional compliance flexibilities may be available through other means. EPCA provides that a manufacturer whose annual gross revenue from all of its operations does not exceed $8 million may apply for an exemption from all or part of an energy conservation standard for a period not longer than 24 months after the effective date of a final rule establishing the standard. (42 U.S.C. 6295(t)) Additionally, manufacturers subject to DOE's energy efficiency standards may apply to DOE's Office of Hearings and Appeals for exception relief under certain circumstances. Manufacturers should refer to 10 CFR part 430, subpart E, and 10 CFR part 1003 for additional details.

[71] U.S. Department of Energy's Compliance Certification Database is available at: *www.regulations.doe.gov/certification-data/#q=Product_Group_s%3A** (Last accessed February 21, 2023).

[72] California Energy Commission's Modernized Appliance Efficiency Database System is available at: *cacertappliances.energy.ca.gov/Pages/Search/AdvancedSearch.aspx.* (Last accessed February 21, 2023.)

[73] U.S. Environmental Protection Agency's ENERGY STAR Product Finder data set is available at: *www.energystar.gov/productfinder/* (Last accessed February 21, 2023.)

[74] S&P Global. Panjiva Market Intelligence is available at: *panjiva.com/import-export/United-States* (Last accessed May 5, 2022).

[75] The Dun & Bradstreet Hoovers subscription login is available at *app.dnbhoovers.com.* (Last accessed March 23, 2023).

C. Review Under the Paperwork Reduction Act

Manufacturers of dehumidifiers must certify to DOE that their products comply with any applicable energy conservation standards. In certifying compliance, manufacturers must test their products according to the DOE test procedures for dehumidifiers, including any amendments adopted for those test procedures. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment, including dehumidifiers. (*See generally* 10 CFR part 429). The collection-of-information requirement for the certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act (''PRA''). This requirement has been approved by OMB under OMB control number 1910–1400. Public reporting burden for the certification is estimated to average 35 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

D. Review Under the National Environmental Policy Act of 1969

DOE is analyzing this proposed regulation in accordance with the National Environmental Policy Act of 1969 (''NEPA'') and DOE's NEPA implementing regulations (10 CFR part 1021). DOE's regulations include a categorical exclusion for rulemakings that establish energy conservation standards for consumer products or industrial equipment. 10 CFR part 1021, subpart D, appendix B5.1. DOE anticipates that this rulemaking qualifies for categorical exclusion B5.1 because it is a rulemaking that establishes energy conservation standards for consumer products or industrial equipment, none of the exceptions identified in categorical exclusion B5.1(b) apply, no extraordinary circumstances exist that require further environmental analysis, and it otherwise meets the requirements for application of a categorical exclusion. See 10 CFR 1021.410. DOE will complete its NEPA review before issuing the final rule.

E. Review Under Executive Order 13132

E.O. 13132, ''Federalism,'' 64 FR 43255 (Aug. 10, 1999), imposes certain requirements on Federal agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. The Executive order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE has examined this proposed rule and has tentatively determined that it 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. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of this proposed rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297) Therefore, no further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of E.O. 12988, ''Civil Justice Reform,'' imposes on Federal agencies the general duty to adhere to the following requirements: (1) eliminate drafting errors and ambiguity, (2) write regulations to minimize litigation, (3) provide a clear legal standard for affected conduct rather than a general standard, and (4) promote simplification and burden reduction. 61 FR 4729 (Feb. 7, 1996). Regarding the review required by section 3(a), section 3(b) of E.O. 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) clearly specifies the preemptive effect, if any, (2) clearly specifies any effect on existing Federal law or regulation, (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction, (4) specifies the retroactive effect, if any, (5) adequately defines key terms, and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this proposed rule meets the relevant standards of E.O. 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (''UMRA'') requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, section 201 (codified at 2 U.S.C. 1531). For a proposed regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed ''significant intergovernmental mandate,'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect them. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. DOE's policy statement is also available at *www.energy.gov/sites/prod/files/gcprod/documents/umra_97.pdf.*

This rule does not contain a Federal intergovernmental mandate, nor is it expected to require expenditures of $100 million or more in any one year by the private sector. As a result, the analytical requirements of UMRA do not apply.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires

Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

Pursuant to E.O. 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights,'' 53 FR 8859 (Mar. 15, 1988), DOE has determined that this proposed rule would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under the Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for Federal agencies to review most disseminations of information to the public under information quality guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). Pursuant to OMB Memorandum M–19–15, Improving Implementation of the Information Quality Act (April 24, 2019), DOE published updated guidelines which are available at *www.energy.gov/sites/prod/files/2019/12/f70/DOE%20Final%20Updated%20IQA%20Guidelines%20Dec%202019.pdf.* DOE has reviewed this NOPR under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

E.O. 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OIRA at OMB, a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgates or is expected to lead to promulgation of a final rule, and that (1) is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

DOE has tentatively concluded that this regulatory action, which proposes amended energy conservation standards for dehumidifiers, is not a significant energy action because the proposed standards are not likely to have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as such by the Administrator at OIRA. Accordingly, DOE has not prepared a Statement of Energy Effects on this proposed rule.

L. Information Quality

On December 16, 2004, OMB, in consultation with the Office of Science and Technology Policy (''OSTP''), issued its Final Information Quality Bulletin for Peer Review (''the Bulletin''). 70 FR 2664 (Jan. 14, 2005). The Bulletin establishes that certain scientific information shall be peer reviewed by qualified specialists before it is disseminated by the Federal Government, including influential scientific information related to agency regulatory actions. The purpose of the bulletin is to enhance the quality and credibility of the Government's scientific information. Under the Bulletin, the energy conservation standards rulemaking analyses are ''influential scientific information,'' which the Bulletin defines as ''scientific information the agency reasonably can determine will have, or does have, a clear and substantial impact on important public policies or private sector decisions.'' 70 FR 2664, 2667.

In response to OMB's Bulletin, DOE conducted formal peer reviews of the energy conservation standards development process and the analyses that are typically used and has prepared a report describing that peer review.[76] Generation of this report involved a rigorous, formal, and documented evaluation using objective criteria and qualified and independent reviewers to make a judgment as to the technical/scientific/business merit, the actual or anticipated results, and the productivity and management effectiveness of programs and/or projects. Because available data, models, and technological understanding have changed since 2007, DOE has engaged with the National Academy of Sciences to review DOE's analytical methodologies to ascertain whether modifications are needed to improve DOE's analyses. DOE is in the process of evaluating the resulting report.[77]

VII. Public Participation

A. Participation in the Webinar

The time and date the webinar meeting are listed in the **DATES** section at the beginning of this document. Webinar registration information, participant instructions, and information about the capabilities available to webinar participants will be published on DOE's website: *www1.eere.energy.gov/buildings/appliance_standards/standards.aspx?productid=24.* Participants are responsible for ensuring their systems are compatible with the webinar software.

B. Procedure for Submitting Prepared General Statements for Distribution

Any person who has an interest in the topics addressed in this proposed rule, or who is representative of a group or class of persons that has an interest in these issues, may request an opportunity to make an oral presentation at the webinar. Such persons may submit to *ApplianceStandardsQuestions@ee.doe.gov.* Persons who wish to speak should include with their request a computer file in WordPerfect, Microsoft Word, PDF, or text (ASCII) file format that briefly describes the nature of their interest in this proposed rulemaking and the topics they wish to discuss. Such persons should also provide a daytime telephone number where they can be reached.

C. Conduct of the Webinar

DOE will designate a DOE official to preside at the webinar/public meeting and may also use a professional facilitator to aid discussion. The meeting will not be a judicial or evidentiary-type public hearing, but DOE will conduct it in accordance with section 336 of EPCA (42 U.S.C. 6306). A court reporter will be present to record the proceedings and prepare a transcript. DOE reserves the right to schedule the order of presentations and to establish the procedures governing the conduct of the webinar. There shall not be discussion of proprietary information, costs or prices, market

[76] The 2007 ''Energy Conservation Standards Rulemaking Peer Review Report'' is available at *energy.gov/eere/buildings/downloads/energy-conservation-standards-rulemaking-peer-review-report-0* (last accessed **DATE**).

[77] The report is available at *www.nationalacademies.org/our-work/review-of-methods-for-setting-building-and-equipment-performance-standards.*

share, or other commercial matters regulated by U.S. anti-trust laws. After the webinar and until the end of the comment period, interested parties may submit further comments on the proceedings and any aspect of the proposed rulemaking.

The webinar will be conducted in an informal, conference style. DOE will a general overview of the topics addressed in this rulemaking, allow time for prepared general statements by participants, and encourage all interested parties to share their views on issues affecting this propose rulemaking. Each participant will be allowed to make a general statement (within time limits determined by DOE), before the discussion of specific topics. DOE will permit, as time permits, other participants to comment briefly on any general statements.

At the end of all prepared statements on a topic, DOE will permit participants to clarify their statements briefly. Participants should be prepared to answer questions by DOE and by other participants concerning these issues. DOE representatives may also ask questions of participants concerning other matters relevant to this propose rulemaking. The official conducting the webinar/public meeting will accept additional comments or questions from those attending, as time permits. The presiding official will announce any further procedural rules or modification of the above procedures that may be needed for the proper conduct of the webinar.

A transcript of the webinar will be included in the docket, which can be viewed as described in the *Docket* section at the beginning of this document. In addition, any person may buy a copy of the transcript from the transcribing reporter.

D. Submission of Comments

DOE will accept comments, data, and information regarding this proposed rule before or after the public meeting, but no later than the date provided in the **DATES** section at the beginning of this proposed rule. Interested parties may submit comments, data, and other information using any of the methods described in the **ADDRESSES** section at the beginning of this document.

Submitting comments via *www.regulations.gov.* The *www.regulations.gov* web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment itself or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Otherwise, persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (''CBI'')). Comments submitted through *www.regulations.gov* cannot be claimed as CBI. Comments received through the website will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through *www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *www.regulations.gov* provides after you have successfully uploaded your comment.

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Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via postal mail or hand delivery/courier, please provide all items on a CD, if feasible, in which case it is not necessary to submit printed copies. No telefacsimiles (''faxes'') will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, that are written in English, and that are free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email two well-marked copies: one copy of the document marked ''confidential'' including all the information believed to be confidential, and one copy of the document marked ''non-confidential'' with the information believed to be confidential deleted. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

E. Issues on Which DOE Seeks Comment

Although DOE welcomes comments on any aspect of this proposal, DOE is particularly interested in receiving comments and views of interested parties concerning the following issues:

(1) DOE requests comment on the effects of EPA and CARB regulations on refrigerant choices and on whether changes in refrigerant will affect manufacturer's ability to achieve the efficiency levels in the NOPR analysis and the availability of high-efficiency R–32 compressors.

(2) DOE requests comment regarding consumer's dehumidifier usage patterns and whether consumers typically purchase multiple smaller dehumidifiers to meet dehumidification

requirements as opposed to a single, higher capacity dehumidifier.

(3) DOE requests comment on whether limiting needed chassis size increases are sufficient to preserve consumer utility at the max-tech level.

(4) DOE requests comment on the incremental MPCs from the NOPR engineering analysis.

(5) DOE seeks available data on installation costs for baseline and more efficient units.

(6) DOE seeks comment on the assumption that dehumidifier consumers are most likely to replace a broken unit rather than repair it. DOE also seeks available data on the repair frequency.

(7) DOE seeks data and comment on its efficiency distribution estimate and the assumption of an annual efficiency improvement of 0.25 percent and the expected market respond to updated ENERGY STAR 6.0 specifications.

(8) DOE requests comment on its tentative conclusion that refrigerant desiccant dehumidifier manufacturers would be similarly impacted by potential amended standards and therefore would not warrant a separate subgroup analysis.

(9) DOE requests comment on how to address the climate benefits and other effects of the proposal.

(10) DOE seeks comments, information, and data on the capital conversion costs and product conversion costs estimated for each TSL.

(11) DOE seeks comment on whether manufacturers expect manufacturing capacity constraints or engineering resource constraints would limit product availability to consumers in the timeframe of the amended standard compliance date (2028).

(12) DOE requests information regarding the impact of cumulative regulatory burden on manufacturers of dehumidifiers associated with multiple DOE standards or product-specific regulatory actions of other Federal agencies.

(13) DOE requests comments on the magnitude of costs associated with transitioning dehumidifier products and production facilities to accommodate low-GWP refrigerants that would be incurred between the publication of this NOPR and the proposed compliance date of amended standards. Quantification and categorization of these costs, such as engineering efforts, testing lab time, certification costs, and capital investments (*e.g.,* new charging equipment), would enable DOE to refine its analysis.

(14) DOE seeks comments, information, and data on the number of small businesses in the industry, the names of those small businesses, and their market shares by product class. DOE also requests comment on the potential impacts of the proposed standards on small manufacturers.

(15) Additionally, DOE welcomes comments on other issues relevant to the conduct of this rulemaking that may not specifically be identified in this document.

VIII. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this notice of proposed rulemaking and announcement of public meeting.

List of Subjects in 10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Intergovernmental relations, Small businesses.

Signing Authority

This document of the Department of Energy was signed on October 27, 2023, by Jeffrey Marootian, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on October 27, 2023.

Treena V. Garrett,

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

For the reasons stated in the preamble, DOE is proposing to amend part 430 of Chapter II of Title 10, Code of Federal Regulations as set forth below:

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 1. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 2. Amend § 430.32 by revising paragraph (v) to read as follows:

§ 430.32 Energy and water conservation standards and their compliance dates.

* * * * *

(v) *Dehumidifiers.* (1) Dehumidifiers manufactured on or after June 13, 2019, and before [*date 3 years after date of publication of the final rule*], shall have an integrated energy factor that meets or exceeds the following values:

Portable dehumidifier product capacity (pints/day)	Minimum integrated energy factor (liters/kWh)
25.00 or less	1.30
25.01–50.00	1.60
50.01 or more	2.80
Whole-home dehumidifier product case volume (cubic feet)	
8.0 or less	1.77
More than 8.0	2.41

(2) Dehumidifiers manufactured on or after [*date 3 years after date of publication of the final rule*], shall have an integrated energy factor that meets or exceeds the following values:

Portable dehumidifier product capacity (pints/day)	Minimum integrated energy factor (liters/kWh)
25.00 or less	1.70
25.01–50.00	2.01
50.01 or more	3.10
Whole-home dehumidifier product case volume (cubic feet)	
8.0 or less	2.22
More than 8.0	3.81

* * * * *

[FR Doc. 2023–24106 Filed 11–3–23; 8:45 am]

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Part V

Department of Commerce

National Oceanic and Atmospheric Administration

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Port of Alaska's North Extension Stabilization Step 1 (NES1) Project in Anchorage, Alaska; Notice

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD366]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Port of Alaska's North Extension Stabilization Step 1 (NES1) Project in Anchorage, Alaska

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

ACTION: Notice; proposed incidental harassment authorization; request for comments on proposed authorization and possible renewal.

SUMMARY: NMFS has received a request from the Port of Alaska (POA) for authorization to take marine mammals incidental to the NES1 project at the existing port facility in Anchorage, Alaska. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an incidental harassment authorization (IHA) to incidentally take marine mammals during the specified activities. NMFS is also requesting comments on a possible one-time, 1-year renewal that could be issued under certain circumstances and if all requirements are met, as described in the Request for Public Comments section at the end of this notice. NMFS will consider public comments prior to making any final decision on the issuance of the requested MMPA authorization and agency responses will be summarized in the final notice of our decision.

DATES: Comments and information must be received no later than December 5, 2023.

ADDRESSES: Comments should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service and should be submitted via email to *ITP.tyson.moore@noaa.gov.* Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities.* In case of problems accessing these documents, please call the contact listed above.

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments, including all attachments, must not exceed a 25-megabyte file size. All comments received are a part of the public record and will generally be posted online at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities* without change. All personal identifying information (*e.g.,* name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Reny Tyson Moore, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are proposed or, if the taking is limited to harassment, a notice of a proposed IHA is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other ''means of effecting the least practicable adverse impact'' on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for taking for certain subsistence uses (referred to in shorthand as ''mitigation''); and requirements pertaining to the mitigation, monitoring and reporting of the takings are set forth. The definitions of all applicable MMPA statutory terms cited above are included in the relevant sections below.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.,* the issuance of an IHA) with respect to potential impacts on the human environment. Accordingly, NMFS has prepared an Environmental Assessment (EA) to consider the environmental impacts associated with the issuance of the proposed IHA. NMFS' EA is available at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities.* We will review all comments submitted in response to this notice prior to concluding our NEPA process or making a final decision on the IHA request.

Summary of Request

On July 19, 2022, NMFS received a request from the POA for an IHA to take marine mammals incidental to construction activities related to the NES1 project in Anchorage, Alaska. Following NMFS' review of the application, the POA submitted revised versions on December 27, 2022, July 28, 2023, and August 31, 2023. The application was deemed adequate and complete on September 7, 2023. The POA submitted a final version addressing additional minor corrections on September 21, 2023. The POA's request is for take of seven species of marine mammals by Level B harassment and, for a subset of these species (*i.e.,* harbor seal (*Phoca vitulina*) and harbor porpoise (*Phocoena phocoena*)), Level A harassment. Neither the POA nor NMFS expect serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

NMFS previously issued IHAs to the POA for similar work (85 FR 19294, April 6, 2020; 86 FR 50057, September 7, 2021). The POA complied with all the requirements (*e.g.,* mitigation, monitoring, and reporting) of the previous IHAs, and information regarding their monitoring results may be found in the Effects of the Specified Activity on Marine Mammals and their Habitat and Estimated Take section of this notice and online at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities.*

This proposed IHA would cover 1 year of the ongoing Port of Alaska Modernization Program (PAMP) for which the POA obtained prior IHAs and intends to request additional take authorization for subsequent facets of the program. The PAMP involves construction activities related to the

modernization of the POAs marine terminals.

Description of Proposed Activity

Overview

The POA, located on Knik Arm in upper Cook Inlet, provides critical infrastructure for the citizens of Anchorage and a majority of the citizens of Alaska. The North Extension at the POA is a failed bulkhead structure that was constructed between 2005 and 2011. Parts of the North Extension bulkhead structure and the surrounding upland area are unstable and collapsing, and some of the sheet piles are visibly twisted and buckled. The structure presents safety hazards and logistical impediments to ongoing Port operations, and much of the upland area is currently unusable. The NES project would result in removal of the failed sheet pile structure and reconfiguration and realignment of the shoreline within the North Extension, including the conversion of approximately 0.05 square kilometers (km^2; 13 acres) of developed land back to intertidal and subtidal habitat within Knik Arm. The NES project would be completed in two distinct steps, NES1 and NES2, separated by multiple years and separate permitting efforts. This notice is applicable to a proposed IHA for the incidental take of marine mammals during in-water construction associated with NES1.

The NES1 project would involve the removal of portions of the failed sheet pile structure to stabilize the North Extension. The POA anticipates this project would begin on April 1, 2024 and extend through November 2024. They estimate that work would occur over approximately 250 hours on 110 nonconsecutive days. The NES1 project would remove approximately half of the North Extension structure extending approximately 274 meters (m) north from the southern end of the North Extension. This project would also stabilize the remaining portion of the North Extension by creating an end-state embankment. In-water construction associated with this project includes vibratory installation and removal of 81 24-inch (61-centimeter (cm)) or 36-inch (91-cm) temporary steel pipe stability template piles and vibratory removal, pile splitting and pile cutting (and possible impact removal) of approximately 4,216 sheet piles from the structure tailwalls, cell faces (bulkhead), and closure walls. Sound produced by these construction activities may result in the take of marine mammals, by harassment only.

Dates and Duration

The POA anticipates that NES1 in-water construction activities would begin on April 1, 2024 and extend through November 2024. In-water pile installation and removal associated with the NES1 project is anticipated to take place over approximately 246.5 hours on 110 nonconsecutive days between these dates (see table 1 for estimated production rates and durations). While the exact sequence of demolition and construction is uncertain, an estimated schedule of sheet pile removal and temporary stability template pile installation and removal is shown in Table 2.

TABLE 1—PILE INSTALLATION AND REMOVAL METHODS AND ESTIMATED DURATIONS

Pile type	Pile size	Structural feature	Total estimated number of piles	Estimated number of piles in the water	Average vibratory and/or splitter duration	Maximum impact strikes per day	Total duration of removal and installation in water (hours)	Average production rate, piles per day (range)	Estimated number of days
PS 27.5 and PS 31 Sheets.	19.69 inches (50 cm).	Tailwalls	3,536	2,267	2 hours/day	150	157	50 (10 to 100)	46
PS 27.5 and PS 31 Sheets.	19.69 inches (50 cm).	Cell Faces (Bulkhead).	568	568	2 hours/day	150	41	30 (10 to 60)	19
PZC26 Sheets	27.88 inches (70 cm).	Closure Walls	110	110	2 hours/day	150	8	50 (10 to 100)	3
Steel Pipe	24- or 36-inch (61- or 91-cm) install.	Temporary Stability Templates.	81	81	15 min/pile	0	20.25	4 (2 to 10)	21
Steel Pipe	24- or 36-inch (61- or 91-cm) removal.	Temporary Stability Templates.	81	81	15 min/pile	0	20.25	4 (2 to 10)	21
Total	.....	.....	.....	.....	.....	.....	246.5	.....	110

Note: cm = centimeter(s).

TABLE 2—ESTIMATED TIMING AND DURATION BY MONTH OF PILE INSTALLATION AND REMOVAL ACTIVITIES

Activity	April	May	June	July	August	September	October	November	Total
36-inch (91-cm) or 24-inch (61-cm) stability template pile installation:									
Piles	27	14	14	10	10	3	3	0	81
Hours	6.75	3.50	3.50	2.5	2.5	0.75	0.75	0	20.25
36-inch (91-cm) or 24-inch (61.cm) stability template pile removal:									
Piles	0	27	13	13	13	10	4	1	81
Hours	0	6.75	3.25	3.25	3.25	2.5	1	0.25	20.25
Sheet pile vibratory hammer removal:									
Piles	.....	.....	.....	.....	.....	.....	.....	.....	.....
Hours	10	45	60	60	13	10	4	2	206
Total hours	16.75	55.25	66.75	65.75	18.75	15.25	5.75	2.25	246.50

The POA has presented this schedule using the best available information derived from what is known of the North Extension Site and the POA's experience with similar construction and demolition projects. The POA plans to conduct as much work as possible prior to August through October, when there is higher Cook Inlet beluga whale (CIBW; *Delphinapterus leucas*) abundance. However, as described below, due to the instability of the North Extension site, it is important that the POA attempt to complete the NES1 in a single construction season, which may necessitate work in August through October. Potential consequences of pausing the construction season (*i.e.,* stopping work from August through October) include de-rating the structural capacity of existing POA docks, a shutdown of dock operations due to deteriorated conditions, or an actual collapse of one or more dock structures. The potential for collapse increases with schedule delays, due to both worsening deterioration and the higher probability of a significant seismic event.

A typical construction season at the POA extends from approximately mid-April to mid-October (6 months) and may include November. Exact dates of ice-out in the spring and formation of new ice in the fall vary from year to year and cannot be predicted with accuracy. In-water pile installation and removal cannot occur during the winter months when ice is present because of the hazards associated with moving ice floes that change directions four times a day, preventing the use of tugs, barges, workboats, and other vessels. Ice movement also prevents accurate placement of piles.

Due to the design of the existing sheet pile wall, demolition must occur in a sequential and uninterrupted manner to prevent structural failure of the wall as demolition progresses. This safety requirement limits the POA's ability to re-sequence in-water sheet pile extraction and temporary pile installation, as the already compromised bulkhead structure may become further destabilized. The POA therefore plans to complete all work between April and November 2024, and requests an IHA for the NES1 project for 1 year that is effective as of April 1, 2024. All pile-driving would occur during daylight hours.

Specific Geographic Region

The Municipality of Anchorage is located in the lower reaches of Knik Arm of upper Cook Inlet (see Figure 2–1 in the POA's application). The POA sits on the industrial waterfront of Anchorage, just south of Cairn Point and north of Ship Creek (lat. 61°15′ N, long. 149°52′ W; Seward Meridian). Knik Arm and Turnagain Arm are the two branches of upper Cook Inlet, and Anchorage is located where the two arms join.

Cook Inlet is a large tidal estuary that exchanges waters at its mouth with the Gulf of Alaska. The inlet is roughly 20,000 km² in area, with approximately 1,350 linear kilometer (km) of coastline (Rugh *et al.,* 2000) and an average depth of approximately 100 m. Cook Inlet is generally divided into upper and lower regions by the East and West Forelands. Freshwater input to Cook Inlet comes from snowmelt and rivers, many of which are glacially fed and carry high sediment loads. Currents throughout Cook Inlet are strong and tidally periodic, with average velocities ranging from 3 to 6 knots (Sharma and Burrell, 1970). Extensive tidal mudflats occur throughout Cook Inlet, especially in the upper reaches, and are exposed at low tides.

Cook Inlet is a seismically active region susceptible to earthquakes and has some of the highest tides in North America (NOAA, 2015) that drive surface circulation. Cook Inlet contains substantial quantities of mineral resources, including coal, oil, and natural gas. During winter, sea, beach, and river ice are dominant physical forces within Cook Inlet. In upper Cook Inlet, sea ice generally forms in October to November, and continues to develop through February or March (Moore *et al.,* 2000).

Northern Cook Inlet bifurcates into Knik Arm to the north and Turnagain Arm to the east. Knik Arm is generally considered to begin at Point Woronzof, 7.4 km southwest of the POA. From Point Woronzof, Knik Arm extends about 48 km in a north-northeasterly direction to the mouths of the Matanuska and Knik rivers. At Cairn Point, just northeast of the POA, Knik Arm narrows to about 2.4 km before widening to as much as 8 km at the tidal flats northwest of Eagle Bay at the mouth of Eagle River.

Knik Arm comprises narrow channels flanked by large tidal flats composed of sand, mud, or gravel, depending upon location. Approximately 60 percent of Knik Arm is exposed at Mean Lower Low Water (MLLW). The intertidal (tidally influenced) areas of Knik Arm are mudflats, both vegetated and unvegetated, which consist primarily of fine, silt-sized glacial flour. Freshwater sources often are glacially born waters, which carry high suspended sediment loads, as well as a variety of metals such as zinc, barium, mercury, and cadmium. Surface waters in Cook Inlet typically carry high silt and sediment loads, particularly during summer, making Knik Arm an extremely silty, turbid waterbody with low visibility through the water column. The Matanuska and Knik Rivers contribute the majority of fresh water and suspended sediment into Knik Arm during summer. Smaller rivers and creeks also enter along the sides of Knik Arm (U.S. Department of Transportation and Port of Anchorage, 2008).

Tides in Cook Inlet are semidiurnal, with two unequal high and low tides per tidal day (tidal day = 24 hours, 50 minutes). Due to Knik Arm's predominantly shallow depths and narrow widths, tides near Anchorage are greater than those in the main body of Cook Inlet. The tides at the POA have a mean range of about 8 m, and the maximum water level has been measured at more than 12.5 m at the Anchorage station (NMFS, 2015). Maximum current speeds in Knik Arm, observed during spring ebb tide, exceed 7 knots. These tides result in strong currents in alternating directions through Knik Arm and a well-mixed water column. The navigation harbor at the POA is a dredged basin in the natural tidal flat. Sediment loads in upper Cook Inlet can be high; spring thaws occur, and accompanying river discharges introduce considerable amounts of sediment into the system (Ebersole and Raad, 2004). Natural sedimentation processes act to continuously infill the dredged basin each spring and summer.

The POA's boundaries currently occupy an area of approximately 0.52 km². Other commercial and industrial activities related to secured maritime operations are located near the POA on Alaska Railroad Corporation property immediately south of the POA, on approximately 0.45 km² at a similar elevation. The POA is located north of Ship Creek, an area that experiences concentrated marine mammal activity during seasonal runs of several salmon species. Ship Creek serves as an important recreational fishing resource and is stocked twice each summer. Ship Creek flows into Knik Arm through the Municipality of Anchorage industrial area. Joint Base Elmendorf-Richardson (JBER) is located east of the POA, approximately 30.5 m higher in elevation. The U.S. Army Defense Fuel Support Point-Anchorage site is located east of the POA, south of JBER, and north of Alaska Railroad Corporation property. The perpendicular distance to the west bank directly across Knik Arm from the POA is approximately 4.2 km. The distance from the POA (east side)

to nearby Port MacKenzie (west side) is approximately 4.9 km.

Detailed Description of the Specified Activity

The POA, located on Knik Arm in upper Cook Inlet (Figure 1), provides critical infrastructure for the citizens of Anchorage and a majority of the citizens of Alaska. Marine-side infrastructure and facilities at the POA were constructed largely in the 1960s and are in need of replacement because they are substantially past their design life and in poor and deteriorating structural condition. Those facilities include three general cargo terminals, two petroleum terminals, a dry barge landing, and an upland sheet-pile-supported storage and work area. To address deficiencies, the POA is modernizing its marine terminals through the PAMP to enable safe, reliable, and cost-effective Port operations. The PAMP will support infrastructure resilience in the event of a catastrophic natural disaster over a 75-year design life.

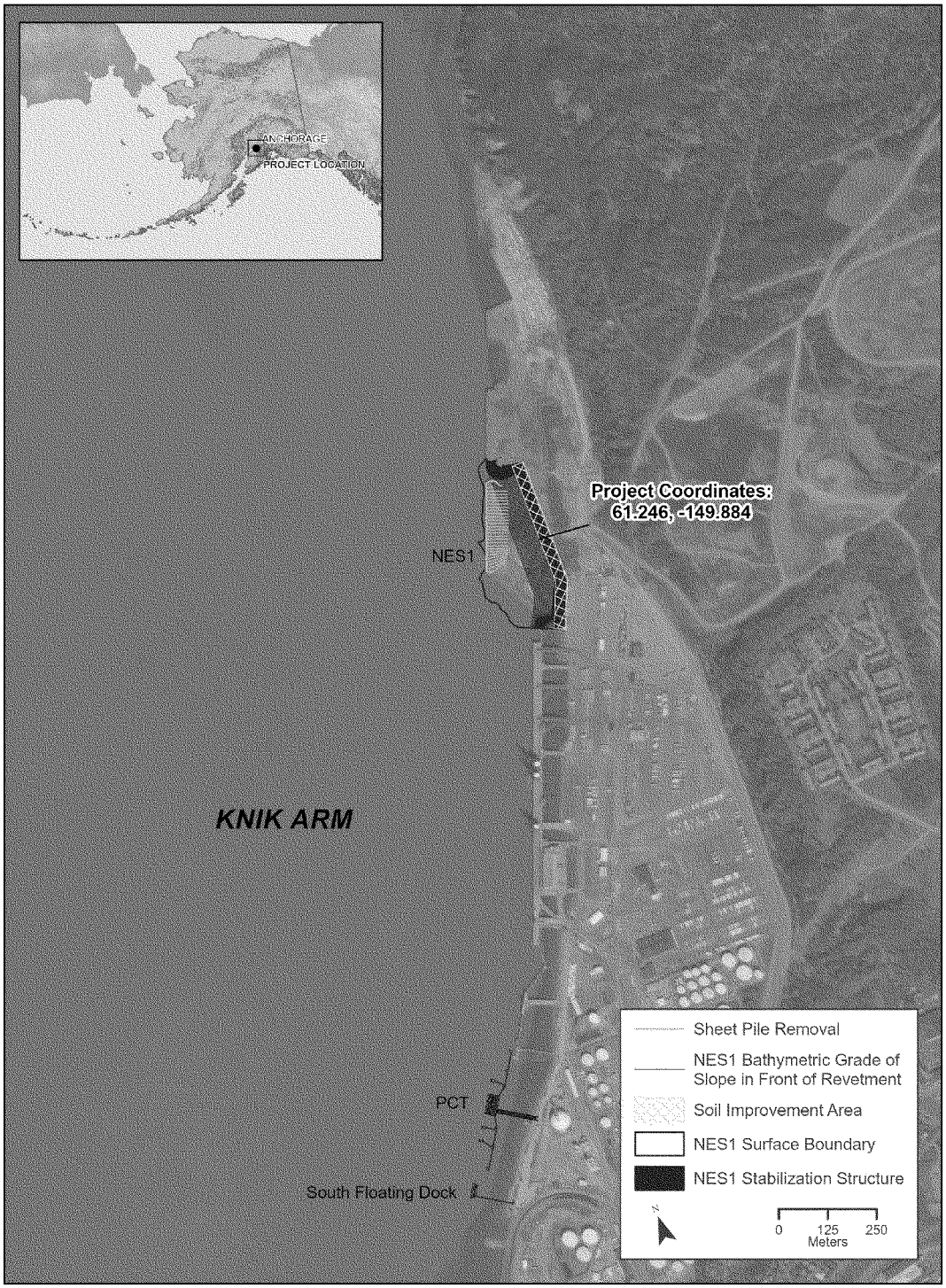

Figure 1 -- Overview of North Extension Stabilization 1

The PAMP is critical to maintaining food and fuel security for the state. At the completion of the PAMP, the POA will have modern, safe, resilient, and efficient facilities through which more than 90 percent of Alaskans will continue to obtain food, supplies, tools, vehicles, and fuel. The PAMP is divided into five separate phases; these phases are designed to include projects that have independent utility yet streamline agency permitting. The projects associated with the PAMP include:

- *Phase 1:* Petroleum and Cement Terminal (PCT Phase 1 and 2) and South Floating Dock (SFD) replacement;
- *Phase 2A:* NES1;
- *Phase 2B:* General Cargo Terminals Replacement (construction planned to begin in 2025);
- *Phase 3:* Petroleum, Oil and Lubricants Terminal 2 Replacement;
- *Phase 4:* NES2; and
- *Phase 5:* Demolition of Terminal 3.

Phase 1 of the PAMP was completed in 2022. IHAs were issued by NMFS for both the PCT (Phase 1 and Phase 2; 85 FR 19294, April 6, 2020) and SFD projects associated with this Phase (86 FR 50057, September 7, 2021). The NES Project would be completed in two distinct steps, NES1 and NES2, separated by multiple years and separate permitting efforts. The project discussed herein, NES1, is Phase 2A of the PAMP. Ground improvements work in preparation for NES1 began in 2023, and on-shore and in-water work for NES1 is planned to commence in April 2024.

The North Extension (the area north of the existing general cargo docks) was constructed in 2005–2011 under the Port Intermodal Expansion Project (PIEP), the predecessor effort to the PAMP. The POA considers the North Extension a failed structure. Parts of the North Extension bulkhead structure and the surrounding upland area are unstable and collapsing, and some of the sheet piles are visibly twisted and buckled. The structure presents safety hazards and logistical impediments to ongoing Port operations, and much of the upland area is currently unusable. The currently proposed NES Project overall would result in removal of the failed sheet pile structure and reconfiguration and realignment of the shoreline within the North Extension. NES1 would include the conversion of approximately 0.05 km^2 (13 acres) of developed land back to intertidal and subtidal habitat within Knik Arm. While the majority of the Project will be demolition work, the term ''construction'' as used herein refers to both construction and demolition work.

The purpose of the NES Project is to stabilize the previously failed North Extension bulkhead structure and create a new shoreline that is structurally and seismically stable and balances the preservation of uplands created in the past while addressing the formation of unwanted sedimentation within the U.S. Army Corps of Engineers (USACE) Anchorage Harbor. The NES Project will also improve safety for maneuvering vessels at the northern berths. Previous establishment of the North Extension changed the hydrodynamics of the area and resulted in more rapid accumulation of sediments at the existing cargo dock faces, as well as a smaller turning area for vessels. The Municipality of Anchorage and the POA have identified the NES Project as a priority for the PAMP, due to the impact of the existing structure's geometry upon the USACE Anchorage Harbor Project, mariners' concerns regarding impacts to safe ship-berthing operations, and engineering concerns regarding structural and geotechnical stability of the system. The existing structure poses significant risk for continued deterioration and could result in significant release of impounded fill material into the Port's vessel operating and mooring areas, and into the USACE Anchorage Harbor Project. Accordingly, a significant portion of the NES work has been designated for inclusion in NES1 as Phase 2A PAMP efforts, specifically those portions of the existing structure that are closest to the north end of the existing cargo terminals. Creation of a safe and stable uplands area will support POA operations while also addressing concerns of adverse impacts upon the Federal Navigation Channel and Dredging Program.

Existing North Extension Structure

The existing North Extension bulkhead structure is an OPEN CELL SHEET PILE (OCSP) design. Demolition of the existing OCSP structure will include removal and disposal of the southerly OCSP bulkhead walls and associated backlands. The OCSP bulkhead is a retaining structure filled with soil that is composed of 29 interconnected open cells, each approximately 8 m wide, with 30 tailwalls that are up to 61 m long (see Figure 1–3 in the POA's application). Each cell is about 20 sheets wide across the face, which is along the water. Each tailwall consists of approximately 118 sheet piles that extend landward into the filled area, orthogonal to the sheet piles along the face (table 1). The sheet piles interlock through a series of thumb-finger joints or interlocks (where two sheet piles are connected along their length; see Figure 1–5 in the POA's application) along the cell faces and tailwalls. Wye joints occur where three sheet piles are connected at the interface between two neighboring sheet pile cell faces and the adjoining tailwall (see Figure 1–6 in the POA's application). Two z-pile closure walls close the gaps between structures, one on each end of the bulkhead (see Figure 1–4 in the POA's application). The total number of sheet piles in the existing structure that would be removed is approximately 4,216, although the exact number of sheet piles in the existing structure is not known with certainty.

Demolition of the failed sheet pile structure would be accomplished through excavation and dredging of impounded soils (fill material), and cutting and removal of the existing sheet piles, most likely through use of a splitter and vibratory hammer. Demolition of the OCSP cell components would not commence until ground improvements necessary to protect the horizontal to vertical ratio (H:V) of 2H:1V embankment slope have been completed. Ground improvements were scheduled for 2023 and are underway. The sequencing of in-water events, including how construction would proceed while maintaining stability among the structure's cells, is unknown. It is anticipated that the actual methods, including types of equipment and numbers of hours and days of each activity, would be determined based on the engineering specifications for the NES1 project as determined by the Construction Contractor and the Design Build Team designer of record (DOR). The NES1 DOR and Construction Contractor have been selected by the POA, but their Construction Work Plan has not yet been completed and some actual construction techniques are likely to be refined adaptively as construction advances due to the stability risk of the existing impounded materials. The following project description is based on the best available information at this time considering the POA's knowledge of the condition of the North Extension and their experience with similar marine construction and demolition projects, which NMFS has determined sufficient for the purposes of the IHA application.

NES1 Project Activities

The NES1 Project would result in a reconfiguration and realignment of the shoreline through removal of portions of the failed sheet pile structure to stabilize the North Extension. Before NES1 commences, the upland area would be prepared with ground improvements to stabilize the existing fill. Ground improvements will take place in the dry, landward of the existing failed sheet pile structure and underneath the area where filter rock and armor rock would later be placed to stabilize the new shoreline. Ground improvement work began in 2023.

Construction of NES1 will include completion of the following tasks:

- Dredging and offshore disposal of approximately 1.35 million cubic yards (CY) of material down to −12 m MLLW;
- Excavation of 115,000 CY of material;
- Demolition and removal of the failed existing sheet pile structure; and
- Shoreline stabilization including placement of granular fill, filter rock, and armor rock along the new face of the shoreline.

NES1 would remove approximately half of the North Extension structure extending approximately 274 m north

from the southern end of the North Extension. NES1 would also stabilize the remaining portion of the North Extension by creating an end-state embankment with a top elevation of +12 m MLLW, sloping to a toe elevation of approximately −12 m MLLW. The lower portion of the embankment slope from −12 m MLLW to approximately 0 m MLLW would be constructed with a 6H:1V slope and would be unarmored. A grade-break would occur above these elevations as the slope will transition to a 2H:1V slope armored rock revetment.

At the cell faces, the depth of the face wall sections varies, with most extending from a tip elevation of approximately −60 MLLW to a cutoff elevation of approximately +9 m MLLW (27 m long). The mudline at the face sheets varies but is thought to be at approximately −11 m MLLW. This translates into a requirement to demolish sheet piles approximately 25 m high from the −14-m MLLW elevation to the top of the containment.

Demolition of the failed sheet pile structure would be accomplished through excavation and dredging of impounded soils (fill material), and cutting and removal of the existing sheet piles. Approximately 1,465,000 CY of material would be removed. The material removed from excavation (115,000 CY) would be stockpiled in the North Extension area for future use, while the dredged material (1,350,000 CY) would be disposed of offshore into the Anchorage Harbor Open Water Disposal Site, which is the authorized USACE offshore disposal area used by the POA under USACE permit POA–2003–00503–M20.

The NES1 Project in-water work would begin with landside excavation and in-water dredging along the south shoreline and south half of the failed sheet pile structure. Any methodology considered for cutting and removing the steel sheet piles would account for worker safety, constructability, and minimization of potential acoustic impacts that the operation may have on marine mammals. The first attempt would be to extract the sheet piles with direct vertical pulling or with a vibratory hammer; however, there may be complications with the sheet pile interlocks, which could become seized, and other means of pile removal may be required (*i.e.* shearing or torching). Demolition activities would begin with the south half of the existing structure, followed by the north half of NES1 (see Figure 1–8 in the POA's application). The majority of the demolition work would occur from the water side to eliminate safety hazards from unexpected movements of fill material or the sheet piles themselves. The demolition plan also includes stabilization of the face sheets through installation of temporary piles and dredging back into the cell to relieve pressure on the sheet piles and to eliminate any release of material into Cook Inlet beyond natural tidal forces.

Safety is a top priority regarding planning and executing the work. There are several risks at the project site to consider when planning demolition activities, such as strong currents and large tidal swings. Existing sheet piles and their interlocks are in poor condition. Many of the sheets may be damaged and bound up, making removal difficult. There are stability concerns with the failed OCSP structure, where the POA would have to closely manage allowable fill differentials between adjacent cells and loading on the face sheets. In-water NES1 activities and quantities are summarized in Table 3 (NES1 activities to be completed on land are summarized in table 1–2 in the POA's application).

TABLE 3—SUMMARY OF IN-WATER NES1 PROJECT STAGES, ACTIVITIES, AND APPROXIMATE QUANTITIES

Type of activity	Size and type	Total anticipated amount or number
Dredging of fill material	Granular fill	1,350,000 CY.
At-sea transit and disposal of dredged fill	Granular fill	1,350,000 CY.
Cutting piles with sheet splitter (vertical)	19.69-inch (50 cm) sheet piles, cut into vertical	Unknown.[1]
Cutting piles with shears or torch (horizontal)[2]	19.69-inch (50 cm) sheet piles	Unknown.[1]
Vibratory or direct pull removal of sheet piles[3]	19.69-inch (50 cm) sheet piles, removed in vertical panels.	4,216 sheet piles.
Installation and removal of temporary steel pipe piles	81 24- or 36-inch (61- or 91-cm) piles	81 installations, 81 removals.
Slope construction	Bedding, filter rock, armor stone	60,500 CY.

[1] The total number of sheet piles to be cut would be a subset of the estimated 4,216 sheet piles needed to be removed.
[2] Deploying divers or underwater shear equipment would be the last resort for removing sheet piles.
[3] Most of the waterside face and tailwall sheets would be cut in the dry to improve operational safety.

Dredging and Disposal

Dredging would be performed with a derrick barge using a clamshell bucket, and would likely take place for 24 hours per day for the duration of the project. One barge would perform the dredging associated with the sheet pile removal, working concurrently and in support of the crane barge removing the sheets. Another barge would perform dredging in the remaining proposed project area. This barge would start with removing the existing armor rock on the south slope and work its way north behind the OSCP bulkhead. Dredged material would be placed on a dump barge and taken by tug boat for disposal at the Anchorage Harbor Open Water Disposal Site.

Dredging for NES1 will take place in an area that has been part of a working port for more than 50 years, where dredging activities are common. Take of marine mammals by dredging is not anticipated or proposed to be authorized due to the low intensity and stationary nature of the sounds produced by dredging and its perennial presence over many years in the same general location near the project site. Further, the sounds produced by dredging are not meaningfully different and are unlikely to exceed sounds produced by ongoing normal industrial activities at the port. Lastly, mitigation measures described in the Proposed Mitigation section would ensure that direct physical interaction with marine mammals during dredging activities would be avoided. Therefore, dredging will not be considered further in this notice.

Excavation

Landside excavation would occur with loaders and excavators to remove the top portion of fill material and open up work for initial sheet pile cutting and removal. This excavation would begin to relieve pressure along the sheet wall face and expose the tops of the sheet piles to mitigate the risk of damaging sheets while dredging with a clamshell

bucket. The sheet piles could be more easily extracted if undamaged. The removal elevation would remain above +5 m MLLW in order for the land equipment to reach the excavation depth with the groundwater and tidal elevations and ensure that the removed material would be in good condition. The material removed would be stockpiled at the POA for future use. Excavation would occur out of water. Therefore, take of marine mammals related to excavation activities is not anticipated or proposed to be authorized, and it will not be considered further in this notice.

Pile Installation and Removal

The sheet pile removal process would begin with the installation of stability templates (steel pipe piles) along the face of the sheet pile structure, following excavation and initial dredging work. Once landside excavation has removed the top portion of fill along the face of the wall, the POA would follow behind and begin dredging the material within the cells while maintaining the allowable fill differential between adjacent cells to maintain structural integrity. Before dredging deeper than the allowable elevation determined by the engineer, a crane barge would install temporary stability templates along the face of the sheet pile structure. The addition of about 27 temporary stability templates would support about one-third of the bulkhead sheet pile wall during removal of the impounded material. These templates would reinforce the sheets as material is dredged and hold them upright to prohibit any sheet deformation and improve the efficiency and effectiveness of removal. The templates would also minimize the need to perform horizontal cuts at multiple elevations, including underwater. With strong currents and low visibility, performing horizontal cuts underwater poses significant challenges. After that area has been demolished, the temporary stability template piles would be removed and re-installed along the next third of the bulkhead. It is anticipated that three sets of 27 temporary piles would be required for a total of 81 installations and 81 removals (table 1). The POA anticipates that the temporary stability template piles would be 24-inch (61-cm) steel pipe piles. However, it is possible that 36-inch (91-cm) steel pipe piles would be used instead. Temporary piles would be installed and removed with a vibratory hammer.

The POA would begin on the southern end of the sheet pile structure and work their way north along the sheet wall face, installing templates and dredging fill material while managing fill elevations from cell to cell (see Figure 1–10 in the POA's application for an example section for the proposed demolition work). Fill material would slide down into the dredge area and would continue to be removed until a cell has been dredged down to −12 m MLLW adjacent to the face sheets and all pressure of the fill material on the face has been relieved. At this point in time, the crane barge would begin removing the sheet piles, starting with the face sheets.

Some sheet piles from the tailwalls would be removed in the dry, potentially during excavation, depending on construction sequencing and tide heights. To minimize potential impacts on marine mammals from in-water sheet pile removal with a vibratory hammer, removal in the dry would be maximized as feasible; however, until the Construction Contractor and DOR are under contract, the exact number of sheet piles that may be removed in the dry is unknown. It is estimated that approximately 20–30 percent of sheet piles would be removed in the dry.

Additionally, it is possible that some sheet piles may be removed by direct pulling. Removal of sheet piles by direct pulling where and when possible would also be maximized as feasible. Once fill material and impounded soils have been excavated or dredged from both sides of the sheet piles, it may be adequate to dislodge the sheet piles out of interlock by lifting or direct pulling.

Although some sheet piles and sheet pile sections would be removed by direct pulling and/or in the dry, it is anticipated that some sheet piles and sheet pile sections would need to be removed with a vibratory hammer in water. Sheet piles may not be extracted easily if soil adheres to the sheet piles along the embedded length. It is also possible that competent portions of the interlocks would resist movement, or that interlocks that are bent or damaged by shearing would be difficult to separate and require shaking with a vibratory hammer.

During vibratory removal, a vibratory hammer would be suspended from a crane and connected to a powerpack. The extractor jaw would be hydraulically locked onto the web of the sheet pile. The pile would be vibrated as upward vertical force is applied to extract the pile. Ideally, the piles would slide within the interlock, separating from the adjacent piles. This may not always be the case, as the pile may bind, and multiple piles may be dislodged from the original installed position. Another potential outcome of a pile that binds up is that the pile web (the thin, flat part between the interlocks) may be compromised from corrosion or other damage, resulting in the web steel tearing and partially ripping the pile, necessitating the application of vertical force to a neighboring pile.

Vertical cuts to split the sheet piles into panels may be made with a sheet splitter if the interlocks do not release (see Figure 1–10 in the POA's application). The specific tools that would be used for pile splitting are not known, but it is anticipated that a splitter would be used. A pile splitter is a stiffened steel H-beam with some of the webbing removed. The edges of the H-beam webbing are hardened and form a large wedge between the flanges. The wedge is set on top of the sheet pile webbing where a cut is required. The splitter is then driven with a hammer down the webbing of the sheet pile until the tip of the H-beam passes the tip of the sheets, cutting the sheet pile all the way through and separating it into two parts. Multiple cuts split the sheet pile wall into tall vertical panels that can be removed in smaller pieces. Cuts in the sheet piles may be spaced 4 to 6 sheets apart and multiple sheets or pieces would be removed together. Splitters can be used in the air, water, or in soils and can be driven with impact or vibratory hammers. The splitter would be used in conjunction with a vibratory hammer and the POA assumed splitting would produce the same or similar sound levels to a vibratory hammer used without the splitter attachment. Therefore, the POA combined use of a vibratory hammer to remove sheet piles and use of a splitter into a single category (*i.e.,* vibratory hammer removal) and treated them the same for time (*i.e.,* table 1) and take estimation (see the Estimated Take section).

The POA estimates that an average of approximately 5 minutes of vibratory hammer application would be required to remove sheet pile sections. It is unknown how many sheet piles may be included in a section; the POA anticipates that this number will vary widely. If sheet piles remain seized in the sediments and cannot be loosened or broken free with a vibratory hammer, they may be dislodged with an impact hammer. Use of an impact hammer to dislodge is expected to be uncommon, with up to 150 strikes (an estimated 50 strikes per pile for up to three piles) on any individual day or approximately 5 percent of active hammer duration for each sheet pile. The POA would not use two vibratory hammers with or without splitters simultaneously.

Alternative means of pile removal include dredging or excavation to reduce further pile embedment, and cutting sheet piles using hydraulic shears or underwater ultrathermic cutting. When feasible, sheet piles would be removed in one piece, without cutting. Similarly, use of cutting methods to cut piles into sections that could be more easily removed would take place out of water when feasible. The POA anticipates that hydraulic shears may be used to cut sheet piles both in and out of water. The POA anticipates that sounds produced by hydraulic shears would be brief, low level, and intermittent, imparting minimal sound energy into the water column. A single closure of the shears on sheet pile is anticipated to successfully sever one or multiple sheets depending on the model and jaw depth. The POA anticipates that a single cut may require up to 2 minutes for the shears to close, although the duration of a single cut is likely to be less than 2 minutes. Therefore, take of marine mammals associated with hydraulic shearing is not anticipated or proposed to be authorized.

Underwater ultrathermic cutting is performed by commercial divers using hand-held equipment to cut or melt through ferrous and non-ferrous metals, and could be used to cut the zinc-coated OCSP structure. These systems operate through a torch-like process, initiated by applying a melting amperage to a steel tube packed with alloy steel rods, sometimes mixed with aluminum rods to increase the heat output. In the hands of skilled commercial divers, underwater ultrathermic cutting is reputed to be relatively fast and efficient, cutting through approximately 2 to 4 inches (5 to 10 cm) per minute, depending upon the number of divers deployed. This efficacy may be constrained by the requirement to secure the severed piles from falling into the inlet to prevent an extreme hazard to the diver cutting the piles. Tidally driven currents in Cook Inlet may limit dive times to approximately 2 to 3 hours per high- and low-tide event, depending upon the tide cycle and the ability of divers to efficiently perform the cutting task while holding position during high current periods. Take of marine mammals associated with underwater ultrathermic cutting is not anticipated or proposed to be authorized as this activity is not considered to produce sound.

Once the face sheets have been removed, the crane barge would remove the stability templates for use on other cells. At this point, the tailwalls would become independent walls with only fill material between them. The crane barge would work to extract as many tailwall sheets as possible until additional relief dredging is required to allow for vibratory removal. At this point, the crane barge would continue ahead to the north while the dredge rig falls back to continue dredging between the sheets. The POA would continue to remove the face wall and tailwall sheets from south to north until the OCSP structure has been removed.

A key consideration of the NES1 project is to avoid rapid release of the impounded soils into the inlet. This is an important safety issue presenting a risk to construction personnel working in or near the cells in the immediate area of such an event. It is also an important operational issue to the POA, as releasing large quantities of materials into the inlet could quickly foul the adjoining cargo terminal berths (see Figure 1–7 in the POA's application). To avoid rapid release of the impounded soils, the demolition would need to be managed to account for the soil pressure of the adjacent adjoining cells. Failure to properly manage this process would likely result in the earth pressure generated by adjacent adjoining cells exerting lateral forces that would cause catastrophic tailwall failures. Also, the sheets joined in interlock are susceptible to bending in the weak axis, which could result in rotational forces that may overcome the vertical interlocks, causing the interlocks to unzip, again resulting in catastrophic tailwall failures and or face wall failures. Qualified professional engineers on the Design Build Team would develop the Construction Work Plan with the technical details to ameliorate these risks.

The sheet pile interlocks would not prevent the flow of seawater into soils impounded within the OCSP cells. The water infiltration would be most prevalent at the face sheets; however, dynamic wave forces, the variable sea level height of the inlet, and variations in the impounded soils and associated permeability would make the interface elevation between unsaturated and saturated soils dynamic. Because saturated soils cannot resist shear, land-based excavation could be safely accomplished at a height above the saturated soil depth to be determined by the DOR, lest the equipment weight exceed the soil-bearing capacity.

Shoreline Stabilization

After the existing sheet pile structure has been removed, the sloped shoreline would be secured with armor stone placed on a layer of filter rock and granular fill. Placement of armor rock requires good visibility of the shore as each rock would be placed carefully to interlock with surrounding armor rock. The POA therefore anticipates that placement of armor rock would occur in the dry at low tide levels when feasible; however, some placement of armor rock, filter rock, and granular fill would occur in water. No impacts on marine mammals from placement of armor rock, filter rock, and granular fill in the dry are anticipated and therefore this activity will not be discussed further.

Proposed mitigation, monitoring, and reporting measures are described in detail later in this document (please see Proposed Mitigation and Proposed Monitoring and Reporting).

Description of Marine Mammals in the Area of Specified Activities

There are seven species of marine mammals that may be found in upper Cook Inlet during the proposed construction and demolition activities. Sections 3 and 4 of the IHA application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history of the potentially affected species. NMFS fully considered all of this information, and we refer the reader to these descriptions, instead of reprinting the information. Additional information regarding population trends and threats may be found in NMFS' Stock Assessment Reports (SARs; *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*) and more general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS' website (*https://www.fisheries.noaa.gov/find-species*).

Additional information on CIBWs may be found in NMFS' 2016 Recovery Plan for the CIBW, available online at *https://www.fisheries.noaa.gov/resource/document/recovery-plan-cook-inlet-beluga-whale-delphinapterus-leucas,* and NMFS' 2023 report on the abundance and trend of CIBWs in Cook Inlet in June 2021 and June 2022, available online at *https://www.fisheries.noaa.gov/resource/document/abundance-and-trend-belugas-delphinapterus-leucas-cook-inlet-alaska-june-2021-and.*

Table 4 lists all species or stocks for which take is expected and proposed to be authorized for this activity, and summarizes information related to the population or stock, including regulatory status under the MMPA and Endangered Species Act (ESA) and potential biological removal (PBR), where known. PBR is defined by the MMPA as the maximum number of

animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS' SARs). While no serious injury or mortality is anticipated or proposed to be authorized here, PBR and annual serious injury and mortality from anthropogenic sources are included here as gross indicators of the status of the species or stocks and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS' stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS' U.S. Alaska and Pacific SARs (*e.g.,* Carretta, *et al.,* 2023; Young *et al.,* 2023). Values presented in Table 4 are the most recent available at the time of publication and are available online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments.* The most recent abundance estimate for CIBWs, however, is available from Goetz *et al.* (2023) and available online at *https://www.fisheries.noaa.gov/feature-story/new-abundance-estimate-endangered-cook-inlet-beluga-whales.*

TABLE 4—SPECIES LIKELY IMPACTED BY THE SPECIFIED ACTIVITIES

Common name	Scientific name	MMPA stock	ESA/ MMPA status; strategic (Y/N) [1]	Stock abundance N_{best}, (CV, N_{min}, most recent abundance survey) [2]	PBR	Annual M/SI [3]
Order Cetartiodactyla—Cetacea—Superfamily Mysticeti (baleen whales)						
Family Eschrichtiidae:						
Gray whale	*Eschrichtius robustus*	Eastern N Pacific	-/-; N	26,960 (0.05, 25,849, 2016).	801	131
Family Balaenopteridae (rorquals):						
Humpback whale	*Megaptera novaeangliae*	Hawaii	-, -, N	11,278 (0.56, 7,265, 2020).	127	27.09
		Mexico-North Pacific	T, D, Y	N/A (N/A, N/A, 2006)	[6] UND	0.57
Order Cetartiodactyla—Superfamily Odontoceti (toothed whales, dolphins, and porpoises)						
Family Delphinidae:						
Beluga whale	*Delphinapterus leucas*	Cook Inlet	E/D; Y	[5] 331 (0.076, 290, 2022)	0.53	0
Killer whale	*Orcinus orca*	Eastern North Pacific Alaska Resident.	-/-; N	1,920 (N/A, 1,920, 2019)	19	1.3
		Eastern North Pacific Gulf of Alaska, Aleutian Islands and Bering Sea Transient.	-/-; N	587 (N/A, 587, 2012)	5.9	0.8
Family Phocoenidae (porpoises):						
Harbor porpoise	*Phocoena phocoena*	Gulf of Alaska	-/-; Y	31,046 (0.214, N/A, 1998).	[6] UND	72
Order Carnivora—Superfamily Pinnipedia						
Family Otariidae (eared seals and sea lions):						
Steller sea lion	*Eumetopias jubatus*	Western	E/D; Y	52,932 (N/A, 52,932 2019).	318	255
Family Phocidae (earless seals):						
Harbor seal	*Phoca vitulina*	Cook Inlet/Shelikof Strait	-/-; N	28,411 (N/A, 26,907, 2018).	807	107

[1] Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

[2] NMFS marine mammal stock assessment reports online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments.* CV is coefficient of variation; Nmin is the minimum estimate of stock abundance. In some cases, CV is not applicable (N.A.).

[3] These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

[4] UNK means unknown.

[5] This abundance estimate is from Goetz *et al.* (2023).

[6] UND means undetermined.

On June 15, 2023, NMFS released an updated abundance estimate for endangered CIBWs in Alaska (Goetz *et al.,* 2023) that incorporates aerial survey data from June 2021 and 2022, but which is not included in the most recent SAR (Young *et al.,* 2023). Data collected during NMFS recent aerial survey effort suggest that the whale population is stable or may be increasing slightly. Goetz *et al.* (2023) estimated that the population size is currently between 290 and 386, with a median best estimate of 331. In accordance with the MMPA, this population estimate will be incorporated into the next draft CIBW SAR, which will be reviewed by an independent panel of experts, the Alaska Scientific Review Group. After this review, the SAR will be made available as a draft for public review before being finalized. We have determined that it is appropriate to consider the CIBW estimate of abundance reported by Goetz *et al.* (2023) in our analysis rather than the older estimate currently available from

the Alaska SAR (Young *et al.,* 2023) because it is based on the most recent and best available science.

As indicated above, all seven species (with nine managed stocks) in Table 4 temporally and spatially co-occur with the activity to the degree that take is reasonably likely to occur. Minke whales (*Balaenoptera acutorostrata*) and Dall's porpoises (*Phocoenoides dalli*) also occur in Cook Inlet; however, the spatial occurrence of these species is such that take is not expected to occur, and they are not discussed further beyond the explanation provided here. Data from the Alaska Marine Mammal Stranding Network database (NMFS, unpublished data) provide additional support for these determinations. From 2011 to 2020, only one minke whale and one Dall's porpoise were documented as stranded in the portion of Cook Inlet north of Point Possession. Both were dead upon discovery; it is unknown if they were alive upon their entry into upper Cook Inlet or drifted into the area with the tides. With very few exceptions, minke whales and Dall's porpoises do not occur in upper Cook Inlet, and therefore take of these species is considered unlikely.

In addition, sea otters (*Enhydra lutris*) may be found in Cook Inlet. However, sea otters are managed by the U.S. Fish and Wildlife Service (USFWS) and are not considered further in this document.

Gray Whale

The stock structure for gray whales in the Pacific has been studied for a number of years and remains uncertain as of the most recent (2022) Pacific SARs (Carretta *et al.,* 2023). Gray whale population structure is not determined by simple geography and may be in flux due to evolving migratory dynamics (Carretta *et al.,* 2023). Currently, the SARs delineate a western North Pacific (WNP) gray whale stock and an eastern North Pacific (ENP) stock based on genetic differentiation (Carretta *et al.,* 2023). WNP gray whales are not known to feed in or travel to upper Cook Inlet (Conant and Lohe, 2023; Weller *et al.,* 2023). Therefore, we assume that gray whales near the project area are members of the ENP stock.

An Unusual Mortality Event (UME) along the West Coast and in Alaska was declared for gray whales in January 2019 (NMFS, 2022a). Since 2019, 143 gray whales have stranded off the coast of Alaska. Preliminary findings for several of the whales indicate evidence of emaciation, but the UME is still under investigation, and the cause of the mortalities remains unknown (NMFS, 2022a; see *https://www.fisheries.noaa.gov/national/marine-life-distress/2019-2023-gray-whale-unusual-mortality-event-along-west-coast-and* for more information).

Gray whales are infrequent visitors to Cook Inlet, but can be seasonally present during spring and fall in the lower inlet (Bureau of Ocean Energy Management (BOEM), 2021). Migrating gray whales pass through the lower inlet during their spring and fall migrations to and from their primary summer feeding areas in the Bering, Chukchi, and Beaufort seas (Swartz, 2018; Silber *et al.,* 2021; BOEM, 2021).

Gray whales are rarely documented in upper Cook Inlet and in the project area. Gray whales were not documented during POA construction or scientific monitoring from 2005 to 2011 or during 2016 (Prevel-Ramos *et al.,* 2006; Markowitz and McGuire, 2007; Cornick and Saxon-Kendall, 2008, 2009; Cornick *et al.,* 2010, 2011; Integrated Concepts and Research Corporation (ICRC), 2009, 2010, 2011, 2012; Cornick and Pinney, 2011; Cornick and Seagars, 2016); however, one gray whale was observed near Port MacKenzie during 2020 PCT construction (61 North (61N) Environmental, 2021) and a second whale was observed off of Ship Creek during 2021 PCT construction monitoring (61N Environmental, 2022a, Easley-Appleyard and Leonard, 2022). The whale observed in 2020 is believed to be the same whale that later stranded in the Twentymile River, at the eastern end of Turnagain Arm, approximately 80 km southeast of Knik Arm. There was no indication that work at the PCT had any effect on the animal (see *https://www.fisheries.noaa.gov/feature-story/alaska-gray-whale-ume-update-twentymile-river-whale-likely-one-twelve-dead-gray-whales* for more information). No gray whales were observed during POA's transitional dredging or SFD construction monitoring from May to August, 2022 (61N Environmental, 2022b, 2022c).

Humpback Whale

On September 8, 2016, NMFS divided the humpback whales into 14 distinct population segments (DPS) under the ESA, removed the species-level listing as endangered, and, in its place, listed four DPSs as endangered and one DPS as threatened (81 FR 62259, September 8, 2016). The remaining nine DPSs were not listed. There are four DPSs in the North Pacific, including Western North Pacific and Central America, which are listed as endangered, Mexico, which is listed as threatened, and Hawaii, which is not listed.

The 2022 Alaska and Pacific SARs described a revised stock structure for humpback whales which modifies the previous stocks designated under the MMPA to align more closely with the ESA-designated DPSs (Carretta *et al.,* 2023; Young *et al.,* 2023). Specifically, the three previous North Pacific humpback whale stocks (Central and Western North Pacific stocks and a CA/OR/WA stock) were replaced by five stocks, largely corresponding with the ESA-designated DPSs. These include Western North Pacific and Hawaii stocks and a Central America/Southern Mexico-CA/OR/WA stock (which corresponds with the Central America DPS). The remaining two stocks, corresponding with the Mexico DPS, are the Mainland Mexico-CA/OR/WA and Mexico-North Pacific stocks (Carretta *et al.,* 2023; Young *et al.,* 2023). The former stock is expected to occur along the west coast from California to southern British Columbia, while the latter stock may occur across the Pacific, from northern British Columbia through the Gulf of Alaska and Aleutian Islands/Bering Sea region to Russia.

The Hawaii stock consists of one demographically independent population (DIP) (Hawaii—Southeast Alaska/Northern British Columbia DIP) and the Hawaii—North Pacific unit, which may or may not be composed of multiple DIPs (Wade *et al.,* 2021). The DIP and unit are managed as a single stock at this time, due to the lack of data available to separately assess them and lack of compelling conservation benefit to managing them separately (NMFS, 2019, 2022b, 2023). The DIP is delineated based on two strong lines of evidence: genetics and movement data (Wade *et al.,* 2021). Whales in the Hawaii—Southeast Alaska/Northern British Columbia DIP winter off Hawaii and largely summer in Southeast Alaska and Northern British Columbia (Wade *et al.,* 2021). The group of whales that migrate from Russia, western Alaska (Bering Sea and Aleutian Islands), and central Alaska (Gulf of Alaska excluding Southeast Alaska) to Hawaii have been delineated as the Hawaii-North Pacific unit (Wade *et al.,* 2021). There are a small number of whales that migrate between Hawaii and southern British Columbia/Washington, but current data and analyses do not provide a clear understanding of which unit these whales belong to (Wade *et al.,* 2021; Carretta *et al.,* 2023; Young *et al.,* 2023).

The Mexico-North Pacific stock is likely composed of multiple DIPs, based on movement data (Martien *et al.,* 2021; Wade, 2021; Wade *et al.,* 2021). However, because currently available data and analyses are not sufficient to delineate or assess DIPs within the unit, it was designated as a single stock (NMFS, 2019, 2022c, 2023). Whales in

this stock winter off Mexico and the Revillagigedo Archipelago and summer primarily in Alaska waters (Martien *et al.,* 2021; Carretta *et al.,* 2023; Young *et al.,* 2023).

The most comprehensive photo-identification data available suggest that approximately 89 percent of all humpback whales in the Gulf of Alaska are members of the Hawaii stock, 11 percent are from the Mexico stock, and less than 1 percent are from the Western North Pacific stock (Wade, 2021). Members of different stocks are known to intermix in feeding grounds.

On October 9, 2019, NMFS proposed to designate critical habitat for the Western North Pacific, Mexico, and Central America DPSs of humpback whales (84 FR 54354). NMFS issued a final rule on April 21, 2021 to designate critical habitat for ESA-listed humpback whales pursuant to Section 4 of the ESA (86 FR 21082). There is no designated critical habitat for humpback whales in or near the Project area (86 FR 21082, April 21, 2021).

Humpback whales are encountered regularly in lower Cook Inlet and occasionally in mid-Cook Inlet; however, sightings are rare in upper Cook Inlet (*e.g.,* Witteveen *et al.,* 2011). During aerial surveys conducted in summers between 2005 and 2012, Shelden *et al.* (2013) reported dozens of sightings in lower Cook Inlet, a handful of sightings in the vicinity of Anchor Point and in lower Cook Inlet, and no sightings north of 60° N latitude. NMFS changed to a biennial survey schedule starting in 2014 after analysis showed there would be little reduction in the ability to detect a trend given the current growth rate of the population (Hobbs, 2013). No survey took place in 2020. Instead, consecutive surveys took place in 2021 and 2022 (Shelden *et al.,* 2022). During the 2014–2022 aerial surveys, sightings of humpback whales were recorded in lower Cook Inlet and mid-Cook Inlet, but none were observed in upper Cook Inlet (Shelden *et al.,* 2015b, 2017, 2019, 2022). Vessel-based observers participating in the Apache Corporation's 2014 survey operations recorded three humpback whale sightings near Moose Point in upper Cook Inlet and two sightings near Anchor Point, while aerial and land-based observers recorded no humpback whale sightings, including in the upper inlet (Lomac-MacNair *et al.,* 2014). Observers monitoring waters between Point Campbell and Fire Island during summer and fall 2011 and spring and summer 2012 recorded no humpback whale sightings (Brueggeman *et al.,* 2013). Monitoring of Turnagain Arm during ice-free months between 2006 and 2014 yielded one humpback whale sighting (McGuire, unpublished data, cited in LGL Alaska Research Associates, Inc., and DOWL, 2015).

There have been few sightings of humpback whales in the vicinity of the proposed project area. Humpback whales were not documented during POA construction or scientific monitoring from 2005 to 2011, in 2016, or during 2020 (Prevel-Ramos *et al.,* 2006; Markowitz and McGuire, 2007; Cornick and Saxon-Kendall, 2008, 2009; Cornick *et al.,* 2010, 2011; ICRC, 2009, 2010, 2011, 2012; Cornick and Pinney, 2011; Cornick and Seagars, 2016; 61N Environmental, 2021). Observers monitoring the Ship Creek Small Boat Launch from August 23 to September 11, 2017 recorded two sightings, each of a single humpback whale, which was presumed to be the same individual (POA, 2017). One other humpback whale sighting has been recorded for the immediate vicinity of the project area. This event involved a stranded whale that was sighted near a number of locations in upper Cook Inlet before washing ashore at Kincaid Park in 2017; it is unclear as to whether the humpback whale was alive or deceased upon entering Cook Inlet waters. Another juvenile humpback stranded in Turnagain Arm in April 2019 near mile 86 of the Seward Highway. One additional humpback whale was observed in July during 2022 transitional dredging monitoring (61N Environmental, 2022c). No humpback whales were observed during the 2020 to 2021 PCT construction monitoring, the NMFS marine mammal monitoring, or the 2022 SFD construction monitoring from April to June (61N Environmental, 2021, 2022a, 2022b, 2022c; Easley-Appleyard and Leonard, 2022).

Beluga Whale

Five stocks of beluga whales are recognized in Alaska: the Beaufort Sea stock, eastern Chukchi Sea stock, eastern Bering Sea stock, Bristol Bay stock, and Cook Inlet stock (Young *et al.,* 2023). The Cook Inlet stock is geographically and genetically isolated from the other stocks (O'Corry-Crowe *et al.,* 1997; Laidre *et al.,* 2000) and resides year-round in Cook Inlet (Laidre *et al.,* 2000; Castellote *et al.,* 2020). Only the Cook Inlet stock (CIBWs) inhabits the proposed project area. CIBWs were designated as a DPS and listed as endangered under the ESA in October 2008 (73 FR 62919, October 10, 2008).

Shelden and Wade (2019) analyzed time-series CIBW abundance data from 2008 to 2018 and reported that the CIBW population was declining at an annual rate of 2.3 percent during this time. Goetz *et al.,* (2023) suggest that this decline could have been part of a natural oscillation in the population or possibly due to impacts of the unprecedented heatwave in the Gulf of Alaska during the same time period. The CIBW time-series abundance data were analyzed using a Bayesian statistical method to estimate group size for calculating CIBW abundance. This method produced an abundance estimate of 279 CIBWs, with a 95 percent probability range of 250 to 317 whales (Shelden and Wade, 2019).

In June 2023, NMFS released an updated abundance estimate for CIBWs in Alaska that incorporates aerial survey data from June 2021 and 2022 and accounted for visibility bias (*i.e.,* availability bias due to diving behavior; proximity bias due to individuals concealed by another individual in the video data; perception bias due to individuals not detected because of small image size in the video data; and individual observer bias in visual observer data) (Goetz *et al.,* 2023). This report estimated that CIBW abundance is between 290 and 386, with a median best estimate of 331. Goetz *et al.* (2023) also present an analysis of population trends for the most recent 10-year period (2012–2022). The addition of data from the 2021 and 2022 survey years in the analysis resulted in a 65.1 percent probability that the CIBW population is now increasing at 0.9 percent per year (95 percent prediction interval of −3 to 5.7 percent). This increase drops slightly to 0.2 percent per year (95 percent prediction interval of −1.8 to 2.6 percent) with a 60 percent probability that the CIBW population is increasing more than 1 percent per year when data from 2021, which had limited survey coverage due to poor weather, are excluded from the analysis. Median group size estimates in 2021 and 2022 were 34 and 15, respectively (Goetz *et al.,* 2023). For management purposes, NMFS has determined that the carrying capacity of Cook Inlet is 1,300 CIBWs (65 FR 34590, May 31, 2000) based on historical CIBW abundance estimated by Calkins (1989).

Live stranding events of CIBWs have been regularly observed in upper Cook Inlet. This can occur when an individual or group of individuals strands as the tide recedes. Most live strandings have occurred in Knik Arm and Turnagain Arm, which are shallow and have large tidal ranges, strong currents, and extensive mudflats. Most whales involved in a live stranding event survive, although some associated deaths may not be observed if the whales die later from live-stranding-

related injuries (Vos and Shelden, 2005; Burek-Huntington *et al.,* 2015). Between 2014 and 2018, there were reports of approximately 79 CIBWs involved in three known live stranding events, plus one suspected live stranding event with two associated deaths reported (NMFS, 2016b; NMFS, unpublished data; Muto *et al.,* 2020). In 2014, necropsy results from two whales found in Turnagain Arm suggested that a live stranding event contributed to their deaths as both had aspirated mud and water. No live stranding events were reported prior to the discovery of these dead whales, suggesting that not all live stranding events are observed.

Another source of CIBW mortality in Cook Inlet is predation by transient-type (mammal-eating) killer whales (NMFS, 2016b; Shelden *et al.,* 2003). No human-caused mortality or serious injury of CIBWs through interactions with commercial, recreational, and subsistence fisheries, takes by subsistence hunters, and or human-caused events (*e.g.,* entanglement in marine debris, ship strikes) has been recently documented and harvesting of CIBWs has not occurred since 2008 (NMFS, 2008b).

Recovery Plan. In 2010, a Recovery Team, consisting of a Science Panel and Stakeholder Panel, began meeting to develop a Recovery Plan for the CIBW. The Final Recovery Plan was published in the **Federal Register** on January 5, 2017 (82 FR 1325). In September 2022, NMFS completed the ESA 5-year review for the CIBW DPS and determined that the CIBW DPS should remain listed as endangered (NMFS, 2022d).

In its Recovery Plan (82 FR 1325, January 5, 2017), NMFS identified several potential threats to CIBWs, including: (1) high concern: catastrophic events (*e.g.,* natural disasters, spills, mass strandings), cumulative effects of multiple stressors, and noise; (2) medium concern: disease agents (*e.g.,* pathogens, parasites, and harmful algal blooms), habitat loss or degradation, reduction in prey, and unauthorized take; and (3) low concern: pollution, predation, and subsistence harvest. The recovery plan did not treat climate change as a distinct threat but rather as a consideration in the threats of high and medium concern. Other potential threats most likely to result in direct human-caused mortality or serious injury of this stock include vessel strikes.

Critical Habitat. On April 11, 2011, NMFS designated two areas of critical habitat for CIBW (76 FR 20179). The designation includes 7,800 km² of marine and estuarine habitat within Cook Inlet, encompassing approximately 1,909 km² in Area 1 and 5,891 km² in Area 2 (see Figure 1 in 76 FR 20179). Area 1 of the CIBW critical habitat encompasses all marine waters of Cook Inlet north of a line connecting Point Possession (lat. 61.04° N, long. 150.37° W) and the mouth of Three Mile Creek (lat. 61.08.55° N, long. 151.04.40° W), including waters of the Susitna, Little Susitna, and Chickaloon Rivers below mean higher high water. From spring through fall, Area 1 critical habitat has the highest concentration of CIBWs due to its important foraging and calving habitat. Area 2 critical habitat has a lower concentration of CIBWs in spring and summer but is used by CIBWs in fall and winter. Critical habitat does not include two areas of military usage: the Eagle River Flats Range on Fort Richardson and military lands of JBER between Mean Higher High Water and MHW. Additionally, the POA, adjacent navigation channel, and turning basin were excluded from critical habitat designation due to national security reasons (76 FR 20180, April 11, 2011). The POA exclusion area is within Area 1, however, marine mammal monitoring results from the POA suggest that this exclusion area is not a particularly important feeding or calving area. CIBWs have been occasionally documented to forage around Ship Creek (south of the POA) but are typically transiting through the area to other, potentially richer, foraging areas to the north (*e.g.,* Six Mile Creek, Eagle River, Eklutna River) (*e.g.,* 61N Environmental, 2021, 2022a, 2022b, 2022c, Easley-Appleyard and Leonard, 2022). These locations contain predictable salmon runs, an important food source for CIBWs, and the timing of these runs has been correlated with CIBW movements into the upper reaches of Knik Arm (Ezer *et al.,* 2013). More information on CIBW critical habitat can be found at *https://www.fisheries.noaa.gov/action/critical-habitat-cook-inlet-beluga-whale.*

The designation identified the following Primary Constituent Elements, essential features important to the conservation of the CIBW:

(1) Intertidal and subtidal waters of Cook Inlet with depths of less than 9 m (MLLW) and within 8 km of high- and medium-flow anadromous fish streams;

(2) Primary prey species, including four of the five species of Pacific salmon (chum (*Oncorhynchus keta*), sockeye (*Oncorhynchus nerka*), Chinook (*Oncorhynchus tshawytscha*), and coho (*Oncorhynchus kisutch*)), Pacific eulachon (*Thaleichthys pacificus*), Pacific cod (*Gadus macrocephalus*), walleye Pollock (*Gadus chalcogrammus*), saffron cod (*Eleginus gracilis*), and yellowfin sole (*Limanda aspera*);

(3) The absence of toxins or other agents of a type or amount harmful to CIBWs;

(4) Unrestricted passage within or between the critical habitat areas; and

(5) The absence of in-water noise at levels resulting in the abandonment of habitat by CIBWs.

Biologically Important Areas. Wild *et al.* (2023) delineated portions of Cook Inlet, including near the proposed project area, as a Biologically Important Area (BIA) for the small and resident population of CIBWs based on scoring methods outlined by Harrison *et al.* (2023) (see *https://oceannoise.noaa.gov/biologically-important-areas* for more information). The BIA is used year-round by CIBWs for feeding and breeding, and there are limits on food supply such as salmon runs and seasonal movement of other fish species (Wild *et al.,* 2023). The boundary of the CIBW BIA is consistent with NMFS' critical habitat designation, and does not include the aforementioned exclusion areas (*e.g.,* the POA and surrounding waters) (Wild *et al.,* 2023).

Foraging Ecology. CIBWs feed on a wide variety of prey species, particularly those that are seasonally abundant. From late spring through summer, most CIBW stomachs sampled contained salmon, which corresponded to the timing of fish runs in the area. Anadromous smolt and adult fish aggregate at river mouths and adjacent intertidal mudflats (Calkins, 1989). All five Pacific salmon species (*i.e.,* Chinook, pink (*Oncorhynchus gorbuscha*), coho, sockeye, and chum) spawn in rivers throughout Cook Inlet (Moulton, 1997; Moore *et al.,* 2000). Overall, Pacific salmon represent the highest percent frequency of occurrence of prey species in CIBW stomachs. This suggests that their spring feeding in upper Cook Inlet, principally on fat-rich fish such as salmon and eulachon, is important to the energetics of these animals (NMFS, 2016b).

The nutritional quality of Chinook salmon in particular is unparalleled, with an energy content four times greater than that of a Coho salmon. It is suggested the decline of the Chinook salmon population has left a nutritional void in the diet of the CIBWs that no other prey species can fill in terms of quality or quantity (Norman *et al.,* 2020, 2022).

In fall, as anadromous fish runs begin to decline, CIBWs return to consume fish species (cod and bottom fish) found in nearshore bays and estuaries. Stomach samples from CIBWs are not available for winter (December through

March), although dive data from CIBWs tagged with satellite transmitters suggest that they feed in deeper waters during winter (Hobbs *et al.,* 2005), possibly on such prey species as flatfish, cod, sculpin, and pollock.

Distribution in Cook Inlet. The CIBW stock remains within Cook Inlet throughout the year, showing only small seasonal shifts in distribution (Goetz *et al.,* 2012a; Lammers *et al.,* 2013; Castallotte *et al.,* 2015; Shelden *et al.,* 2015a, 2018; Lowery *et al.,* 2019). During spring and summer, CIBWs generally aggregate near the warmer waters of river mouths where prey availability is high and predator occurrence is low (Moore *et al.,* 2000; Shelden and Wade, 2019; McGuire *et al.,* 2020). In particular, CIBW groups are seen in the Susitna River Delta, the Beluga River and along the shore to the Little Susitna River, Knik Arm, and along the shores of Chickaloon Bay. Small groups were recorded farther south in Kachemak Bay, Redoubt Bay (Big River), and Trading Bay (McArthur River) prior to 1996, but rarely thereafter. Since the mid-1990s, most CIBWs (96 to 100 percent) aggregate in shallow areas near river mouths in upper Cook Inlet, and they are only occasionally sighted in the central or southern portions of Cook Inlet during summer (Hobbs *et al.,* 2008). Almost the entire population can be found in northern Cook Inlet from late spring through the summer and into the fall (Muto *et al.,* 2020).

Data from tagged whales (14 tags deployed July 2000 through March 2003) show that CIBWs use upper Cook Inlet intensively between summer and late autumn (Hobbs *et al.,* 2005). CIBWs tagged with satellite transmitters continue to use Knik Arm, Turnagain Arm, and Chickaloon Bay as late as October, but some range into lower Cook Inlet to Chinitna Bay, Tuxedni Bay, and Trading Bay (McArthur River) in fall (Hobbs *et al.,* 2005, 2012). From September through November, CIBWs move between Knik Arm, Turnagain Arm, and Chickaloon Bay (Hobbs *et al.,* 2005; Goetz *et al.,* 2012b). By December, CIBWs are distributed throughout the upper to mid-inlet. From January into March, they move as far south as Kalgin Island and slightly beyond in central offshore waters. CIBWs make occasional excursions into Knik Arm and Turnagain Arm in February and March in spite of ice cover (Hobbs *et al.,* 2005). Although tagged CIBWs move widely around Cook Inlet throughout the year, there is no indication of seasonal migration in and out of Cook Inlet (Hobbs *et al.,* 2005). Data from NMFS aerial surveys, opportunistic sighting reports, and corrected satellite-tagged CIBWs confirm that they are more widely dispersed throughout Cook Inlet during winter (November–April), with animals found between Kalgin Island and Point Possession. Generally fewer observations of CIBWs are reported from the Anchorage and Knik Arm area from November through April (76 FR 20179, April 11, 2011; Rugh *et al.,* 2000, 2004).

The NMFS Marine Mammal Lab has conducted long-term passive acoustic monitoring demonstrating seasonal shifts in CIBW concentrations throughout Cook Inlet. Castellote *et al.* (2015) conducted long-term acoustic monitoring at 13 locations throughout Cook Inlet between 2008 and 2015: North Eagle Bay, Eagle River Mouth, South Eagle Bay, Six Mile, Point MacKenzie, Cairn Point, Fire Island, Little Susitna, Beluga River, Trading Bay, Kenai River, Tuxedni Bay, and Homer Spit; the former six stations being located within Knik Arm. In general, the observed seasonal distribution is in accordance with descriptions based on aerial surveys and satellite telemetry: CIBW detections are higher in the upper inlet during summer, peaking at Little Susitna, Beluga River, and Eagle Bay, followed by fewer detections at those locations during winter. Higher detections in winter at Trading Bay, Kenai River, and Tuxedni Bay suggest a broader CIBW distribution in the lower inlet during winter.

Goetz *et al.* (2012b) modeled habitat preferences using NMFS' 1994–2008 June abundance survey data. In large areas, such as the Susitna Delta (Beluga to Little Susitna Rivers) and Knik Arm, there was a high probability that CIBWs were in larger groups. CIBW presence and acoustic foraging behavior also increased closer to rivers with Chinook salmon runs, such as the Susitna River (*e.g.,* Castellote *et al.,* 2021). Movement has been correlated with the peak discharge of seven major rivers emptying into Cook Inlet. Boat-based surveys from 2005 to the present (McGuire and Stephens, 2017) and results from passive acoustic monitoring across the entire inlet (Castellote *et al.,* 2015) also support seasonal patterns observed with other methods. Based on long-term passive acoustic monitoring, seasonally, foraging behavior was more prevalent during summer, particularly at upper inlet rivers, than during winter. Foraging index was highest at Little Susitna, with a peak in July-August and a secondary peak in May, followed by Beluga River and then Eagle Bay; monthly variation in the foraging index indicates CIBWs shift their foraging behavior among these three locations from April through September.

CIBWs are believed to mostly calve in the summer, and concurrently breed between late spring and early summer (NMFS, 2016b), primarily in upper Cook Inlet. The only known observed occurrence of calving occurred on July 20, 2015, in the Susitna Delta area (T. McGuire, personal communication, March 27, 2017). The first neonates encountered during each field season from 2005 through 2015 were always seen in the Susitna River Delta in July. The photographic identification team's documentation of the dates of the first neonate of each year indicate that calving begins in mid-late July/early August, generally coinciding with the observed timing of annual maximum group size. Probable mating behavior of CIBWs was observed in April and May of 2014, in Trading Bay. Young CIBWs are nursed for 2 years and may continue to associate with their mothers for a considerable time thereafter (Colbeck *et al.,* 2013). Important calving grounds are thought to be located near the river mouths of upper Cook Inlet.

Presence in Project Area. Knik Arm is one of three areas in upper Cook Inlet where CIBWs are concentrated during spring, summer, and early fall. Most CIBWs observed in or near the POA are transiting between upper Knik Arm and other portions of Cook Inlet, and the POA itself is not considered high-quality foraging habitat. CIBWs tend to follow their anadromous prey and travel in and out of Knik Arm with the tides. The predictive habitat model derived by Goetz *et al.* (2012a) indicated that CIBW density ranges from 0 to 1.12 whales per km^2 in Cook Inlet. The highest predicted densities of CIBWs are in Knik Arm, near the mouth of the Susitna River, and in Chickaloon Bay. The model suggests that the density of CIBWs at the mouth of Knik Arm, near the POA, ranges between approximately 0.013 and 0.062 whales per km^2. The distribution presented by Goetz *et al.* (2012a) is generally consistent with CIBW distribution documented in upper Cook Inlet throughout ice-free months (NMFS, 2016b).

Several marine mammal monitoring programs and studies have been conducted at or near the POA during the last 17 years. These studies offer some of the best available information on the presence of CIBWs in the proposed project area. Studies that occurred prior to 2020 are summarized in Section 4.5.5 of the POA's application. More recent programs, which most accurately portray current information regarding CIBW presence in the proposed project area, are summarized here.

PCT Construction Monitoring (2020–2021). A marine mammal monitoring program was implemented during construction of the PCT in 2020 (Phase 1) and 2021 (Phase 2), as required by the NMFS IHAs (85 FR 19294, April 6, 2020). PCT Phase 1 construction included impact installation of 48-inch (122-cm) attenuated piles; impact installation of 36-inch (91-cm) and 48-inch (122-cm) unattenuated piles; vibratory installation of 24-inch (61-cm), 36-inch (91-cm), and 48-inch (122 cm) attenuated and unattenuated piles; and vibratory installation of an unattenuated 72-inch (183-cm) bubble curtain across 95 days. PCT Phase 2 construction included vibratory installation of 36-inch (91-cm) attenuated piles and impact and vibratory installation of 144-inch (366-cm) attenuated breasting and mooring dolphins across 38 days. Marine mammal monitoring in 2020 occurred during 128 non-consecutive days, with a total of 1,238.7 hours of monitoring from April 27 to November 24, 2020 (61N Environmental, 2021). Marine mammal monitoring in 2021 occurred during 74 non-consecutive days, with a total of 734.9 hours of monitoring from April 26 to June 24 and September 7 to 29, 2021 (61N Environmental, 2022a). A total of 1,504 individual CIBWs across 377 groups were sighted during PCT construction monitoring. Sixty-five and sixty-seven percent of CIBW observations occurred on non-pile driving days or before pile driving occurred on a given day during PCT Phase 1 and PCT Phase 2 construction, respectively.

The monitoring effort and data collection were conducted before, during, and after pile driving activities from four locations as stipulated by the PCT IHAs (85 FR 19294, April 6, 2020): (1) the Anchorage Public Boat Dock by Ship Creek, (2) the Anchorage Downtown Viewpoint near Point Woronzof, (3) the PCT construction site, and (4) the North End (North Extension) at the north end of the POA, near Cairn Point. Marine mammal sighting data from April to September both before, during, and after pile driving indicate that CIBWs swam near the POA and lingered there for periods of time ranging from a few minutes to a few hours. CIBWs were most often seen traveling at a slow or moderate pace, either from the north near Cairn Point or from the south or milling at the mouth of Ship Creek. Groups of CIBWs were also observed swimming north and south in front of the PCT construction, and did not appear to exhibit avoidance behaviors either before, during, or after pile driving activities (61N Environmental, 2021, 2022a). CIBW sightings in June were concentrated on the west side of Knik Arm from the Little Susitna River Delta to Port MacKenzie. From July through September, CIBWs were most often seen milling and traveling on the east side of Knik Arm from Point Woronzof to Cairn Point (61N Environmental, 2021, 2022a).

SFD Construction Monitoring and Transitional Dredging (2022). In 2022, a marine mammal monitoring program almost identical to that used during PCT construction was implemented during construction of the SFD, as required by the NMFS IHA (86 FR 50057, September 7, 2021). SFD construction included the vibratory installation of ten 36-inch (91-cm) attenuated plumb piles and two unattenuated battered piles (61N Environmental, 2022b). Marine mammal monitoring was conducted during 13 non-consecutive days, with a total of 108.2 hours of monitoring observation from May 20 through June 11, 2022 (61N Environmental, 2022b). Forty-one individual CIBWs across 9 groups were sighted (61N Environmental, 2022b). One group was observed on a day with no pile-driving, three groups were seen on days before pile driving activities started, and five groups were seen during vibratory pile driving activities (61N Environmental, 2022b).

During SFD construction, the position of the Ship Creek monitoring station was adjusted to allow monitoring of a portion of the shoreline north of Cairn Point that could not be seen by the station at the northern end of the POA (61N Environmental, 2022b). Eleven protected species observers (PSOs) worked from four monitoring stations located along a 9-km (6-mi) stretch of coastline surrounding the POA. The monitoring effort and data collection were conducted at the following four locations: (1) Point Woronzof approximately 6.5 km (4 mi) southwest of the SFD, (2) the promontory near the boat launch at Ship Creek, (3) the SFD project site, and (4) the northern end of the POA (61N Environmental, 2022b).

Ninety groups comprised of 529 CIBWs were also sighted during the transitional dredging monitoring that occurred from May 3 to 15, 2022 and June 27 to August 24, 2022 (61N Environmental, 2022b). Of the nine groups of CIBWs sighted during SFD construction, traveling was recorded as the primary behavior for each group (61N Environmental, 2022b). CIBWs traveled and milled between the SFD construction area, Ship Creek, and areas to the south of the POA for more than an hour at a time, delaying some construction activities.

Killer Whale

Along the west coast of North America, seasonal and year-round occurrence of killer whales has been noted along the entire Alaska coast (Braham and Dahlheim, 1982), in British Columbia and Washington inland waterways (Bigg *et al.,* 1990), and along the outer coasts of Washington, Oregon, and California (Green *et al.,* 1992; Barlow 1995, 1997; Forney *et al.,* 1995). Killer whales from these areas have been labeled as ''resident,'' ''transient,'' and ''offshore'' type killer whales (Bigg *et al.,* 1990; Ford *et al.,* 2000; Dahlheim *et al.,* 2008) based on aspects of morphology, ecology, genetics, and behavior (Ford and Fisher, 1982; Baird and Stacey, 1988; Baird *et al.,* 1992; Hoelzel *et al.,* 1998, 2002; Barrett Lennard, 2000; Dahlheim *et al.,* 2008). Based on data regarding association patterns, acoustics, movements, and genetic differences, eight killer whale stocks are now recognized within the U.S. Pacific, two of which have the potential to be found in the proposed project area: the Eastern North Pacific Alaska Resident stock and the Gulf of Alaska, Aleutian Islands, and the Bering Sea Transient stock. Both stocks overlap the same geographic area; however, they maintain social and reproductive isolation and feed on different prey species. Resident killer whales are primarily fish-eaters, while transients primarily hunt and consume marine mammals, such as harbor seals, Dall's porpoises, harbor porpoises, beluga whales and sea lions. Killer whales are not harvested for subsistence in Alaska. Potential threats most likely to result in direct human-caused mortality or serious injury of killer whales in this region include oil spills, vessel strikes, and interactions with fisheries.

Killer whales are rare in Cook Inlet, and most individuals are observed in lower Cook Inlet (Shelden *et al.,* 2013). The infrequent sightings of killer whales that are reported in upper Cook Inlet tend to occur when their primary prey (anadromous fish for resident killer whales and beluga whales for transient killer whales) are also in the area (Shelden *et al.,* 2003). During CIBW aerial surveys between 1993 and 2012, killer whales were sighted in lower Cook Inlet 17 times, with a total of 70 animals (Shelden *et al.,* 2013); no killer whales were observed in upper Cook Inlet during this time. Surveys over 20 years by Shelden *et al.* (2003) documented an increase in CIBW sightings and strandings in upper Cook Inlet beginning in the early 1990s. Several of these sightings and strandings reported evidence of killer whale

predation on CIBWs. The pod sizes of killer whales preying on CIBWs ranged from one to six individuals (Shelden *et al.,* 2003). Passive acoustic monitoring efforts throughout Cook Inlet documented killer whales at the Beluga River, Kenai River, and Homer Spit, although they were not encountered within Knik Arm (Castellote *et al.,* 2016). These detections were likely resident killer whales. Transient killer whales likely have not been acoustically detected due to their propensity to move quietly through waters to track prey (Small, 2010; Lammers *et al.,* 2013).

Few killer whales, if any, are expected to approach or be in the vicinity of the proposed project area. No killer whales were spotted in the vicinity of the POA during surveys by Funk *et al.* (2005), Ireland *et al.* (2005), or Brueggeman *et al.* (2007, 2008a, 2008b). Killer whales have also not been documented during any POA construction or scientific monitoring from 2005 to 2011, in 2016, or in 2020 (Prevel-Ramos *et al.,* 2006; Markowitz and McGuire, 2007; Cornick and Saxon-Kendall, 2008; ICRC, 2009, 2010, 2011, 2012; Cornick *et al.,* 2010, 2011; Cornick and Pinney, 2011; Cornick and Seagars, 2016; 61N Environmental, 2021). Two killer whales, one male and one juvenile of unknown sex, were sighted offshore of Point Woronzof in September 2021 during PCT Phase 2 construction monitoring (61N Environmental, 2022a). The pair of killer whales moved up Knik Arm, reversed direction near Cairn Point, and moved southwest out of Knik Arm toward the open water of Upper Cook Inlet. No killer whales were sighted during the 2021 NMFS marine mammal monitoring or the 2022 transitional dredging and SFD construction monitoring that occurred between May and June 2022 (61N Environmental, 2022b, 2022c; Easley-Appleyard and Leonard, 2022).

Harbor Porpoise

In the eastern North Pacific Ocean, harbor porpoise range from Point Barrow, along the Alaska coast, and down the west coast of North America to Point Conception, California. The 2022 Alaska SARs describe a revised stock structure for harbor porpoises (Young *et al.,* 2023). Previously, NMFS had designated three stocks of harbor porpoises: the Bering Sea stock, the Gulf of Alaska stock, and the Southeast Alaska stock (Muto *et al.,* 2022; Zerbini *et al.,* 2022). The 2022 Alaska SARs splits the Southeast Alaska stock into three separate stocks, resulting in five separate stocks in Alaskan waters for this species. This update better aligns harbor porpoise stock structure with genetics, trends in abundance, and information regarding discontinuous distribution trends (Young *et al.,* 2023). Harbor porpoises found in Cook Inlet are assumed to be members of the Gulf of Alaska stock (Young *et al.,* 2023).

Harbor porpoises occur most frequently in waters less than 100 m deep (Hobbs and Waite, 2010). They can be opportunistic foragers but consume primarily schooling forage fish (Bowen and Siniff, 1999). Given their shallow water distribution, harbor porpoise are vulnerable to physical modifications of nearshore habitats resulting from urban and industrial development (including waste management and nonpoint source runoff) and activities such as construction of docks and other over-water structures, filling of shallow areas, dredging, and noise (Linnenschmidt *et al.,* 2013). Subsistence users have not reported any harvest from the Gulf of Alaska harbor porpoise stock since the early 1900s (Shelden *et al.,* 2014). Calving occurs from May to August; however, this can vary by region. Harbor porpoises are often found traveling alone, or in small groups of less than 10 individuals (Schmale, 2008).

Harbor porpoises occur throughout Cook Inlet, with passive acoustic detections being more prevalent in lower Cook Inlet. Although harbor porpoises have been frequently observed during aerial surveys in Cook Inlet (Shelden *et al.,* 2014), most sightings are of single animals and are concentrated at Chinitna and Tuxedni bays on the west side of lower Cook Inlet (Rugh *et al.,* 2005). The occurrence of larger numbers of porpoise in the lower Cook Inlet may be driven by greater availability of preferred prey and possibly less competition with CIBWs, as CIBWs move into upper inlet waters to forage on Pacific salmon during the summer months (Shelden *et al.,* 2014).

An increase in harbor porpoise sightings in upper Cook Inlet was observed over recent decades (*e.g.,* 61N Environmental, 2021, 2022a; Shelden *et al.,* 2014). Small numbers of harbor porpoises have been consistently reported in upper Cook Inlet between April and October (Prevel-Ramos *et al.,* 2008). The overall increase in the number of harbor porpoise sightings in upper Cook Inlet is unknown, although it may be an artifact from increased studies and marine mammal monitoring programs in upper Cook Inlet. It is also possible that the contraction in the CIBW's range has opened up previously occupied CIBW range to harbor porpoises (Shelden *et al.,* 2014).

Harbor porpoises have been observed within Knik Arm during monitoring efforts from 2005 to 2016. Between April 27 and November 24, 2020, 18 harbor porpoises were observed near the POA during the PCT Phase 1 construction monitoring (61N Environmental, 2021). Twenty-seven harbor porpoises were observed near the POA during the PCT Phase 2 construction monitoring conducted between April 26 and September 29, 2021 (61N Environmental, 2022a). During NMFS marine mammal monitoring conducted in 2021, one harbor porpoise was observed in August and six harbor porpoises were observed in October (Easley-Appleyard and Leonard, 2022). During 2022, five harbor porpoises were sighted during transitional dredging monitoring (61N Environmental, 2022c). No harbor porpoises were sighted at the POA during the 2022 SFD construction monitoring that occurred between May and June 2022 (61N Environmental, 2022b).

Steller Sea Lion

Two Distinct Population Segments (DPSs) of Steller sea lion occur in Alaska: the western DPS and the eastern DPS. The western DPS includes animals that occur west of Cape Suckling, Alaska, and therefore includes individuals within the Project area. The western DPS was listed under the ESA as threatened in 1990 (55 FR 49204, November 26, 1990), and its continued population decline resulted in a change in listing status to endangered in 1997 (62 FR 24345, May 5, 1997). Since 2000, studies indicate that the population east of Samalga Pass (*i.e.,* east of the Aleutian Islands) has increased and is potentially stable (Young *et al.,* 2023).

There is uncertainty regarding threats currently impeding the recovery of Steller sea lions, particularly in the Aleutian Islands. Many factors have been suggested as causes of the steep decline in abundance of western Steller sea lions observed in the 1980s, including competitive effects of fishing, environmental change, disease, contaminants, killer whale predation, incidental take, and illegal and legal shooting (Atkinson *et al.,* 2008; NMFS, 2008a). A number of management actions have been implemented since 1990 to promote the recovery of the Western U.S. stock of Steller sea lions, including 5.6-km (3-nautical mile) no-entry zones around rookeries, prohibition of shooting at or near sea lions, and regulation of fisheries for sea lion prey species (*e.g.,* walleye pollock, Pacific cod, and Atka mackerel (*Pleurogrammus monopterygius*)) (Sinclair *et al.,* 2013; Tollit *et al.,* 2017). Additionally, potentially deleterious events, such as harmful algal blooms

(Lefebvre *et al.,* 2016) and disease transmission across the Arctic (VanWormer *et al.,* 2019) that have been associated with warming waters, could lead to potentially negative population-level impacts on Steller sea lions.

NMFS designated critical habitat for Steller sea lions on August 27, 1993 (58 FR 45269). The critical habitat designation for the Western DPS of was determined to include a 37-km (20-nautical mile) buffer around all major haul-outs and rookeries, and associated terrestrial, atmospheric, and aquatic zones, plus three large offshore foraging areas, none of which occurs in the project area.

Steller sea lions are opportunistic predators, feeding primarily on a wide variety of seasonally abundant fishes and cephalopods, including Pacific herring (*Clupea pallasi*), walleye pollock, capelin (*Mallotus villosus*), Pacific sand lance (*Ammodytes hexapterus*), Pacific cod, salmon (*Oncorhynchus spp.*), and squid (*Teuthida spp.*); (Jefferson *et al.,* 2008; Wynne *et al.,* 2011). Steller sea lions do not generally eat every day, but tend to forage every 1–2 days and return to haulouts to rest between foraging trips (Merrick and Loughlin, 1997; Rehberg *et al.,* 2009). Steller sea lions feed largely on walleye pollock, salmon, and arrowtooth flounder during the summer, and walleye pollock and Pacific cod during the winter (Sinclair and Zeppelin, 2002). Except for salmon, none of these are found in abundance in upper Cook Inlet (Nemeth *et al.,* 2007).

Within Cook Inlet, Steller sea lions primarily inhabit lower Cook Inlet. However, they occasionally venture to upper Cook Inlet and Knik Arm and may be attracted to salmon runs in the region. Steller sea lions have not been documented in upper Cook Inlet during CIBW aerial surveys conducted annually in June from 1994 through 2012 and in 2014 (Shelden *et al.,* 2013, 2015b, 2017; Shelden and Wade, 2019); however, there has been an increase in individual Steller sea lion sightings near the POA in recent years.

Steller sea lions were observed near the POA in 2009, 2016, and 2019 through 2022 (ICRC, 2009; Cornick and Seagars, 2016; POA, 2019; 61N Environmental, 2021, 2022a, 2022b, 2022c). In 2009, there were three Steller sea lion sightings that were believed to be the same individual (ICRC, 2009). In 2016, Steller sea lions were observed on 2 separate days. On May 2, 2016, one individual was sighted, while on May 25, 2016, there were five Steller Sea lion sightings within a 50-minute period, and these sightings occurred in areas relatively close to one another (Cornick and Seagars, 2016). Given the proximity in time and space, it is believed these five sightings were of the same individual sea lion. In 2019, one Steller sea lion was observed in June at the POA during transitional dredging (POA, 2019). There were six sightings of individual Steller sea lions near the POA during PCT Phase 1 construction monitoring (61N Environmental, 2021). At least two of these sightings may have been re-sights on the same individual. An additional seven unidentified pinnipeds were observed that could have been Steller sea lions or harbor seals (61N Environmental, 2021). In 2021, there were a total of eight sightings of individual Steller sea lions observed near the POA during PCT Phase 2 construction monitoring (61N Environmental, 2022a). During NMFS marine mammal monitoring, one Steller sea lion was observed in August 2021 in the middle of the inlet (Easley-Appleyard and Leonard, 2022). In 2022, there were three Steller sea lion sightings during the transitional dredging monitoring and three during SFD construction monitoring (61N Environmental, 2022b, 2022c). All sightings occurred during summer, when the sea lions were likely attracted to ongoing salmon runs. Sea lion observations near the POA may be increasing due to more consistent observation effort or due to increased presence; observations continue to be occasional.

Harbor Seal

Harbor seals inhabit waters all along the western coast of the United States, British Columbia, and north through Alaska waters to the Pribilof Islands and Cape Newenham. NMFS currently identifies 12 stocks of harbor seals in Alaska based largely on genetic structure (Young *et al.,* 2023). Harbor seals in the proposed project area are members of the Cook Inlet/Shelikof stock, which ranges from the southwest tip of Unimak Island east along the southern coast of the Alaska Peninsula to Elizabeth Island off the southwest tip of the Kenai Peninsula, including Cook Inlet, Knik Arm, and Turnagain Arm. Distribution of the Cook Inlet/Shelikof stock extends from Unimak Island, in the Aleutian Islands archipelago, north through all of upper and lower Cook Inlet (Young *et al.,* 2023).

Harbor seals forage in marine, estuarine, and occasionally freshwater habitat. They are opportunistic feeders that adjust their local distribution to take advantage of locally and seasonally abundant prey (Baird, 2001; Bjørge, 2002). In Cook Inlet, harbor seals have been documented in higher concentrations near steelhead (*Oncorhynchus mykiss*), Chinook, and salmon spawning streams during summer and may target more offshore prey species during winter (Boveng *et al.,* 2012).

Harbor seals haul out on rocks, reefs, beaches, and drifting glacial ice (Young *et al.,* 2023). Their movements are influenced by tides, weather, season, food availability, and reproduction, as well as individual sex and age class (Lowry *et al.,* 2001; Small *et al.,* 2003; Boveng *et al.,* 2012). The results of past and recent satellite tagging studies in Southeast Alaska, Prince William Sound, Kodiak Island, and Cook Inlet are also consistent with the conclusion that harbor seals are non-migratory (Lowry *et al.,* 2001; Small *et al.,* 2003; Boveng *et al.,* 2012). However, some long-distance movements of tagged animals in Alaska have been recorded (Pitcher and McAllister, 1981; Lowry *et al.,* 2001; Small *et al.,* 2003; Womble, 2012; Womble and Gende, 2013). Strong fidelity of individuals for haul-out sites during the breeding season has been documented in several populations (Härkönen and Harding, 2001), including some regions in Alaska such as Kodiak Island, Prince William Sound, Glacier Bay/Icy Strait, and Cook Inlet (Pitcher and McAllister, 1981; Small *et al.,* 2005; Boveng *et al.,* 2012; Womble, 2012; Womble and Gende, 2013). Harbor seals usually give birth to a single pup between May and mid-July; birthing locations are dispersed over several haulout sites and not confined to major rookeries (Klinkhart *et al.,* 2008).

Harbor seals inhabit the coastal and estuarine waters of Cook Inlet and are observed in both upper and lower Cook Inlet throughout most of the year (Boveng *et al.,* 2012; Shelden *et al.,* 2013). Recent research on satellite-tagged harbor seals observed several movement patterns within Cook Inlet (Boveng *et al.,* 2012), including a strong seasonal pattern of more coastal and restricted spatial use during the spring and summer (breeding, pupping, molting) and more wide-ranging movements within and outside of Cook Inlet during the winter months, with some seals ranging as far as Shumagin Islands. During summer months, movements and distribution were mostly confined to the west side of Cook Inlet and Kachemak Bay, and seals captured in lower Cook Inlet generally exhibited site fidelity by remaining south of the Forelands in lower Cook Inlet after release (Boveng *et al.,* 2012). In the fall, a portion of the harbor seals appeared to move out of Cook Inlet and into Shelikof Strait, northern Kodiak Island, and coastal habitats of the

Alaska Peninsula. The western coast of Cook Inlet had higher usage by harbor seals than eastern coast habitats, and seals captured in lower Cook Inlet generally exhibited site fidelity by remaining south of the Forelands in lower Cook Inlet after release (south of Nikiski; Boveng *et al.,* 2012).

The presence of harbor seals in upper Cook Inlet is seasonal. Harbor seals are commonly observed along the Susitna River and other tributaries within upper Cook Inlet during eulachon and salmon migrations (NMFS, 2003). The major haulout sites for harbor seals are in lower Cook Inlet; however, there are a few haulout sites in upper Cook Inlet, including near the Little and Big Susitna rivers, Beluga River, Theodore River, and Ivan River (Barbara Mahoney, personal communication, November 16, 2020; Montgomery *et al.,* 2007). During CIBW aerial surveys of upper Cook Inlet from 1993 to 2012, harbor seals were observed 24 to 96 km south-southwest of Anchorage at the Chickaloon, Little Susitna, Susitna, Ivan, McArthur, and Beluga rivers (Shelden *et al.,* 2013). Harbor seals have been observed in Knik Arm and in the vicinity of the POA (Shelden *et al.,* 2013), but they are not known to haul out within the proposed project area.

Harbor seals were observed during construction monitoring at the POA from 2005 through 2011 and in 2016 (Prevel-Ramos *et al.,* 2006; Markowitz and McGuire, 2007; Cornick and Saxon-Kendall, 2008, 2009; Cornick *et al.,* 2010, 2011). Harbor seals were observed in groups of one to seven individuals (Cornick *et al.,* 2011; Cornick and Seagars, 2016). Harbor seals were also observed near the POA during construction monitoring for PCT Phase 1 in 2020 and PCT Phase 2 in 2021, NMFS marine mammal monitoring in 2021, and transitional dredging monitoring and SFD construction monitoring in 2022 (61N Environmental, 2021, 2022a, 2022b, 2022c, Easley-Appleyard and Leonard, 2022). During the 2020 PCT Phase 1 and 2021 PCT Phase 2 construction monitoring, harbor seals were regularly observed in the vicinity of the POA with frequent observations near the mouth of Ship Creek, located approximately 2,500 m southeast of the NES1 location. Harbor seals were observed almost daily during 2020 PCT Phase 1 construction, with 54 individuals documented in July, 66 documented in August, and 44 sighted in September (61N Environmental, 2021). During the 2021 PCT Phase 2 construction, harbor seals were observed with the highest numbers of sightings in June (87 individuals) and in September (124 individuals) (61 N Environmental, 2022a). Over the 13 days of SFD construction monitoring in May and June 2022, 27 harbor seals were observed (61N Environmental, 2022b). Seventy-two groups of 75 total harbor seals (3 groups of 2 individuals) were observed during transitional dredging monitoring in 2022 (61N Environmental, 2022c). Sighting rates of harbor seals have been highly variable and may have increased since 2005. It is unknown whether any potential increase was due to local population increases or habituation to ongoing construction activities. It is possible that increased sighting rates are correlated with more intensive monitoring efforts in 2020 and 2021, when the POA used 11 PSOs spread among four monitoring stations.

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Not all marine mammal species have equal hearing capabilities (*e.g.,* Richardson *et al.,* 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007, 2019) recommended that marine mammals be divided into hearing groups based on directly measured (behavioral or auditory evoked potential techniques) or estimated hearing ranges (behavioral response data, anatomical modeling, *etc.*). Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.,* low-frequency cetaceans). Subsequently, NMFS (2018) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65-decibel (dB) threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. Marine mammal hearing groups and their associated hearing ranges are provided in Table 5. Specific to this action, gray whales and humpback whales are considered low-frequency (LF) cetaceans, beluga whales and killer whales are considered mid-frequency (MF) cetaceans, harbor porpoises are considered high-frequency (HF) cetaceans, Steller sea lions are otariid pinnipeds, and harbor seals are phocid pinnipeds.

TABLE 5—MARINE MAMMAL HEARING GROUPS

[NMFS, 2018]

Hearing group	Generalized hearing range *
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 35 kHz.
Mid-frequency (MF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
High-frequency (HF) cetaceans (true porpoises, *Kogia,* river dolphins, Cephalorhynchid, *Lagenorhynchus cruciger* & *L. australis*).	275 Hz to 160 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	50 Hz to 86 kHz.
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 39 kHz.

* Represents the generalized hearing range for the entire group as a composite (*i.e.,* all species within the group), where individual species' hearing ranges are typically not as broad. Generalized hearing range chosen based on ~65-dB threshold from normalized composite audiogram, with the exception for lower limits for LF cetaceans (Southall *et al.,* 2007) and PW pinniped (approximation).

The pinniped functional hearing group was modified from Southall *et al.* (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.,* 2006; Kastelein *et al.,* 2009; Reichmuth and Holt, 2013). This division between phocid and otariid pinnipeds is now reflected in the updated hearing groups proposed in Southall *et al.* (2019).

For more detail concerning these groups and associated frequency ranges,

please see NMFS (2018) for a review of available information.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

This section provides a discussion of the ways in which components of the specified activity may impact marine mammals and their habitat. The Estimated Take of Marine Mammals section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The Negligible Impact Analysis and Determination section considers the content of this section, the Estimated Take section, and the Proposed Mitigation section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and whether those impacts are reasonably expected to, or reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

Acoustic effects on marine mammals during the specified activity are expected to potentially occur from vibratory pile installation and removal, and impact pile removal. The effects of underwater noise from the POA's proposed activities have the potential to result in Level B harassment of marine mammals in the action area and, for some species as a result of certain activities, Level A harassment.

Background on Sound

This section contains a brief technical background on sound, on the characteristics of certain sound types, and on metrics used relevant to the specified activity and to a discussion of the potential effects of the specified activity on marine mammals found later in this document. For general information on sound and its interaction with the marine environment, please see: Erbe and Thomas (2022); Au and Hastings (2008); Richardson *et al.* (1995); Urick (1983); as well as the Discovery of Sound in the Sea website at *https://dosits.org/.*

Sound is a vibration that travels as an acoustic wave through a medium such as a gas, liquid or solid. Sound waves alternately compress and decompress the medium as the wave travels. In water, sound waves radiate in a manner similar to ripples on the surface of a pond and may be either directed in a beam (narrow beam or directional sources) or sound may radiate in all directions (omnidirectional sources), as is the case for sound produced by the construction activities considered here. The compressions and decompressions associated with sound waves are detected as changes in pressure by marine mammals and human-made sound receptors such as hydrophones.

Sound travels more efficiently in water than almost any other form of energy, making the use of sound as a primary sensory modality ideal for inhabitants of the aquatic environment. In seawater, sound travels at roughly 1,500 meters per second (m/s). In air, sound waves travel much more slowly at about 340 m/s. However, the speed of sound in water can vary by a small amount based on characteristics of the transmission medium such as temperature and salinity.

The basic characteristics of a sound wave are frequency, wavelength, velocity, and amplitude. Frequency is the number of pressure waves that pass by a reference point per unit of time and is measured in hertz (Hz) or cycles per second. Wavelength is the distance between two peaks or corresponding points of a sound wave (length of one cycle). Higher frequency sounds have shorter wavelengths than lower frequency sounds, and typically attenuate (decrease) more rapidly with distance, except in certain cases in shallower water. The amplitude of a sound pressure wave is related to the subjective ''loudness'' of a sound and is typically expressed in decibels (dB), which are a relative unit of measurement that is used to express the ratio of one value of a power or pressure to another. A sound pressure level (SPL) in dB is described as the ratio between a measured pressure and a reference pressure, and is a logarithmic unit that accounts for large variations in amplitude; therefore, a relatively small change in dB corresponds to large changes in sound pressure. For example, a 10-dB increase is a ten-fold increase in acoustic power. A 20-dB increase is then a 100-fold increase in power and a 30-dB increase is a 1000-fold increase in power. However, a ten-fold increase in acoustic power does not mean that the sound is perceived as being 10 times louder. The dB is a relative unit comparing two pressures; therefore, a reference pressure must always be indicated. For underwater sound, this is 1 microPascal (µPa). For in-air sound, the reference pressure is 20 microPascal (µPa). The amplitude of a sound can be presented in various ways; however, NMFS typically considers three metrics: sound exposure level (SEL), root-mean-square (RMS) SPL, and peak SPL (defined below). The source level represents the SPL referenced at a standard distance from the source, typically 1 m (Richardson *et al.,* 1995; American National Standards Institute (ANSI, 2013), while the received level is the SPL at the receiver's position. For pile driving activities, the SPL is typically referenced at 10 m.

SEL (represented as dB referenced to 1 micropascal squared second (re 1 μPa^2-s)) represents the total energy in a stated frequency band over a stated time interval or event, and considers both intensity and duration of exposure. The per-pulse SEL (*e.g.,* single strike or single shot SEL) is calculated over the time window containing the entire pulse (*i.e.,* 100 percent of the acoustic energy). SEL can also be a cumulative metric; it can be accumulated over a single pulse (for pile driving this is the same as single-strike SEL, above; SEL_{ss}), or calculated over periods containing multiple pulses (SEL_{cum}). Cumulative SEL (SEL_{cum}) represents the total energy accumulated by a receiver over a defined time window or during an event. The SEL metric is useful because it allows sound exposures of different durations to be related to one another in terms of total acoustic energy. The duration of a sound event and the number of pulses, however, should be specified as there is no accepted standard duration over which the summation of energy is measured.

RMS SPL is equal to 10 times the logarithm (base 10) of the ratio of the mean-square sound pressure to the specified reference value, and given in units of dB (International Organization for Standardization (ISO), 2017). RMS is calculated by squaring all of the sound amplitudes, averaging the squares, and then taking the square root of the average (Urick, 1983). RMS accounts for both positive and negative values; squaring the pressures makes all values positive so that they may be accounted for in the summation of pressure levels (Hastings and Popper, 2005). This measurement is often used in the context of discussing behavioral effects, in part because behavioral effects, which often result from auditory cues, may be better expressed through averaged units than by peak SPL. For impulsive sounds, RMS is calculated by the portion of the waveform containing 90 percent of the sound energy from the impulsive event (Madsen, 2005).

Peak SPL (also referred to as zero-to-peak sound pressure or 0-pk) is the maximum instantaneous sound pressure measurable in the water, which can arise from a positive or negative sound pressure, during a specified time, for a specific frequency range at a specified distance from the source, and is represented in the same units as the RMS sound pressure (ISO, 2017). Along with SEL, this metric is used in evaluating the potential for permanent

threshold shift (PTS) and temporary threshold shift (TTS) associated with impulsive sound sources.

Sounds are also characterized by their temporal components. Continuous sounds are those whose sound pressure level remains above that of the ambient or background sound with negligibly small fluctuations in level (ANSI, 2005) while intermittent sounds are defined as sounds with interrupted levels of low or no sound (National Institute for Occupational Safety and Health (NIOSH), 1998). A key distinction between continuous and intermittent sound sources is that intermittent sounds have a more regular (predictable) pattern of bursts of sounds and silent periods (*i.e.,* duty cycle), which continuous sounds do not.

Sounds may be either impulsive or non-impulsive (defined below). The distinction between these two sound types is important because they have differing potential to cause physical effects, particularly with regard to noise-induced hearing loss (*e.g.,* Ward, 1997 in Southall *et al.,* 2007). Please see NMFS (2018) and Southall *et al.* (2007, 2019) for an in-depth discussion of these concepts.

Impulsive sound sources (*e.g.,* explosions, gunshots, sonic booms, seismic airgun shots, impact pile driving) produce signals that are brief (typically considered to be less than 1 second), broadband, atonal transients (ANSI, 1986, 2005; NIOSH, 1998) and occur either as isolated events or repeated in some succession. Impulsive sounds are all characterized by a relatively rapid rise from ambient pressure to a maximal pressure value followed by a rapid decay period that may include a period of diminishing, oscillating maximal and minimal pressures, and generally have an increased capacity to induce physical injury as compared with sounds that lack these features. Impulsive sounds are intermittent in nature. The duration of such sounds, as received at a distance, can be greatly extended in a highly reverberant environment.

Non-impulsive sounds can be tonal, narrowband, or broadband, brief or prolonged, and may be either continuous or non-continuous (ANSI, 1995; NIOSH, 1998). Some of these non-impulsive sounds can be transient signals of short duration but without the essential properties of impulses (*e.g.,* rapid rise time). Examples of non-impulsive sounds include those produced by vessels, aircraft, machinery operations such as drilling or dredging, vibratory pile driving, and active sonar systems.

Even in the absence of sound from the specified activity, the underwater environment is characterized by sounds from both natural and anthropogenic sound sources. Ambient sound is defined as a composite of naturally-occurring (*i.e.,* non-anthropogenic) sound from many sources both near and far (ANSI, 1995). Background sound is similar, but includes all sounds, including anthropogenic sounds, minus the sound produced by the proposed activities (NMFS, 2012, 2016a). The sound level of a region is defined by the total acoustical energy being generated by known and unknown sources. These sources may include physical (*e.g.,* wind and waves, earthquakes, ice, atmospheric sound), biological (*e.g.,* sounds produced by marine mammals, fish, and invertebrates), and anthropogenic (*e.g.,* vessels, dredging, construction) sound. A number of sources contribute to background and ambient sound, including wind and waves, which are a main source of naturally occurring ambient sound for frequencies between 200 Hz and 50 kilohertz (kHz) (Mitson, 1995). In general, background and ambient sound levels tend to increase with increasing wind speed and wave height. Precipitation can become an important component of total sound at frequencies above 500 Hz, and possibly down to 100 Hz during quiet times. Marine mammals can contribute significantly to background and ambient sound levels, as can some fish and snapping shrimp. The frequency band for biological contributions is from approximately 12 Hz to over 100 kHz. Sources of background sound related to human activity include transportation (surface vessels), dredging and construction, oil and gas drilling and production, geophysical surveys, sonar, and explosions. Vessel noise typically dominates the total background sound for frequencies between 20 and 300 Hz. In general, the frequencies of many anthropogenic sounds, particularly those produced by construction activities, are below 1 kHz (Richardson *et al.,* 1995). When sounds at frequencies greater than 1 kHz are produced, they generally attenuate relatively rapidly (Richardson *et al.,* 1995), particularly above 20 kHz due to propagation losses and absorption (Urick, 1983).

Transmission loss (*TL*) defines the degree to which underwater sound has spread in space and lost energy after having moved through the environment and reached a receiver. It is defined by the ISO as the reduction in a specified level between two specified points that are within an underwater acoustic field (ISO, 2017). Careful consideration of transmission loss and appropriate propagation modeling is a crucial step in determining the impacts of underwater sound, as it helps to define the ranges (isopleths) to which impacts are expected and depends significantly on local environmental parameters such as seabed type, water depth (bathymetry), and the local speed of sound. Geometric spreading laws are powerful tools which provide a simple means of estimating *TL,* based on the shape of the sound wave front in the water column. For a sound source that is equally loud in all directions and in deep water, the sound field takes the form of a sphere, as the sound extends in every direction uniformly. In this case, the intensity of the sound is spread across the surface of the sphere, and thus we can relate intensity loss to the square of the range (as area = $4*pi*r^2$). When expressing logarithmically in dB as *TL,* we find that $TL = 20*\mathrm{Log}_{10}(\mathrm{range})$, this situation is known as spherical spreading. In shallow water, the sea surface and seafloor will bound the shape of the sound, leading to a more cylindrical shape, as the top and bottom of the sphere is truncated by the largely reflective boundaries. This situation is termed cylindrical spreading, and is given by $TL = 10*\mathrm{Log}_{10}(\mathrm{range})$ (Urick, 1983). An intermediate scenario may be defined by the equation $TL = 15*\mathrm{Log}_{10}(\mathrm{range})$, and is referred to as practical spreading. Though these geometric spreading laws do not capture many often important details (scattering, absorption, *etc.*), they offer a reasonable and simple approximation of how sound decreases in intensity as it is transmitted. In the absence of measured data indicating the level of transmission loss at a given site for a specific activity, NMFS recommends practical spreading (*i.e.,* $15*\mathrm{Log}_{10}(\mathrm{range})$) to model acoustic propagation for construction activities in most nearshore environments.

The sum of the various natural and anthropogenic sound sources at any given location and time depends not only on the source levels, but also on the propagation of sound through the environment. Sound propagation is dependent on the spatially and temporally varying properties of the water column and sea floor, and is frequency-dependent. As a result of the dependence on a large number of varying factors, background and ambient sound levels can be expected to vary widely over both coarse and fine spatial and temporal scales. Sound levels at a given frequency and location

can vary by 10 to 20 dB from day to day (Richardson *et al.,* 1995). The result is that, depending on the source type and its intensity, sound from the specified activity may be a negligible addition to the local environment or could form a distinctive signal that may affect marine mammals.

Background underwater noise levels in the NES1 Project area are both variable and relatively high, primarily because of extreme tidal activity, elevated sediment loads in the water column, periodic high winds, the seasonal presence of ice, and anthropogenic activities. Sources of anthropogenic noise in the NES1 Project area consist of dredging operations, boats, ships, oil and gas operations, construction noise, and aircraft overflights from JBER and Ted Stevens International Airport, all of which contribute to high underwater noise levels in upper Cook Inlet (*e.g.,* Blackwell and Greene, 2002; (Knik Arm Bridge and Toll Authority (KABATA), 2011). The lower range of broadband (10 to 10,000 Hz) background sound levels obtained during underwater measurements at Port MacKenzie, located across Knik Arm from the POA, ranged from 115 to 133 dB re 1 µPa RMS (Blackwell, 2005). Background sound levels measured during the 2007 test pile study for the POA's Marine Terminal Redevelopment Project (MTRP) site ranged from 105 to 135 dB (URS Corporation, 2007). The background SPLs obtained in that study were highly variable, with most SPL recordings exceeding 120 dB RMS. Background sound levels measured in 2008 at the MTRP site ranged from 120 to 150 dB RMS (Scientific Fishery Systems, Inc., 2009). These measurements included industrial sounds from maritime operations, but ongoing USACE maintenance dredging and pile driving from construction were not underway at the time of the study.

Background sound levels were measured at the POA during the PAMP 2016 Test Pile Program (TPP) in the absence of pile driving at two locations during a 3-day break in pile installation. Median background noise levels, measured at a location just offshore of the POA SFD and at a second location about 1 km offshore, were 117 and 122.2 dB RMS, respectively (Austin *et al.,* 2016). NMFS considers the median sound levels to be most appropriate when considering background noise levels for purposes of evaluating the potential impacts of the proposed project on marine mammals (NMFS, 2012). By using the median value, which is the 50th percentile of the measurements, for background noise levels, one will be able to eliminate the few transient loud identifiable events that do not represent the true ambient condition of the area. This is relevant because during 2 of the 4 days (50 percent) when background measurement data were being collected, the USACE was dredging Terminal 3 (located just north of the Ambient-Offshore hydrophone) for 24 hours per day with two 1-hour breaks for crew change. On the last 2 days of data collection, no dredging was occurring. Therefore, the median provides a better representation of background noise levels when the NES1 project would be occurring. During the measurements, some typical sound signals were noted, such as noise from current flow and the passage of vessels.

With regard to spatial considerations of the measurements, the offshore location is most applicable to assessing background sound during the NES1 Project (NMFS, 2012). The median background noise level measured at the offshore hydrophone was 122.2 dB RMS. The measurement location closer to the POA was quieter, with a median of 117 dB; however, that hydrophone was placed very close to a dock. During PCT acoustic monitoring, noise levels in Knik Arm absent pile driving were also collected (Illingworth & Rodkin (I&R), 2021a, 2022b)); however, the PCT IHAs did not require background noise measurements to be collected. These measurements were not collected in accordance to NMFS (2012) guidance for measuring background noise and thus cannot be used here for that purpose. Despite this, the noise levels measured during the PCT project were not significantly different from 122.2 dB (I&R, 2021a, 2022b). If additional background data are collected in the future in this region, NMFS may re-evaluate the data to appropriately characterize background sound levels in Knik Arm.

Description of Sound Sources for the Specified Activities

In-water construction activities associated with the project that have the potential to incidentally take marine mammals through exposure to sound would include impact sheet pile removal, vibratory pile installation and removal, and pile splitting (assumed to be similar to vibratory pile installation and removal). Impact hammers typically operate by repeatedly dropping and/or pushing a heavy piston onto a pile to drive the pile into the substrate. For the NES1 project, a small number of strikes from an impact hammer may be used to loosen sheet piles for removal. Sound generated by impact hammers is impulsive, characterized by rapid rise times and high peak levels, a potentially injurious combination (Hastings and Popper, 2005). Vibratory hammers install piles by vibrating them and allowing the weight of the hammer to push them into the sediment. Vibratory hammers typically produce less sound (*i.e.,* lower levels) than impact hammers. Peak SPLs may be 180 dB or greater, but are generally 10 to 20 dB lower than SPLs generated during impact pile driving of the same-sized pile (Oestman *et al.,* 2009; California Department of Transportation (CALTRANS), 2015, 2020). Sounds produced by vibratory hammers are non-impulsive; the rise time is slower, reducing the probability and severity of injury, and the sound energy is distributed over a greater amount of time (Nedwell and Edwards, 2002; Carlson *et al.,* 2005).

The likely or possible impacts of the POA's proposed activities on marine mammals could involve both non-acoustic and acoustic stressors. Potential non-acoustic stressors could result from the physical presence of the equipment and personnel; however, given there are no known pinniped haul-out sites in the vicinity of the NES1 project site, visual and other non-acoustic stressors would be limited, and any impacts to marine mammals are expected to primarily be acoustic in nature.

Acoustic Impacts

The introduction of anthropogenic noise into the aquatic environment from pile driving is the primary means by which marine mammals may be harassed from the POA's specified activity. In general, animals exposed to natural or anthropogenic sound may experience physical and psychological effects, ranging in magnitude from none to severe (Southall *et al.,* 2007, 2019). Exposure to pile driving noise has the potential to result in auditory threshold shifts and behavioral reactions (*e.g.,* avoidance, temporary cessation of foraging and vocalizing, changes in dive behavior). Exposure to anthropogenic noise can also lead to non-observable physiological responses, such as an increase in stress hormones. Additional noise in a marine mammal's habitat can mask acoustic cues used by marine mammals to carry out daily functions, such as communication and predator and prey detection. The effects of pile driving noise on marine mammals are dependent on several factors, including, but not limited to, sound type (*e.g.,* impulsive vs. non-impulsive), the species, age and sex class (*e.g.,* adult male vs. mom with calf), duration of

exposure, the distance between the pile and the animal, received levels, behavior at time of exposure, and previous history with exposure (Wartzok *et al.,* 2004; Southall *et al.,* 2007). Here we discuss physical auditory effects (threshold shifts) followed by behavioral effects and potential impacts on habitat.

NMFS defines a noise-induced threshold shift (TS) as a change, usually an increase, in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS, 2018). The amount of threshold shift is customarily expressed in dB. A TS can be permanent or temporary. As described in NMFS (2018) there are numerous factors to consider when examining the consequence of TS, including, but not limited to, the signal temporal pattern (*e.g.,* impulsive or non-impulsive), likelihood an individual would be exposed for a long enough duration or to a high enough level to induce a TS, the magnitude of the TS, time to recovery (seconds to minutes or hours to days), the frequency range of the exposure (*i.e.,* spectral content), the hearing frequency range of the exposed species relative to the signal's frequency spectrum (*i.e.,* how animal uses sound within the frequency band of the signal; *e.g.,* Kastelein *et al.,* 2014), and the overlap between the animal and the source (*e.g.,* spatial, temporal, and spectral).

Permanent Threshold Shift (PTS). NMFS defines PTS as a permanent, irreversible increase in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS, 2018). PTS does not generally affect more than a limited frequency range, and an animal that has incurred PTS has incurred some level of hearing loss at the relevant frequencies; typically animals with PTS are not functionally deaf (Au and Hastings, 2008; Finneran, 2016). Available data from humans and other terrestrial mammals indicate that a 40-dB threshold shift approximates PTS onset (see Ward *et al.,* 1958, 1959, 1960; Kryter *et al.,* 1966; Miller, 1974; Ahroon *et al.,* 1996; Henderson *et al.,* 2008). PTS levels for marine mammals are estimates, as with the exception of a single study unintentionally inducing PTS in a harbor seal (Kastak *et al.,* 2008), there are no empirical data measuring PTS in marine mammals largely due to the fact that, for various ethical reasons, experiments involving anthropogenic noise exposure at levels inducing PTS are not typically pursued or authorized (NMFS, 2018).

Temporary Threshold Shift (TTS). A temporary, reversible increase in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS, 2018). Based on data from marine mammal TTS measurements (see Southall *et al.,* 2007, 2019), a TTS of 6 dB is considered the minimum threshold shift clearly larger than any day-to-day or session-to-session variation in a subject's normal hearing ability (Finneran *et al.,* 2000, 2002; Schlundt *et al.,* 2000). As described in Finneran (2015), marine mammal studies have shown the amount of TTS increases with SEL_{cum} in an accelerating fashion: at low exposures with lower SEL_{cum}, the amount of TTS is typically small and the growth curves have shallow slopes. At exposures with higher SEL_{cum}, the growth curves become steeper and approach linear relationships with the noise SEL.

Depending on the degree (elevation of threshold in dB), duration (*i.e.,* recovery time), and frequency range of TTS, and the context in which it is experienced, TTS can have effects on marine mammals ranging from discountable to serious (similar to those discussed in auditory masking, below). For example, a marine mammal may be able to readily compensate for a brief, relatively small amount of TTS in a non-critical frequency range that takes place during a time when the animal is traveling through the open ocean, where ambient noise is lower and there are not as many competing sounds present. Alternatively, a larger amount and longer duration of TTS sustained during time when communication is critical for successful mother/calf interactions could have more serious impacts. We note that reduced hearing sensitivity as a simple function of aging has been observed in marine mammals, as well as humans and other taxa (Southall *et al.,* 2007), so we can infer that strategies exist for coping with this condition to some degree, though likely not without cost.

Many studies have examined noise-induced hearing loss in marine mammals (see Finneran (2015) and Southall *et al.* (2019) for summaries). TTS is the mildest form of hearing impairment that can occur during exposure to sound (Kryter, 2013). While experiencing TTS, the hearing threshold rises, and a sound must be at a higher level in order to be heard. In terrestrial and marine mammals, TTS can last from minutes or hours to days (in cases of strong TTS). In many cases, hearing sensitivity recovers rapidly after exposure to the sound ends. For cetaceans, published data on the onset of TTS are limited to captive bottlenose dolphin (*Tursiops truncatus*), beluga whale, harbor porpoise, and Yangtze finless porpoise (*Neophocoena asiaeorientalis*) (Southall *et al.,* 2019). For pinnipeds in water, measurements of TTS are limited to harbor seals, elephant seals (*Mirounga angustirostris*), bearded seals (*Erignathus barbatus*) and California sea lions (*Zalophus californianus*) (Kastak *et al.,* 1999, 2007; Kastelein *et al.,* 2019b, 2019c, 2021, 2022a, 2022b; Reichmuth *et al.,* 2019; Sills *et al.,* 2020). TTS was not observed in spotted (*Phoca largha*) and ringed (*Pusa hispida*) seals exposed to single airgun impulse sounds at levels matching previous predictions of TTS onset (Reichmuth *et al.,* 2016). These studies examine hearing thresholds measured in marine mammals before and after exposure to intense or long-duration sound exposures. The difference between the pre-exposure and post-exposure thresholds can be used to determine the amount of threshold shift at various post-exposure times.

The amount and onset of TTS depends on the exposure frequency. Sounds at low frequencies, well below the region of best sensitivity for a species or hearing group, are less hazardous than those at higher frequencies, near the region of best sensitivity (Finneran and Schlundt, 2013). At low frequencies, onset-TTS exposure levels are higher compared to those in the region of best sensitivity (*i.e.,* a low frequency noise would need to be louder to cause TTS onset when TTS exposure level is higher), as shown for harbor porpoises and harbor seals (Kastelein *et al.,* 2019a, 2019c). Note that in general, harbor seals and harbor porpoises have a lower TTS onset than other measured pinniped or cetacean species (Finneran, 2015). In addition, TTS can accumulate across multiple exposures, but the resulting TTS will be less than the TTS from a single, continuous exposure with the same SEL (Mooney *et al.,* 2009; Finneran *et al.,* 2010; Kastelein *et al.,* 2014, 2015). This means that TTS predictions based on the total, cumulative SEL will overestimate the amount of TTS from intermittent exposures, such as sonars and impulsive sources. Nachtigall *et al.* (2018) describe measurements of hearing sensitivity of multiple odontocete species (bottlenose dolphin, harbor porpoise, beluga, and false killer whale (*Pseudorca crassidens*)) when a relatively loud sound was preceded by

a warning sound. These captive animals were shown to reduce hearing sensitivity when warned of an impending intense sound. Based on these experimental observations of captive animals, the authors suggest that wild animals may dampen their hearing during prolonged exposures or if conditioned to anticipate intense sounds. Another study showed that echolocating animals (including odontocetes) might have anatomical specializations that might allow for conditioned hearing reduction and filtering of low-frequency ambient noise, including increased stiffness and control of middle ear structures and placement of inner ear structures (Ketten *et al.,* 2021). Data available on noise-induced hearing loss for mysticetes are currently lacking (NMFS, 2018). Additionally, the existing marine mammal TTS data come from a limited number of individuals within these species.

Relationships between TTS and PTS thresholds have not been studied in marine mammals, and there is no PTS data for cetaceans, but such relationships are assumed to be similar to those in humans and other terrestrial mammals. PTS typically occurs at exposure levels at least several decibels above that inducing mild TTS (*e.g.,* a 40-dB threshold shift approximates PTS onset (Kryter *et al.,* 1966; Miller, 1974), while a 6-dB threshold shift approximates TTS onset (Southall *et al.,* 2007, 2019). Based on data from terrestrial mammals, a precautionary assumption is that the PTS thresholds for impulsive sounds (such as impact pile driving pulses as received close to the source) are at least 6 dB higher than the TTS threshold on a peak-pressure basis and PTS cumulative sound exposure level thresholds are 15 to 20 dB higher than TTS cumulative sound exposure level thresholds (Southall *et al.,* 2007, 2019). Given the higher level of sound or longer exposure duration necessary to cause PTS as compared with TTS, it is considerably less likely that PTS could occur.

Behavioral Harassment. Exposure to noise also has the potential to behaviorally disturb marine mammals to a level that rises to the definition of harassment under the MMPA. Generally speaking, NMFS considers a behavioral disturbance that rises to the level of harassment under the MMPA a non-minor response—in other words, not every response qualifies as behavioral disturbance, and for responses that do, those of a higher level, or accrued across a longer duration, have the potential to affect foraging, reproduction, or survival. Behavioral disturbance may include a variety of effects, including subtle changes in behavior (*e.g.,* minor or brief avoidance of an area or changes in vocalizations), more conspicuous changes in similar behavioral activities, and more sustained and/or potentially severe reactions, such as displacement from or abandonment of high-quality habitat. Behavioral responses may include changing durations of surfacing and dives, changing direction and/or speed; reducing/increasing vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding); eliciting a visible startle response or aggressive behavior (such as tail/fin slapping or jaw clapping); avoidance of areas where sound sources are located. Pinnipeds may increase their haul out time, possibly to avoid in-water disturbance (Thorson and Reyff, 2006). Behavioral responses to sound are highly variable and context-specific and any reactions depend on numerous intrinsic and extrinsic factors (*e.g.,* species, state of maturity, experience, current activity, reproductive state, auditory sensitivity, time of day), as well as the interplay between factors (*e.g.,* Richardson *et al.,* 1995; Wartzok *et al.,* 2004; Southall *et al.,* 2007, 2019; Weilgart, 2007; Archer *et al.,* 2010). Behavioral reactions can vary not only among individuals but also within an individual, depending on previous experience with a sound source, context, and numerous other factors (Ellison *et al.,* 2012), and can vary depending on characteristics associated with the sound source (*e.g.,* whether it is moving or stationary, number of sources, distance from the source). In general, pinnipeds seem more tolerant of, or at least habituate more quickly to, potentially disturbing underwater sound than do cetaceans, and generally seem to be less responsive to exposure to industrial sound than most cetaceans. Please see Appendices B and C of Southall *et al.* (2007) and Gomez *et al.* (2016) for reviews of studies involving marine mammal behavioral responses to sound.

Habituation can occur when an animal's response to a stimulus wanes with repeated exposure, usually in the absence of unpleasant associated events (Wartzok *et al.,* 2004). Animals are most likely to habituate to sounds that are predictable and unvarying. It is important to note that habituation is appropriately considered as a ''progressive reduction in response to stimuli that are perceived as neither aversive nor beneficial,'' rather than as, more generally, moderation in response to human disturbance (Bejder *et al.,* 2009). The opposite process is sensitization, when an unpleasant experience leads to subsequent responses, often in the form of avoidance, at a lower level of exposure.

As noted above, behavioral state may affect the type of response. For example, animals that are resting may show greater behavioral change in response to disturbing sound levels than animals that are highly motivated to remain in an area for feeding (Richardson *et al.,* 1995; Wartzok *et al.,* 2004; National Research Council (NRC), 2005). Controlled experiments with captive marine mammals have showed pronounced behavioral reactions, including avoidance of loud sound sources (Ridgway *et al.,* 1997; Finneran *et al.,* 2003). Observed responses of wild marine mammals to loud pulsed sound sources (*e.g.,* seismic airguns) have been varied but often consist of avoidance behavior or other behavioral changes (Richardson *et al.,* 1995; Morton and Symonds, 2002; Nowacek *et al.,* 2007).

Available studies show wide variation in response to underwater sound; therefore, it is difficult to predict specifically how any given sound in a particular instance might affect marine mammals perceiving the signal. If a marine mammal does react briefly to an underwater sound by changing its behavior or moving a small distance, the impacts of the change are unlikely to be significant to the individual, let alone the stock or population. However, if a sound source displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on individuals and populations could be significant (*e.g.,* Lusseau and Bejder, 2007; Weilgart, 2007; NRC, 2005). However, there are broad categories of potential response, which we describe in greater detail here, that include alteration of dive behavior, alteration of foraging behavior, effects to breathing, interference with or alteration of vocalization, avoidance, and flight.

Changes in dive behavior can vary widely and may consist of increased or decreased dive times and surface intervals as well as changes in the rates of ascent and descent during a dive (*e.g.,* Frankel and Clark, 2000; Costa *et al.,* 2003; Ng and Leung, 2003; Nowacek *et al.,* 2004; Goldbogen *et al.,* 2013a, 2013b). Variations in dive behavior may reflect interruptions in biologically significant activities (*e.g.,* foraging) or they may be of little biological significance. The impact of an alteration to dive behavior resulting from an acoustic exposure depends on what the animal is doing at the time of the exposure and the type and magnitude of the response.

Disruption of feeding behavior can be difficult to correlate with anthropogenic sound exposure, so it is usually inferred by observed displacement from known foraging areas, the appearance of secondary indicators (*e.g.,* bubble nets or sediment plumes), or changes in dive behavior. As for other types of behavioral response, the frequency, duration, and temporal pattern of signal presentation, as well as differences in species sensitivity, are likely contributing factors to differences in response in any given circumstance (*e.g.,* Croll *et al.,* 2001; Nowacek *et al.,* 2004; Madsen *et al.,* 2006; Yazvenko *et al.,* 2007). A determination of whether foraging disruptions incur fitness consequences would require information on or estimates of the energetic requirements of the affected individuals and the relationship between prey availability, foraging effort and success, and the life history stage of the animal.

Variations in respiration naturally vary with different behaviors and alterations to breathing rate as a function of acoustic exposure can be expected to co-occur with other behavioral reactions, such as a flight response or an alteration in diving. However, respiration rates in and of themselves may be representative of annoyance or an acute stress response. Various studies have shown that respiration rates may either be unaffected or could increase, depending on the species and signal characteristics, again highlighting the importance in understanding species differences in the tolerance of underwater noise when determining the potential for impacts resulting from anthropogenic sound exposure (*e.g.,* Kastelein *et al.,* 2001, 2005, 2006; Gailey *et al.,* 2007). For example, harbor porpoise' respiration rate increased in response to pile driving sounds at and above a received broadband SPL of 136 dB (zero-peak SPL: 151 dB re 1 µPa; SEL of a single strike: 127 dB re 1 μPa^2-s) (Kastelein *et al.,* 2013).

Marine mammals vocalize for different purposes and across multiple modes, such as whistling, echolocation click production, calling, and singing. Changes in vocalization behavior in response to anthropogenic noise can occur for any of these modes and may result from a need to compete with an increase in background noise or may reflect increased vigilance or a startle response. For example, in the presence of potentially masking signals, humpback whales and killer whales have been observed to increase the length of their songs (Miller *et al.,* 2000; Fristrup *et al.,* 2003) or vocalizations (Foote *et al.,* 2004), respectively, while North Atlantic right whales (*Eubalaena glacialis*) have been observed to shift the frequency content of their calls upward while reducing the rate of calling in areas of increased anthropogenic noise (Parks *et al.,* 2007). In some cases, animals may cease sound production during production of aversive signals (Bowles *et al.,* 1994).

Avoidance is the displacement of an individual from an area or migration path as a result of the presence of a sound or other stressors, and is one of the most obvious manifestations of disturbance in marine mammals (Richardson *et al.,* 1995). For example, gray whales are known to change direction—deflecting from customary migratory paths—in order to avoid noise from seismic surveys (Malme *et al.,* 1984). Avoidance may be short-term, with animals returning to the area once the noise has ceased (*e.g.,* Bowles *et al.,* 1994; Goold, 1996; Stone *et al.,* 2000; Morton and Symonds, 2002; Gailey *et al.,* 2007). Longer-term displacement is possible, however, which may lead to changes in abundance or distribution patterns of the affected species in the affected region if habituation to the presence of the sound does not occur (*e.g.,* Blackwell *et al.,* 2004; Bejder *et al.,* 2006; Teilmann *et al.,* 2006).

A flight response is a dramatic change in normal movement to a directed and rapid movement away from the perceived location of a sound source. The flight response differs from other avoidance responses in the intensity of the response (*e.g.,* directed movement, rate of travel). Relatively little information on flight responses of marine mammals to anthropogenic signals exist, although observations of flight responses to the presence of predators have occurred (Connor and Heithaus, 1996; Bowers *et al.,* 2018). The result of a flight response could range from brief, temporary exertion and displacement from the area where the signal provokes flight to, in extreme cases, marine mammal strandings (England *et al.,* 2001). However, it should be noted that response to a perceived predator does not necessarily invoke flight (Ford and Reeves, 2008), and whether individuals are solitary or in groups may influence the response.

Behavioral disturbance can also impact marine mammals in more subtle ways. Increased vigilance may result in costs related to diversion of focus and attention (*i.e.,* when a response consists of increased vigilance, it may come at the cost of decreased attention to other critical behaviors such as foraging or resting). These effects have generally not been demonstrated for marine mammals, but studies involving fishes and terrestrial animals have shown that increased vigilance may substantially reduce feeding rates (*e.g.,* Beauchamp and Livoreil, 1997; Fritz *et al.,* 2002; Purser and Radford, 2011). In addition, chronic disturbance can cause population declines through reduction of fitness (*e.g.,* decline in body condition) and subsequent reduction in reproductive success, survival, or both (*e.g.,* Harrington and Veitch, 1992; Daan *et al.,* 1996; Bradshaw *et al.,* 1998). However, Ridgway *et al.* (2006) reported that increased vigilance in bottlenose dolphins exposed to sound over a 5-day period did not cause any sleep deprivation or stress effects.

Many animals perform vital functions, such as feeding, resting, traveling, and socializing, on a diel cycle (24-hour cycle). Disruption of such functions resulting from reactions to stressors such as sound exposure are more likely to be significant if they last more than one diel cycle or recur on subsequent days (Southall *et al.,* 2007). Consequently, a behavioral response lasting less than 1 day and not recurring on subsequent days is not considered particularly severe unless it could directly affect reproduction or survival (Southall *et al.,* 2007). Note that there is a difference between multi-day substantive (*i.e.,* meaningful) behavioral reactions and multi-day anthropogenic activities. For example, just because an activity lasts for multiple days does not necessarily mean that individual animals are either exposed to activity-related stressors for multiple days or, further, exposed in a manner resulting in sustained multi-day substantive behavioral responses.

Behavioral Reactions Observed at the POA. Specific to recent construction at the POA, behavioral reactions to pile driving have not been reported in non-CIBW species. During POA's PCT construction, 81 harbor seals were observed within estimated Level B harassment zones associated with vibratory and impact installation and or removal of 36-inch (61-cm) and 144-inch (366-cm) piles, and five harbor seals were observed within estimated Level A harassment zones during the installation of 144-inch (366-cm) piles. No observable behavioral reactions were observed in any of these seals (61N Environmental, 2021, 2022a). One harbor porpoise was observed within the estimated Level B harassment zone during vibratory driving of a 36-inch (61-cm) pile in May 2021. The animal was travelling at a moderate pace. No observable reactions to pile driving were noted by the PSOs. Another harbor porpoise may have been within the

estimated Level B harassment zone during the impact installation of 36-inch (61-cm) piles in June 2021, but PSOs did not record any behavioral responses of this individual to the pile driving activities. Similarly 13 harbor seals observed within estimated Level B harassment zones associated with pile driving 36-inch (61-cm) piles during POA's SFD construction did not exhibit observable behavioral reactions (61N Environmental, 2022b).

Specific to CIBWs, several years of marine mammal monitoring data demonstrate the behavioral responses to pile driving at the POA. Previous pile driving activities at the POA include the installation and removal of sheet piles, the vibratory and impact installation of 24-inch (61-cm), 36-inch (91-cm), 48-in (122-cm), and 144-inch (366-cm) pipe piles, and the vibratory installation of 72-inch (183-cm) air bubble casings.

Kendall and Cornick (2015) provide a comprehensive overview of 4 years of scientific marine mammal monitoring conducted before (2005–2006) and during the POA's MTR Project P (2008–2009). These were observations made by PSOs independent of the POA and their pile driving activities (*i.e.,* not construction based PSOs). The authors investigated CIBW behavior before and during pile driving activity at the POA. Sighting rates, mean sighting duration, behavior, mean group size, group composition, and group formation were compared between the two periods. A total of about 2,329 hours of sampling effort was completed across 349 days from 2005 to 2009. Overall, 687 whales in 177 groups were documented during the 69 days that whales were sighted. A total of 353 and 1,663 hours of pile driving took place in 2008 and 2009, respectively. There was no relationship between monthly CIBW sighting rates and monthly pile driving rates ($r = 0.19$, $p = 0.37$). Sighting rates before (n = 12; 0.06 ± 0.01) and during (n = 13; 0.01 ± 0.03) pile driving were not significantly different. However, sighting duration of CIBWs decreased significantly during pile driving (39 ± 6 min before and 18 ± 3 min during). There were also significant differences in behavior before versus during pile driving. CIBWs primarily traveled through the study area both before and during pile driving; however, traveling increased relative to other behaviors during pile driving. Documentation of milling was observed on 21 occasions during pile driving. Mean group size decreased during pile driving; however, this difference was not statistically significant. In addition, group composition was significantly different before and during pile driving, with more white (*i.e.,* likely older) animals being present during pile driving (Kendall and Cornick, 2015). CIBWs were primarily observed densely packed before and during pile driving; however, the number of densely packed groups increased by approximately 67 percent during pile driving. There were also significant increases in the number of dispersed groups (approximately 81 percent) and lone white whales (approximately 60 percent) present during pile driving than before pile driving (Kendall and Cornick, 2015).

During PCT and SFD construction monitoring, behaviors of CIBWs groups were compared by month and by construction activity (61N Environmental, 2021, 2022a, 2022b). Little variability was evident in the behaviors recorded from month to month, or between sightings that coincided with in-water pile installation and removal and those that did not (61N Environmental, 2021, 2022a). Definitive behavioral reactions to in-water pile driving or avoidance behaviors were not documented; however, potential reactions (where a group reversed its trajectory shortly after the start of in-water pile driving occurred; a group reversed its trajectory as it got closer to the sound source during active in-water pile driving; or upon an initial sighting, a group was already moving away from in-water pile driving, raising the possibility that it had been moving towards, but was only sighted after they turned away) and instances where CIBWs moved toward active in-water pile driving were recorded. During these instances, impact driving appeared to cause potential behavioral reactions more readily than vibratory hammering (61N Environmental, 2021, 2022a, 2022b). One minor difference documented during PCT construction was a slightly higher incidence of milling behavior and diving during the periods of no pile driving and slightly higher rates of traveling behavior during periods when potential CIBW behavioral reactions to pile driving, as described above, were recorded (61N Environmental, 2021, 2022a). Note, narratives of each CIBW reaction can be found in the appendices of the POA's final monitoring reports (61N Environmental, 2021, 2022a, 2022b).

Acoustically, Saxon-Kendall *et al.* (2013) recorded echolocation clicks (which can be indicative of feeding behavior) during the MTR Project at the POA both while pile driving was occurring and when it was not. This indicates that while feeding is not a predominant behavior observed in CIBWs sighted near the POA (61N Environmental, 2021, 2022a, 2022b, 2022c; Easley-Appleyard and Leonard, 2022) CIBWs can and still exhibit feeding behaviors during pile driving activities. In addition, Castellote *et al.* (2020) found low echolocation detection rates in lower Knik Arm (*i.e.,* Six Mile, Port MacKenzie, and Cairn Point) and suggested that CIBWs moved through that area relatively quickly when entering or exiting the Arm. No whistles or noisy vocalizations were recorded during the MTR construction activities; however, it is possible that persistent noise associated with construction activity at the MTR project masked beluga vocalizations and or that CIBWs did not use these communicative signals when they were near the MTR Project (Saxon-Kendall *et al.,* 2013).

Recently, McHuron *et al.* (2023) developed a model to predict general patterns related to the movement and foraging decisions of pregnant CIBWs in Cook Inlet. They found that the effects of disturbance from human activities, such as pile driving activities occurring at the POA assuming no prescribed mitigation measures implemented, are inextricably linked with prey availability. If prey are abundant during the summer and early fall, and prey during winter is above some critical threshold, pregnant CIBWs can likely cope with intermittent disruptions, such as those produced by pile driving at the POA (McHuron *et al.,* 2023). However, they stress that more information needs to be acquired regarding CIBW prey and CIBW body condition, specifically in their critical habitat, to better understand possible behavioral responses to disturbance.

Stress responses. An animal's perception of a threat may be sufficient to trigger stress responses consisting of some combination of behavioral responses, autonomic nervous system responses, neuroendocrine responses, or immune responses (*e.g.,* Selye, 1950; Moberg, 2000). In many cases, an animal's first and sometimes most economical (in terms of energetic costs) response is behavioral avoidance of the potential stressor. Autonomic nervous system responses to stress typically involve changes in heart rate, blood pressure, and gastrointestinal activity. These responses have a relatively short duration and may or may not have a significant long-term effect on an animal's fitness.

Neuroendocrine stress responses often involve the hypothalamus-pituitary-adrenal system. Virtually all neuroendocrine functions that are affected by stress—including immune competence, reproduction, metabolism, and behavior—are regulated by pituitary hormones. Stress-induced changes in

the secretion of pituitary hormones have been implicated in failed reproduction, altered metabolism, reduced immune competence, and behavioral disturbance (*e.g.,* Moberg, 1987; Blecha, 2000). Increases in the circulation of glucocorticoids are also equated with stress (Romano *et al.,* 2004).

The primary distinction between stress (which is adaptive and does not normally place an animal at risk) and ''distress'' is the cost of the response. During a stress response, an animal uses glycogen stores that can be quickly replenished once the stress is alleviated. In such circumstances, the cost of the stress response would not pose serious fitness consequences. However, when an animal does not have sufficient energy reserves to satisfy the energetic costs of a stress response, energy resources must be diverted from other functions. This state of distress will last until the animal replenishes its energetic reserves sufficient to restore normal function.

Relationships between these physiological mechanisms, animal behavior, and the costs of stress responses are well-studied through controlled experiments and for both laboratory and free-ranging animals (*e.g.,* Holberton *et al.,* 1996; Hood *et al.,* 1998; Jessop *et al.,* 2003; Krausman *et al.,* 2004; Lankford *et al.,* 2005). Stress responses due to exposure to anthropogenic sounds or other stressors and their effects on marine mammals have also been reviewed (Fair and Becker, 2000; Romano *et al.,* 2002b) and, more rarely, studied in wild populations (*e.g.,* Romano *et al.,* 2002a). For example, Rolland *et al.* (2012) found that noise reduction from reduced ship traffic in the Bay of Fundy was associated with decreased stress in North Atlantic right whales. These and other studies lead to a reasonable expectation that some marine mammals will experience physiological stress responses upon exposure to acoustic stressors and that it is possible that some of these would be classified as ''distress.'' In addition, any animal experiencing TTS would likely also experience stress responses (NRC, 2005), however distress is an unlikely result of this project based on observations of marine mammals during previous, similar construction projects.

Norman (2011) reviewed environmental and anthropogenic stressors for CIBWs. Lyamin *et al.* (2011) determined that the heart rate of a beluga whale increases in response to noise, depending on the frequency and intensity. Acceleration of heart rate in the beluga whale is the first component of the ''acoustic startle response.'' Romano *et al.* (2004) demonstrated that captive beluga whales exposed to high-level impulsive sounds (*i.e.,* seismic airgun and/or single pure tones up to 201 dB RMS) resembling sonar pings showed increased stress hormone levels of norepinephrine, epinephrine, and dopamine when TTS was reached. Thomas *et al.* (1990) exposed beluga whales to playbacks of an oil-drilling platform in operation (''Sedco 708,'' 40 Hz–20 kHz; source level 153 dB). Ambient SPL at ambient conditions in the pool before playbacks was 106 dB and 134 to 137 dB RMS during playbacks at the monitoring hydrophone across the pool. All cell and platelet counts and 21 different blood chemicals, including epinephrine and norepinephrine, were within normal limits throughout baseline and playback periods, and stress response hormone levels did not increase immediately after playbacks. The difference between the Romano *et al.* (2004) and Thomas *et al.* (1990) studies could be the differences in the type of sound (seismic airgun and/or tone versus oil drilling), the intensity and duration of the sound, the individual's response, and the surrounding circumstances of the individual's environment. The construction sounds in the Thomas *et al.* (1990) study would be more similar to those of pile installation than those in the study investigating stress response to water guns and pure tones. Therefore, no more than short-term, low-hormone stress responses, if any, of beluga whales or other marine mammals are expected as a result of exposure to in-water pile installation and removal during the NES1 project.

Auditory Masking. Since many marine mammals rely on sound to find prey, moderate social interactions, and facilitate mating (Tyack, 2008), noise from anthropogenic sound sources can interfere with these functions, but only if the noise spectrum overlaps with the hearing sensitivity of the receiving marine mammal (Southall *et al.,* 2007; Clark *et al.,* 2009; Hatch *et al.,* 2012). Chronic exposure to excessive, though not high-intensity, noise could cause masking at particular frequencies for marine mammals that utilize sound for vital biological functions (Clark *et al.,* 2009). Acoustic masking is when other noises such as from human sources interfere with an animal's ability to detect, recognize, or discriminate between acoustic signals of interest (*e.g.,* those used for intraspecific communication and social interactions, prey detection, predator avoidance, navigation) (Richardson *et al.,* 1995; Erbe *et al.,* 2016). Therefore, under certain circumstances, marine mammals whose acoustical sensors or environment are being severely masked could also be impaired from maximizing their performance fitness in survival and reproduction. The ability of a noise source to mask biologically important sounds depends on the characteristics of both the noise source and the signal of interest (*e.g.,* signal-to-noise ratio, temporal variability, direction), in relation to each other and to an animal's hearing abilities (*e.g.,* sensitivity, frequency range, critical ratios, frequency discrimination, directional discrimination, age or TTS hearing loss), and existing ambient noise and propagation conditions (Hotchkin and Parks, 2013).

Under certain circumstances, marine mammals experiencing significant masking could also be impaired from maximizing their performance fitness in survival and reproduction. Therefore, when the coincident (masking) sound is human-made, it may be considered harassment when disrupting or altering critical behaviors. It is important to distinguish TTS and PTS, which persist after the sound exposure, from masking, which occurs during the sound exposure. Because masking (without resulting in TS) is not associated with abnormal physiological function, it is not considered a physiological effect, but rather a potential behavioral effect (though not necessarily one that would be associated with harassment).

The frequency range of the potentially masking sound is important in determining any potential behavioral impacts. For example, low-frequency signals may have less effect on high-frequency echolocation sounds produced by odontocetes but are more likely to affect detection of mysticete communication calls and other potentially important natural sounds such as those produced by surf and some prey species. The masking of communication signals by anthropogenic noise may be considered as a reduction in the communication space of animals (*e.g.,* Clark *et al.,* 2009) and may result in energetic or other costs as animals change their vocalization behavior (*e.g.,* Miller *et al.,* 2000; Foote *et al.,* 2004; Parks *et al.,* 2007; Di Iorio and Clark, 2010; Holt *et al.,* 2009). Masking can be reduced in situations where the signal and noise come from different directions (Richardson *et al.,* 1995), through amplitude modulation of the signal, or through other compensatory behaviors (Hotchkin and Parks, 2013). Masking can be tested directly in captive species (*e.g.,* Erbe, 2008), but in wild populations it must be either modeled

or inferred from evidence of masking compensation. There are few studies addressing real-world masking sounds likely to be experienced by marine mammals in the wild (*e.g.,* Branstetter *et al.,* 2013).

Marine mammals at or near the proposed NES1 project site may be exposed to anthropogenic noise which may be a source of masking. Vocalization changes may result from a need to compete with an increase in background noise and include increasing the source level, modifying the frequency, increasing the call repetition rate of vocalizations, or ceasing to vocalize in the presence of increased noise (Hotchkin and Parks, 2013). For example, in response to loud noise, beluga whales may shift the frequency of their echolocation clicks to prevent masking by anthropogenic noise (Tyack, 2000; Eickmeier and Vallarta, 2022).

Masking is more likely to occur in the presence of broadband, relatively continuous noise sources such as vibratory pile driving. Energy distribution of pile driving covers a broad frequency spectrum, and sound from pile driving would be within the audible range of pinnipeds and cetaceans present in the proposed action area. While some construction during the POA's activities may mask some acoustic signals that are relevant to the daily behavior of marine mammals, the short-term duration and limited areas affected make it very unlikely that the fitness of individual marine mammals would be impacted.

Airborne Acoustic Effects. Pinnipeds that occur near the project site could be exposed to airborne sounds associated with construction activities that have the potential to cause behavioral harassment, depending on their distance from these activities. Airborne noise would primarily be an issue for pinnipeds that are swimming or hauled out near the project site within the range of noise levels elevated above airborne acoustic harassment criteria. Although pinnipeds are known to haul-out regularly on man-made objects, we believe that incidents of take resulting solely from airborne sound are unlikely given there are no known pinniped haulout or pupping sites within the vicinity of the proposed project area; the nearest known pinniped haulout is located a minimum of 24 km south-southwest of Anchorage for harbor seals. Cetaceans are not expected to be exposed to airborne sounds that would result in harassment as defined under the MMPA.

We recognize that pinnipeds in the water could be exposed to airborne sound that may result in behavioral harassment when looking with their heads above water. Most likely, airborne sound would cause behavioral responses similar to those discussed above in relation to underwater sound. For instance, anthropogenic sound could cause hauled-out pinnipeds to exhibit changes in their normal behavior, such as reduction in vocalizations, or cause them to temporarily abandon the area and move further from the source. However, these animals would previously have been 'taken' because of exposure to underwater sound above the behavioral harassment thresholds, which are in all cases larger than those associated with airborne sound. Thus, the behavioral harassment of these animals is already accounted for in these estimates of potential take. Therefore, we do not believe that authorization of incidental take resulting from airborne sound for pinnipeds is warranted, and airborne sound is not discussed further here.

Potential Effects on Marine Mammal Habitat

The proposed project will occur within the same footprint as existing marine infrastructure. The nearshore and intertidal habitat where the proposed project will occur is an area of relatively high marine vessel traffic. Temporary, intermittent, and short-term habitat alteration may result from increased noise levels during the proposed construction activities. Effects on prey species will be limited in time and space.

Removal of the North Extension bulkhead and impounded fill would result in restoration of subtidal and intertidal habitats that were lost when that structure was constructed in 2005–2011. Removal of approximately 1.35 million CY of fill material from below the high tide line would re-create approximately 0.05 km^2 (13 acres) of intertidal and subtidal habitat, returning them to their approximate original slope and shoreline configuration. The proposed project area is not considered to be high-quality habitat for marine mammals or marine mammal prey, such as fish, and it is anticipated that the removal of the North Extension bulkhead would increase the amount of available habitat for both marine mammals and fish because they would be able to swim through the area at higher water levels. The area is expected to be of higher quality to marine mammals and fish as it returns to its natural state and is colonized by marine organisms.

Water quality—Temporary and localized reduction in water quality would occur as a result of in-water construction activities. Most of this effect would occur during the installation and removal of piles when bottom sediments are disturbed. The installation and removal of piles would disturb bottom sediments and may cause a temporary increase in suspended sediment in the project area. During pile removal, sediment attached to the pile moves vertically through the water column until gravitational forces cause it to slough off under its own weight. The small resulting sediment plume is expected to settle out of the water column within a few hours. Studies of the effects of turbid water on fish (marine mammal prey) suggest that concentrations of suspended sediment can reach thousands of milligrams per liter before an acute toxic reaction is expected (Burton, 1993).

Effects to turbidity and sedimentation are expected to be short-term, minor, and localized. Since the currents are so strong in the area, following the completion of sediment-disturbing activities, suspended sediments in the water column should dissipate and quickly return to background levels in all construction scenarios. Turbidity within the water column has the potential to reduce the level of oxygen in the water and irritate the gills of prey fish species in the proposed project area. However, turbidity plumes associated with the project would be temporary and localized, and fish in the proposed project area would be able to move away from and avoid the areas where plumes may occur. Therefore, it is expected that the impacts on prey fish species from turbidity, and therefore on marine mammals, would be minimal and temporary. In general, the area likely impacted by the proposed construction activities is relatively small compared to the available marine mammal habitat in Knik Arm.

Potential Effects on Prey. Sound may affect marine mammals through impacts on the abundance, behavior, or distribution of prey species (*e.g.,* crustaceans, cephalopods, fishes, zooplankton). Marine mammal prey varies by species, season, and location and, for some, is not well documented. Studies regarding the effects of noise on known marine mammal prey are described here.

Fishes utilize the soundscape and components of sound in their environment to perform important functions such as foraging, predator avoidance, mating, and spawning (*e.g.,* Zelick *et al.,* 1999; Fay, 2009). Depending on their hearing anatomy and peripheral sensory structures, which vary among species, fishes hear

sounds using pressure and particle motion sensitivity capabilities and detect the motion of surrounding water (Fay *et al.,* 2008). The potential effects of noise on fishes depends on the overlapping frequency range, distance from the sound source, water depth of exposure, and species-specific hearing sensitivity, anatomy, and physiology. Key impacts to fishes may include behavioral responses, hearing damage, barotrauma (pressure-related injuries), and mortality.

Fish react to sounds that are especially strong and/or intermittent low-frequency sounds. Short duration, sharp sounds can cause overt or subtle changes in fish behavior and local distribution. The reaction of fish to noise depends on the physiological state of the fish, past exposures, motivation (*e.g.,* feeding, spawning, migration), and other environmental factors. Hastings and Popper (2005) identified several studies that suggest fish may relocate to avoid certain areas of sound energy. Additional studies have documented effects of pile driving on fishes (*e.g.* Scholik and Yan, 2001, 2002; Popper and Hastings, 2009). Several studies have demonstrated that impulsive sounds might affect the distribution and behavior of some fishes, potentially impacting foraging opportunities or increasing energetic costs (*e.g.,* Fewtrell and McCauley, 2012; Pearson *et al.,* 1992; Skalski *et al.,* 1992; Santulli *et al.,* 1999; Paxton *et al.,* 2017). However, some studies have shown no or slight reaction to impulse sounds (*e.g.,* Peña *et al.,* 2013; Wardle *et al.,* 2001; Jorgenson and Gyselman, 2009; Cott *et al.,* 2012). More commonly, though, the impacts of noise on fishes are temporary.

During the POA's MTRP, the effects of impact and vibratory installation of 30-inch (76-cm) steel sheet piles at the POA on 133 caged juvenile coho salmon in Knik Arm were studied (Hart Crowser Incorporated *et al.,* 2009; Houghton *et al.,* 2010). Acute or delayed mortalities, or behavioral abnormalities were not observed in any of the coho salmon. Furthermore, results indicated that the pile driving had no adverse effect on feeding ability or the ability of the fish to respond normally to threatening stimuli (Hart Crowser Incorporated *et al.,* 2009; Houghton *et al.,* 2010).

SPLs of sufficient strength have been known to cause injury to fishes and fish mortality (summarized in Popper *et al.,* 2014). However, in most fish species, hair cells in the ear continuously regenerate and loss of auditory function likely is restored when damaged cells are replaced with new cells. Halvorsen *et al.* (2012b) showed that a TTS of 4 to 6 dB was recoverable within 24 hours for one species. Impacts would be most severe when the individual fish is close to the source and when the duration of exposure is long. Injury caused by barotrauma can range from slight to severe and can cause death, and is most likely for fish with swim bladders. Barotrauma injuries have been documented during controlled exposure to impact pile driving (Halvorsen *et al.,* 2012a; Casper *et al.,* 2013, 2017).

Fish populations in the proposed project area that serve as marine mammal prey could be temporarily affected by noise from pile installation and removal. The frequency range in which fishes generally perceive underwater sounds is 50 to 2,000 Hz, with peak sensitivities below 800 Hz (Popper and Hastings, 2009). Fish behavior or distribution may change, especially with strong and/or intermittent sounds that could harm fishes. High underwater SPLs have been documented to alter behavior, cause hearing loss, and injure or kill individual fish by causing serious internal injury (Hastings and Popper, 2005).

Essential Fish Habitat (EFH) has been designated in the estuarine and marine waters in the vicinity of the proposed project area for all five species of salmon (*i.e.,* chum salmon, pink salmon, coho salmon, sockeye salmon, and Chinook salmon; North Pacific Fishery Management Council (NPFMC), 2020, 2021), which are common prey of marine mammals, as well as for other species. (NPFMC, 2020). However, there are no designated habitat areas of particular concern in the vicinity of the Port, and therefore, adverse effects on EFH in this area are not expected.

The greatest potential impact to fishes during construction would occur during impact pile removal. However, the use of impact pile driving would be limited to situations when sheet piles remain seized in the sediments and cannot be loosened or broken free with a vibratory hammer. Further, use of an impact hammer to dislodge piles is expected to be uncommon, with a limited number of up to 150 strikes (an estimated 50 strikes per pile for up to three piles) on any individual day or approximately 5 percent of active hammer duration for sheet pile. In-water construction activities would only occur during daylight hours, allowing fish to forage and transit the project area in the evening. Vibratory pile driving would possibly elicit behavioral reactions from fishes such as temporary avoidance of the area but is unlikely to cause injuries to fishes or have persistent effects on local fish populations. Construction also would have minimal permanent and temporary impacts on benthic invertebrate species, a marine mammal prey source. In addition, it should be noted that the area in question is low-quality habitat since it is already highly developed and experiences a high level of anthropogenic noise from normal operations and other vessel traffic at the POA.

Fish species in Knik Arm, including those that are prey for marine mammals, are expected to benefit from removal of the North Extension bulkhead and availability of the resulting exposed subtidal and intertidal habitat. NES1 is not anticipated to impede migration of adult or juvenile salmon or to adversely affect the health and survival of the affected species at the population level. Once in-water pile installation and removal has ceased and NES1 is complete, the newly available habitat is expected to transition back to its original, more natural condition and provide foraging, migrating, and rearing habitats to fish and foraging habitat to marine mammals. In general, any negative impacts on marine mammal prey species are expected to be minor and temporary.

In-Water Construction Effects on Potential Foraging Habitat

The NES1 Project area has not been considered to be high-quality habitat for marine mammals or marine mammal prey, such as fish, and it is anticipated that the long-term impact on marine mammals associated with NES1 would be a permanent increase in potential habitat because of the removal of the North Extension bulkhead, restoring access of the area to marine mammals and fish. The NES1 project is not expected to result in any habitat related effects that could cause significant or long-term negative consequences for individual marine mammals or their populations, since installation and removal of in-water piles would be temporary and intermittent, and the re-creation of intertidal and subtidal habitats would be permanent. Therefore, impacts of the project are not likely to have adverse effects on marine mammal foraging habitat in the proposed project area.

Estimated Take

This section provides an estimate of the number of incidental takes proposed for authorization through the IHA, which will inform both NMFS' consideration of ''small numbers,'' and the negligible impact determinations.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the

MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes would primarily be by Level B harassment, as use of the acoustic sources (*i.e.,* vibratory and impact pile driving) has the potential to result in disruption of behavioral patterns for individual marine mammals. There is also some potential for auditory injury (Level A harassment) to result, primarily for high frequency cetaceans and phocids because predicted auditory injury zones are larger than for mid-frequency cetaceans and otariids. Auditory injury is unlikely to occur for mysticetes, mid-frequency cetaceans, and otariids due to measures described in the Proposed Mitigation section. The proposed mitigation and monitoring measures are expected to minimize the severity of the taking to the extent practicable. As described previously, no serious injury or mortality is anticipated or proposed to be authorized for this activity. Below we describe how the proposed take numbers are estimated.

For acoustic impacts, generally speaking, we estimate take by considering: (1) acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) the number of days of activities. We note that while these factors can contribute to a basic calculation to provide an initial prediction of potential takes, additional information that can qualitatively inform take estimates is also sometimes available (*e.g.,* previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the proposed take estimates.

Acoustic Thresholds

NMFS recommends the use of acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur PTS of some degree (equated to Level A harassment).

Level B Harassment—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source or exposure context (*e.g.,* frequency, predictability, duty cycle, duration of the exposure, signal-to-noise ratio, distance to the source), the environment (*e.g.,* bathymetry, other noises in the area, predators in the area), and the receiving animals (hearing, motivation, experience, demography, life stage, depth) and can be difficult to predict (*e.g.,* Southall *et al.,* 2007, 2021; Ellison *et al.,* 2012). Based on what the available science indicates and the practical need to use a threshold based on a metric that is both predictable and measurable for most activities, NMFS typically uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS generally predicts that marine mammals are likely to be behaviorally harassed in a manner considered to be Level B harassment when exposed to underwater anthropogenic noise above root-mean-squared pressure received levels (RMS SPL) of 120 dB re 1 µPa for continuous (*e.g.,* vibratory pile driving, drilling) and above RMS SPL 160 dB re 1 µPa for non-explosive impulsive (*e.g.,* seismic airguns) or intermittent (*e.g.,* scientific sonar) sources. Generally speaking, Level B harassment take estimates based on these behavioral harassment thresholds are expected to include any likely takes by TTS as, in most cases, the likelihood of TTS occurs at distances from the source less than those at which behavioral harassment is likely. TTS of a sufficient degree can manifest as behavioral harassment, as reduced hearing sensitivity and the potential reduced opportunities to detect important signals (conspecific communication, predators, prey) may result in changes in behavior patterns that would not otherwise occur.

The POA's proposed activity includes the use of continuous (vibratory pile driving) and intermittent (impact pile driving) noise sources, and therefore the RMS SPL thresholds of 120 and 160 dB re 1 µPa are applicable.

Level A harassment. NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0; NMFS, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). The POA's proposed activity includes the use of impulsive (impact pile driving) and non-impulsive (vibratory driving) sources.

These thresholds are provided in the table below. The references, analysis, and methodology used in the development of the thresholds are described in NMFS' 2018 Technical Guidance, which may be accessed at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.*

TABLE 6—THRESHOLDS IDENTIFYING THE ONSET OF PERMANENT THRESHOLD SHIFT

Hearing Group	PTS onset acoustic thresholds * (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	*Cell 1:* $L_{pk,flat}$: 219 dB; $L_{E,LF,24h}$: 183 dB	*Cell 2:* $L_{E,LF,24h}$: 199 dB.
Mid-Frequency (MF) Cetaceans	*Cell 3:* $L_{pk,flat}$: 230 dB; $L_{E,MF,24h}$: 185 dB	*Cell 4:* $L_{E,MF,24h}$: 198 dB.
High-Frequency (HF) Cetaceans	*Cell 5:* $L_{pk,flat}$: 202 dB; $L_{E,HF,24h}$: 155 dB	*Cell 6:* $L_{E,HF,24h}$: 173 dB.
Phocid Pinnipeds (PW) (Underwater)	*Cell 7:* $L_{pk,flat}$: 218 dB; $L_{E,PW,24h}$: 185 dB	*Cell 8:* $L_{E,PW,24h}$: 201 dB.
Otariid Pinnipeds (OW) (Underwater)	*Cell 9:* $L_{pk,flat}$: 232 dB; $L_{E,OW,24h}$: 203 dB	*Cell 10:* $L_{E,OW,24h}$: 219 dB.

* Dual metric acoustic thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds should also be considered.

Note: Peak sound pressure (L_{pk}) has a reference value of 1 µPa, and cumulative sound exposure level (L_E) has a reference value of 1µPa^{2}s. In this Table, thresholds are abbreviated to reflect American National Standards Institute standards (ANSI, 2013). However, peak sound pressure is defined by ANSI as incorporating frequency weighting, which is not the intent for NMFS' 2018 Technical Guidance. Hence, the subscript ''flat'' is being included to indicate peak sound pressure should be flat weighted or unweighted within the generalized hearing range. The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The cumulative sound exposure level thresholds could be exceeded in a multitude of ways (*i.e.,* varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these acoustic thresholds will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that are used in estimating the area ensonified above the acoustic thresholds, including source levels and transmission loss coefficient.

The sound field in the project area is the existing background noise plus additional construction noise from the proposed project. Marine mammals are expected to be affected via sound generated by the primary components of the project (*i.e.,* impact pile removal and vibratory pile installation and removal). Calculation of the area ensonified by the proposed action is dependent on the background sound levels at the project site, the source levels of the proposed activities, and the estimated transmission loss coefficients for the proposed activities at the site. These factors are addressed in order, below.

Background Sound Levels at the Port of Alaska. As noted in the Potential Effects of Specified Activities on Marine Mammals and Their Habitat Section of this notice, the POA is an industrial facility in a location with high levels of commercial vessel traffic, port operations (including dredging), and extreme tidal flow. Previous measurements of background noise at the POA have recorded a background SPL of 122.2 dB RMS (Austin *et al.,* 2016). NMFS concurs that this SPL reasonably represents background noise near the proposed project area, and therefore we have used 122.2 dB RMS as the threshold for Level B harassment (instead of 120 dB RMS).

Sound Source Levels of Proposed Activities. The intensity of pile driving sounds is greatly influenced by factors such as the type of piles (material and diameter), hammer type, and the physical environment (*e.g.,* sediment type) in which the activity takes place. In order to calculate the distances to the Level A harassment and the Level B harassment sound thresholds for the methods and piles being used in this project, the POA used acoustic monitoring data from sound source verification studies to develop proxy source levels for the various pile types, sizes and methods (Table 7). While site-specific sound source verification studies have been conducted at the POA, the vast majority of the measurements recorded in those studies were made when bubble curtains were deployed around the sound source, which act to attenuate sound levels (Austin *et al.,* 2016; I&R, 2021a, 2021b). Bubble curtains are not a feasible mitigation measure for the NES1 project due to the demolition and sequencing nature of the project (see the Proposed Mitigation section of this notice for additional discussion), and therefore the majority of the proposed proxy values for this project are based on measurements recorded from locations other than the POA.

Underwater sound was measured in 2008 at the POA for the MTRP during installation of sheet piles to assess potential impacts of sound on marine species. Sound levels for installation of sheet piles measured at 10 m typically ranged from 147 to 161 dB RMS, with a mean of approximately 155 dB RMS (James Reyff, unpublished data). An SSL of 162 dB RMS was reported in (CALTRANS, 2020) summary tables for 24-inch steel sheet piles. This is a more rigid type of sheet pile that requires a large vibratory driver (James Reyff, personal communication, August 26, 2020). Based on the 2008 measurements at the POA and the CALTRANS data, a value of 160 dB RMS was assumed for vibratory removal of sheet piles.

NMFS concurs that the source levels proposed by the POA for all pile sizes during impact hammering activities and vibratory installation of all pile types are appropriate to use for calculating harassment isopleths for the POA's proposed NES1 activities (Table 7). However, the source levels proposed by the POA for vibratory pile removal were based on limited data collected at the POA. Therefore, NMFS considered and evaluated all data related to unattenuated vibratory removal of 24-inch (61-cm) and 36-inch (91-cm) steel pipe piles available, including sound source verification data measured at the POA during the PCT project (Reyff *et al,* 2021a) and elsewhere (*i.e.,* Coleman, 2011; U.S. Navy, 2012; I&R, 2017). NMFS gathered data from publicly available reports that reported driving conditions and specified vibratory removal for certain piles. If vibratory removal was not specifically noted for a given pile, we excluded that data from the analysis. Mean RMS SPLs reported by these studies were converted into pressure values, and pressure values for piles from each project were averaged to give a single SPL for each project. The calculated project means were then averaged and converted back into dBs to give a single recommended SPL for each pile type.

Ten measurements were available for unattenuated vibratory removal of 24-inch (61-cm) piles: 3 from Columbia River Crossing in Oregon (mean RMS SPL of 172.4 dB; Coleman, 2011), 5 from Joint Expeditionary Base Little Creek in Norfolk, Virginia (mean RMS SPL of 148.2 dB; I&R, 2017), and 2 from the PCT project at the POA (mean RMS SPL of 168.7 dB; I&R, 2021a, 2023). The calculated average SPL for unattenuated vibratory removal of 24-inch (61-cm) steel pipe piles from these studies was 168 dB RMS (Table 7). Forty measurements were available for unattenuated vibratory removal of 36-inch (91-cm) piles: 38 from the U.S. Navy Test Pile Program at Naval Base Kitsap in Bangor, Washington (mean RMS SPL of 159.4 dB; U.S. Navy, 2012), and 2 from the PCT project at the POA (mean RMS SPL of 158.5 dB; I&R, 2021, 2023). The calculated average SPL for unattenuated vibratory removal of 36-inch (91-cm) steel pipe piles from these studies was 159 dB RMS (Table 7). Note that the proxy values in Table 7 represent SPL referenced at a distance of 10 m from the source. Interestingly, the RMS SPLs for the unattenuated vibratory removal of 24-inch (61-cm) piles was much louder than the unattenuated vibratory removal of 36-inch piles (91-cm), and even louder than the unattenuated vibratory installation of 24-inch piles. I&R (2023) suggest that at least for data recorded at the POA, the higher 24-inch (61-cm) removal levels are likely due to the piles being removed at rates of 1,600 to 1,700 revolutions per minute (rpm), while 36-inch (91-cm) piles, which are significantly heavier than 24-inch (61-cm) piles), were removed at a rate of 1,900 rpm. The slower rates combined with the lighter piles would cause the hammer to easily ''jerk'' or excite the 24-inch (61-cm) piles as they were extracted, resulting in a louder rattling sound and louder sound levels. This did not occur for the 36-inch (91-cm) piles, which were considerably heavier due to

increased diameter, longer length, and greater thickness.

TABLE 7—SUMMARY OF UNATTENUATED IN-WATER PILE DRIVING PROXY LEVELS

[at 10 m]

Pile type	Installation or removal	Peak SPL (re 1 μPa)	RMS SPL (re 1 μPa)	SEL (re 1 μPa^2-sec)	Source
Impact driving:					
Sheet pile	Removal	205	189	179	CALTRANS (2020).
Vibratory driving:					
Sheet pile	Removal (hammer or splitter)	NA	160	NA	CALTRANS (2015, 2020).
24-inch (61-cm) steel pipe.	Installation		161		U.S. Navy (2015).
	Removal		168		Coleman (2011), I&R (2017, 2021, 2023).
36-inch (91-cm steel pipe).	Installation		166		U.S. Navy (2015).
	Removal		159		U.S. Navy (2012), I&R (2021, 2023).

The POA assumes that a pile splitter would produce the same or similar sound levels as a vibratory hammer without the splitter attachment; therefore, the POA combined use of a vibratory hammer to remove sheet pile and use of a splitter into a single category (*i.e.,* vibratory hammer removal). NMFS is currently unaware of any hydroacoustic measurements of pile splitting with a vibratory hammer. Without additional data, NMFS preliminary accepts the POAs proposed SPLs and assessments. However, NMFS specifically requests comments on the proposed SPL values for vibratory pile splitting. If available, NMFS requests recommendations for available data on underwater measurements and potential impacts of these construction activities.

Transmission Loss. For unattenuated impact pile driving, the POA proposed to use 15 as the *TL* coefficient, meaning they assume practical spreading loss (*i.e.,* the POA assumes $TL = 15*\mathrm{Log}_{10}(\mathrm{range})$); NMFS concurs with this value and has used the practical spreading loss model for impact driving in this analysis.

The *TL* coefficient that the POA proposed for unattenuated vibratory installation and removal of piles is 16.5 (*i.e., TL* = $16.5*\mathrm{Log}_{10}(\mathrm{range})$). This value is an average of measurements obtained from two 48-in (122-cm) piles installed via an unattenuated vibratory hammer in 2016 (Austin *et al.,* 2016). To assess the appropriateness of this *TL* coefficient to be used for the proposed project, NMFS examined and analyzed additional *TL* measurements recorded at the POA. This includes a *TL* coefficient of 22 (deep hydrophone measurement) from the 2004 unattenuated vibratory installation of one 36-inch (91-cm) pile in Knik Arm (Blackwell, 2004), as well as *TL* coefficients ranging from 10.3 to 18.2 from the unattenuated vibratory removal of 24-inch (61 cm) and 36-inch (91-cm) piles and the unattenuated vibratory installation of one 48-in (122-cm) pile at the POA in 2021 (I&R 2021, 2023). To account for statistical interdependence due to temporal correlations and equipment issues across projects, values were averaged first within each individual project, and then across projects. The mean and median value of the measured *TL* coefficients for unattenuated vibratory piles in Knik Arm by project are equal to 18.9 and 16.5, respectively. NMFS proposes the use of the project median *TL* coefficient of 16.5 during unattenuated vibratory installation and removal of all piles during the NES1 project. This value is representative of all unattenuated vibratory measurements in the Knik Arm. Further, 16.5 is the mean of the 2016 measurements, which were made closer to the NES1 proposed project area than other measurements and were composed of measurements from multiple directions (both north and south/southwest).

Estimated Harassment Isopleths. All estimated Level B harassment isopleths are reported in Table 9. At POA, Level B harassment isopleths from the proposed project will be limited by the coastline along Knik Arm along and across from the project site. The maximum predicted isopleth distance is 5,968 m during vibratory removal of 24-inch (61-cm) steel pipe piles.

The ensonified area associated with Level A harassment is more technically challenging to predict due to the need to account for a duration component. Therefore, NMFS developed an optional User Spreadsheet tool to accompany the Technical Guidance that can be used to relatively simply predict an isopleth distance for use in conjunction with marine mammal density or occurrence to help predict potential takes. We note that because of some of the assumptions included in the methods underlying this optional tool, we anticipate that the resulting isopleth estimates are typically going to be overestimates of some degree, which may result in an overestimate of potential take by Level A harassment. However, this optional tool offers the best way to estimate isopleth distances when more sophisticated modeling methods are not available or practical. For stationary sources such as pile driving, the optional User Spreadsheet tool predicts the distance at which, if a marine mammal remained at that distance for the duration of the activity, it would be expected to incur PTS. Inputs used in the User Spreadsheet are reported in Table 8 and the resulting isopleths and ensonified areas are reported in Table 9.

TABLE 8—NMFS USER SPREADSHEET INPUTS

	Impact pile driving	Vibratory pile driving				
	Sheet pile	Sheet pile	24-inch (61-cm) steel pipe		36-inch (91-cm) steel pipe	
	Removal	Removal	Installation	Removal	Installation	Removal
Spreadsheet Tab Used.	E.1) Impact pile driving.	A.1) Non-Impul, Stat, Cont.	A.1) Non-Impul, Stat, Cont.	A.1) Non-Impul, Stat, Cont.	A.1) Non-Impul, Stat, Cont.	A.1) Non-Impul, Stat, Cont.
Source Level (SPL)	179 dB SEL	160 dB RMS	161 dB RMS	168 dB RMS	166 dB RMS	159 dB RMS.
Transmission Loss Coefficient.	15	16.5	16.5	16.5	16.5	16.5.
Weighting Factor Adjustment (kHz).	2	2.5	2.5	2.5	2.5	2.5.
Time to install/remove single pile (minutes).	.....	5	15	15	15	15.
Number of strikes per pile.	50					
Piles per day	3	24	12	12	12	12.
Distance of sound pressure level measurement (m).	10	10	10	10	10	10.

TABLE 9—CALCULATED DISTANCE AND AREAS OF LEVEL A AND LEVEL B HARASSMENT PER PILE TYPE AND PILE DRIVING METHOD

Activity	Pile type/size	Level A harassment distance (m)					Level B harassment distance (m) all hearing groups	Level B harassment area (km^2) all hearing groups
		LF	MF	HF	PW	OW		
Impact Removal ..	Sheet pile	153	6	182	82	6	858	1.44
Vibratory Installation.	24-inch (61-cm) ...	14	2	20	9	1	2,247	8.39
	36-inch (91-cm) ...	28	4	40	18	2	4,514	26.13
Vibratory or Splitter Removal.	Sheet pile	10	1	14	6	1	1,954	6.47
Vibratory Removal	24-inch (61-cm) ...	37	4	53	24	3	5,968	37.64
	36-inch (91-cm) ...	11	2	15	7	1	1,700	4.99

Marine Mammal Occurrence and Take Estimation

In this section we provide information about the occurrence of marine mammals, including density or other relevant information which will inform the take calculation. We also describe how the information provided above is synthesized to produce a quantitative estimate of the take that is reasonably likely to occur and proposed for authorization.

Gray Whale

Sightings of gray whales in the proposed project area are rare. Few, if any, gray whales are expected to approach the proposed project area. However, based on three separate sightings of single gray whales near the POA in 2020 and 2021 (61N Environmental, 2021, 2022a; Easley-Appleyard and Leonard, 2022), the POA anticipates that up to six individuals could be within estimated harassment zones during NES1 project activities. Therefore, NMFS proposes to authorize six takes by Level B harassment for gray whales during the NES1 project. Take by Level A harassment is not anticipated or proposed to be authorized. The Level A harassment zones (Table 9) are smaller than the required shutdown zones (see the Proposed Mitigation section). It is unlikely that a gray whale would enter and remain within the Level A harassment zone long enough to incur PTS.

Humpback Whale

Sightings of humpback whales in the proposed project area are rare, and few, if any, humpback whales are expected to approach the proposed project area. However, there have been a few observations of humpback whales near the POA as described in the Description of Marine Mammals in the Area of Specified Activities section of this notice. Based on the two sightings in 2017 of what was likely a single individual at the Anchorage Public Boat Dock at Ship Creek (ABR, Inc., 2017) south of the Project area, the POA requested authorization of six takes of humpback whales. However, given the maximum number of humpback whales observed within a single construction season was two (in 2017), NMFS instead anticipates that only up to four humpback whales could be exposed to project-related underwater noise during the NES1 project. Therefore, NMFS proposes to authorize four takes by Level B harassment for humpback whales during the NES1 project. Take by Level A harassment is not anticipated or proposed to be authorized. The Level A harassment zones (Table 9) are smaller than the required shutdown zones (see the Proposed Mitigation section), therefore, it is unlikely that a humpback whale would enter and remain within the Level A harassment zone long enough to incur PTS.

Killer Whale

Few, if any, killer whales are expected to approach the NES1 project area. No killer whales were sighted during previous monitoring programs for POA construction projects, including the 2016 TPP, 2020 PCT, and 2022 SFD projects (Prevel-Ramos *et al.,* 2006; Markowitz and McGuire, 2007; Cornick and Saxon-Kendall, 2008, 2009; Cornick *et al.,* 2010, 2011; ICRC, 2009, 2010, 2011, 2012; Cornick and Pinney, 2011;

Cornick and Seagars, 2016; 61N Environmental, 2021, 2022b), until PCT construction in 2021, when two killer whales were sighted (61N Environmental, 2022a). Previous sightings of transient killer whales have documented pod sizes in upper Cook Inlet between one and six individuals (Shelden *et al.,* 2003). Therefore, the POA conservatively estimates that no more than one small pod (assumed to be six individuals) could be within estimated harassment zones during NES1 project activities.

Take by Level A harassment is not anticipated or proposed to be authorized due to the implementation of shutdown zones, which would be larger than the Level A harassment zones (described below in the Proposed Mitigation section), and the low likelihood that killer whales would approach this distance for sufficient duration to incur PTS. Therefore, NMFS proposes to authorize six takes by Level B harassment for killer whales.

Harbor Porpoise

Monitoring data recorded from 2005 through 2022 were used to evaluate hourly sighting rates for harbor porpoises in the proposed NES1 area (see Table 4–3 in the POA's application). During most years of monitoring, no harbor porpoises were observed. However, there has been an increase in harbor porpoise sightings in upper Cook Inlet in recent decades (*e.g.,* 61N Environmental, 2021, 2022a; Shelden *et al.,* 2014). The highest sighting rate for any recorded year during in-water pile installation and removal was an average of 0.037 harbor porpoises per hour during PCT construction in 2021, when observations occurred across most months. Given the uncertainty around harbor porpoise occurrence at the POA and potential that occurrence is increasing, it is estimated that approximately 0.07 harbor porpoises per hour (the 2021 rate of 0.037 harbor porpoises per hour doubled) may be observed near the proposed NES1 area per hour of hammer use. With 246.5 hours of in-water pile installation and removal, we estimate that there could be 18 instances where harbor porpoises (0.07 harbor porpoises per hour * 246.5 hours = 17.3 harbor porpoises rounded up to 18 harbor porpoises) could be within estimated harassment zones during NES1 project activities.

Harbor porpoises are small, lack a visible blow, have low dorsal fins, an overall low profile, and a short surfacing time, making them difficult to observe (Dahlheim *et al.,* 2015). To account for the possibility that a harbor porpoise could enter a Level A harassment zone and remain there for sufficient duration to incur PTS before activities were shut down, the POA assumed that 5 percent of estimated harbor porpoise takes (one take of harbor porpoise; 5 percent of 18 = 0.9, rounded up to 1) could be taken by Level A harassment. In its request, the POA rounded this estimate up to two to account for the average group size of this species, However, NMFS has determined such adjustments are generally unnecessary for purposes of estimating potential incidents of Level A harassment and does not concur with the request. At relatively close distances, NMFS believes it unlikely that groups will necessarily adhere to each other for sufficient duration for the entire group to incur PTS. While it is unlikely that a harbor porpoise could enter a Level A harassment zone for sufficient duration to incur PTS given the proposed shutdown measures (see the Proposed Mitigation section for more information) and potential for avoidance behavior, this species moves quickly and can be difficult to detect and track, therefore, NMFS proposes to authorize 1 take by Level A harassment and 17 takes by Level B harassment for harbor porpoises, for a total of 18 instances of take.

Steller Sea Lion

Steller sea lions are anticipated to occur in low numbers within the proposed NES1 project area as summarized in the Description of Marine Mammals in the Area of Specified Activities section. Similar to the approach used above for harbor porpoises, the POA used previously recorded sighting rates of Steller sea lions near the POA to estimate requested take for this species. During SFD construction in May and June of 2022, the hourly sighting rate for Steller sea lions was 0.028. The hourly sighting rate for Steller sea lions in 2021, the most recent year with observations across most months, was approximately 0.01. Given the uncertainty around Steller sea lion occurrence at the POA and potential that occurrence is increasing, the POA estimated that approximately 0.06 Steller sea lions per hour (the May and June 2022 rate of 0.028 Steller sea lions per hour doubled) may be observed near the proposed NES1 project areas per hour of hammer use. With 246.5 hours of in-water pile installation and removal, the POA estimates that 15 Steller sea lions (0.06 sea lions per hour * 246.5 hours = 14.79 sea lions rounded up to 15) could be within estimated harassment zones during NES1 project activities. However, the highest number of Steller sea lions that have been observed during the 2020–2022 monitoring efforts at the POA was nine individuals (eight during PCT Phase 1 monitoring and one during NMFS 2021 monitoring). Given the POA's estimate assumes a higher Steller sea lion sighting rate (0.06) than has been observed at the POA and results in an estimate that is much larger than the number of Steller sea lions observed in a year, NMFS believes that the 15 estimated takes requested by the POA overestimates potential exposures of this species. NMFS instead proposed that nine Steller sea lions may be taken, by Level B harassment only, during the NES1 project.

The largest Level A harassment zone for Steller sea lions is 6 m. While it is unlikely that a Steller sea lion would enter a Level A harassment zone for sufficient duration to incur PTS, the POA is aware of a Steller sea lion that popped up next to a work skiff during the TPP in 2016, which was documented as a potential take by Level A harassment by the PSOs on duty at the time. Pile driving, however, was not occurring at the time the event was recorded and a brief observation of an animal within a Level A harassment zone does not necessarily mean the animal experienced Level A harassment (other factors such as duration within the harassment zone need to be taken into consideration). However, as a result of the aforementioned event, the POA requested authorization of an additional two takes of Steller sea lions by Level A harassment. Given the small Level A harassment zone (6 m), and proposed shutdown zones of ≥ 10 m, NMFS believes that it is unlikely that a Steller sea lion would be within the Level A harassment zone for sufficient duration to incur PTS. Therefore, NMFS does not propose to authorize take by Level A harassment for Steller sea lions. Rather, all 9 estimated takes are assumed to occur by Level B harassment, and no take by Level A harassment is proposed for authorization.

Harbor Seal

No known harbor seal haulout or pupping sites occur in the vicinity of the POA. In addition, harbor seals are not known to reside in the proposed NES1 project area, but they are seen regularly near the mouth of Ship Creek when salmon are running, from July through September. With the exception of newborn pups, all ages and sexes of harbor seals could occur in the NES1 project area. Any harassment of harbor seals during in-water pile installation and removal would involve a limited number of individuals that may

potentially swim through the NES1 project area or linger near Ship Creek.

The POA evaluated marine mammal monitoring data to calculate hourly sighting rates for harbor seals in the NES1 project area (see Table 4–1 in the POA's application). Of the 524 harbor seal sightings in 2020 and 2021, 93.7 percent of the sightings were of single individuals; only 5.7 percent of sightings were of two individual harbor seals, and only 0.6 percent of sightings reported three harbor seals. Sighting rates of harbor seals were highly variable and appeared to have increased during monitoring between 2005 and 2022. It is unknown whether any potential increase was due to local population increases or habituation to ongoing construction activities. The highest individual hourly sighting rate recorded for a previous year was used to quantify take of harbor seals for in-water pile installation and removal associated with NES1. This occurred in 2021 during PCT Phase 2 construction, when harbor seals were observed from May through September. A total of 220 harbor seal sightings were observed over 734.9 hours of monitoring, at an average rate of 0.30 harbor seal sightings per hour. The maximum monthly sighting rate occurred in September 2020 and was 0.51 harbor seal sightings per hour. Based on these data, the POA estimated that approximately one harbor seal (the maximum monthly sighting rate (0.51) rounded up) may be observed near the NES1 project per hour of hammer use. This approximate sighting rate of one harbor seal per hour was also used to calculate potential exposures of harbor seals for the SFD project (86 FR 50057, September 7, 2021). Therefore, the POA estimates that during the 246.5 hours of anticipated in-water pile installation and removal, up to 247 harbor seals (1 harbor seal per hour * 246.5 hours = 246.5 harbor seals, rounded up to 247) could be within estimated harassment zones.

Harbor seals often appear curious about onshore activities and may approach closely. The mouth of Ship Creek, where harbor seals linger, is about 2,500 m from the southern end of the NES1 and is therefore outside of the Level A harassment zones calculated for harbor seals (Table 9). However, given the potential difficulty of tracking individual harbor seals along the face of the NES1 site and their consistent low-level use of the POA area, NMFS anticipates the potential for some take by Level A harassment for harbor seals. For the SFD project, NMFS authorized 8.6 percent of estimated harbor seal takes as potential Level A harassment based on the proportion of previous harbor seal sightings within the estimated Level A harassment zones (86 FR 50057, September 7, 2021), but the NES1 Project is more distant from Ship Creek than SFD. NMFS therefore anticipates that a smaller proportion of takes by Level A harassment may occur during the NES1 project, and proposes to reduce this percentage to 5 percent. Therefore, NMFS proposes to authorize 13 harbor seal takes (5 percent of 247 exposures) by Level A harassment and 234 takes (247 potential exposures minus 13) by Level B harassment, for a total of 247 takes.

Beluga Whale

For the POA's PCT and SFD projects, NMFS used a sighting rate methodology to calculate potential exposure (equated to take) of CIBWs to sound levels above harassment criteria produced by the POA's construction activities (85 FR 19294, April 6, 2020; 86 FR 50057, September 7, 2021, respectively). For the PCT project, NMFS used data collected during marine mammal observations from 2005 to 2009 (Kendall and Cornick, 2015) and the total number of monthly observation hours during these efforts to derive hourly sighting rates of CIBWs per month of observation (April through November) (85 FR 19294, April 6, 2020). For the SFD project, observation data from 2020 PCT construction were also incorporated into the analysis (86 FR 50057, September 7, 2021; 61N Environmental, 2021).

The marine mammal monitoring programs for the PCT and SFD projects produced a unique and comprehensive data set of CIBW locations and movements (table 10; 61N Environmental, 2021, 2022a, 2022b; Easley-Appleyard and Leonard, 2022) that is the most current data set available for Knik Arm. During the PCT and SFD projects, the POA's marine mammal monitoring programs included 11 PSOs working from four elevated, specially designed monitoring stations located along a 9-km stretch of coastline surrounding the POA. The number of days data was collected varied among years and project, with 128 days during PCT Phase 1 in 2020, 74 days during PCT Phase 2 in 2021, and 13 days during SFD in 2022 (see Table 6–7 in the POA's application for additional information regarding CIBW monitoring data). PSOs during these projects used 25-power ''big-eye'' and hand-held binoculars to detect and identify marine mammals, and theodolites to track movements of CIBW groups over time and collect location data while they remained in view.

These POA monitoring programs were supplemented in 2021 with a NMFS-funded visual marine mammal monitoring project that collected data during non-pile driving days during PCT Phase 2 (table 10; Easley-Appleyard and Leonard, 2022). NMFS replicated the POA monitoring efforts, as feasible, including use of 2 of the POA's monitoring platforms, equipment (Big Eye binoculars, theodolite, 7x50 reticle binoculars), data collection software, monitoring and data collection protocol, and observers; however, the NMFS-funded program utilized only 4 PSOs and 2 observation stations along with shorter (4- to 8-hour) observation periods compared to PCT or SFD data collection, which included 11 PSOs, 4 observation stations, and most observation days lasting close to 10 hours. Despite the differences in effort, the NMFS dataset fills in gaps during the 2021 season when CIBW presence began to increase from low presence in July and is thus valuable in this analysis. NMFS' PSO's monitored for 231.6 hours on 47 non-consecutive days in July, August, September, and October.

Distances from CIBW sightings to the project site from the POA and NMFS-funded monitoring programs ranged from less than 10 m up to nearly 15 km during these monitoring programs. These robust marine mammal monitoring programs in place from 2020 through 2022 located, identified, and tracked CIBWs at greater distances from the proposed project site than previous monitoring programs (*i.e.,* Kendall and Cornick, 2015), and has contributed to a better understanding of CIBW movements in upper Cook Inlet (*e.g.,* Easley-Appleyard and Leonard, 2022).

Given the evolution of the best available data of CIBW presence in upper Cook Inlet, particularly regarding the distances at which CIBWs were being observed and documented (which increased during the PCT and SFD compared to earlier monitoring efforts), the POA proposes, and NMFS concurs, that the original sighting rate methodology used for the PCT and SFD projects is no longer the best approach for calculating potential take of CIBWs for the NES1 project. The recent and comprehensive data set of CIBW locations and movements from the PCT and SFD projects (61N Environmental, 2021, 2022a, 2022b; Easley-Appleyard and Leonard, 2022) provides the opportunity for refinement of the previously used sighting rate methodology with updated data. Data for 2020, 2021, and 2022 were selected for the updated sighting rate analysis for the NES1 proposed project because they are the most current data available and are therefore most likely to accurately

represent future CIBW occurrence at the proposed project site, which may be affected by CIBW population size, CIBW movement patterns through Knik Arm, environmental change (including climate change), differences in salmon and other prey abundance among years, and other factors (table 10). The data from 2005 to 2009 (Kendall and Cornick, 2015), which was used by NMFS for sighting rate analyses for the PCT and SFD IHAs, were not included in this analysis due to the changes in observation programs and age of the data collected. Monitoring data from the 2016 TPP (Cornick and Seagars, 2016) were also not included in the analysis because of limited hours observed, limited seasonal coverage, and differences in the observation programs.

TABLE 10—MARINE MAMMAL MONITORING DATA USED FOR CIBW SIGHTING RATE CALCULATIONS

Year	Monitoring type and data source	Number of CIBW group fixes	Number of CIBW groups	Number of CIBWs
2020 ..	PCT: POA Construction Monitoring 61N Environmental, 2021	2,653	245	987
2021 ..	PCT: NMFS Monitoring Easley-Appleyard and Leonard, 2022	694	[1]109	575
2021 ..	PCT: POA Construction Monitoring 61N Environmental, 2021, 2022a	1,339	132	517
2022 ..	SFD: POA Construction Monitoring 61N Environmental, 2022b	151	9	41

[1] This number differs slightly from Table 6–8 in the POA's application due to our removal of a few duplicate data points in the NMFS data set.

The sighting rate methodology used for the PCT (85 FR 19294, April 6, 2020) and SFD (86 FR 50057, September 7, 2021) projects used observations of CIBWs recorded in Knik Arm, regardless of observation distance to the POA, to produce a single monthly sighting rate that was then used to calculate potential CIBW take for all activities, regardless of the size of the ensonified areas for the project activities (*i.e.,* take was calculated solely based on the monthly sighting rates and the estimated hours of proposed activities, and did not consider the estimated sizes of the ensonified areas). This method may have overestimated potential CIBW takes when harassment zones were small because distant CIBWs would have been included in the sighting rate. This method also resulted in takes estimates that were identical for installation and removal of all pile sizes, regardless of pile driving method used (*e.g.,* vibratory, impact) or implementation of attenuation systems, since the calculation did not consider the size of the ensonified areas.

NMFS and the POA collaboratively developed a new sighting rate methodology for the NES1 project that incorporates a spatial component for CIBW observations, which would allow for more accurate estimation of potential take of CIBWs for this project. NMFS proposes to use this approach to estimate potential takes of CIBW for authorization. During the POA's and NMFS' marine mammal monitoring programs for the PCT and SFD projects, PSOs had an increased ability to detect, identify, and track CIBWs groups at greater distances from the project work site when compared with previous years because of the POA's expanded monitoring program as described above. This meant that observations of CIBWs in the 2020–2022 dataset (table 10) include sightings of individuals at distances far outside the ensonified areas estimated for the NES1 project (Table 9). Therefore, it would not be appropriate to group all CIBW observations from these datasets into a single sighting rate as was done for the PCT and SFD projects. Rather, we propose that CIBW observations should be considered in relation to their distance to the NES1 project site when determining appropriate sighting rates to use when estimating take for this project. This would help to ensure that the sighting rates used to estimate take are representative of CIBW presence in the proposed ensonified areas.

To incorporate a spatial component into the sighting rate methodology, the POA calculated each CIBW group's closest point of approach (CPOA) relative to the NES1 proposed project site. The 2020–2022 marine mammal monitoring programs (table 10) enabled the collection, in many cases, of multiple locations of CIBW groups as they transited through Knik Arm, which allowed for track lines to be interpolated for many groups. The POA used these track lines, or single recorded locations in instances where only one sighting location was available, to calculate each group's CPOA. CPOAs were calculated in ArcGIS software using the GPS coordinates provided for documented sightings of each group (for details on data collection methods, see 61N Environmental, 2021, 2022a, 2022b; Easley-Appleyard and Leonard, 2022) and the NES1 location midpoint, centered on the proposed project site. A CIBW group was defined as a sighting of one or more CIBWs as determined during data collection. The most distant CPOA location to NES1 was 11,057 m and the closest CPOA location was 15 m.

The cumulative density distribution of CPOA values represents the percentage of CIBW observations that were within various distances to the NES1 action site (Figure 2). This distribution shows how CIBW observations differed with distances to the NES1 site and was used to infer appropriate distances within which to estimate spatially-derived CIBW sighting rates (Figure 2). The POA implemented a piecewise regression model that detected breakpoints (*i.e.,* points within the CPOA data at which statistical properties of the sequence of observational distances changed) in the cumulative density distribution of the CPOA locations, which they proposed to represent spatially-based sighting rate bins for use in calculating CIBW sighting rates. The POA used the ''Segmented'' package (Muggeo, 2020) in the R Statistical Software Package (R Core Team, 2022) to determine statistically significant breakpoints in the linear distances of the CIBW data using this regression method (see Section 6.5.5.3 of the POA's application for more details regarding this statistical analysis). This analysis identified breakpoints in the CPOA locations at 74, 1,651, 2,808, and 7,369 m (Figure 2).

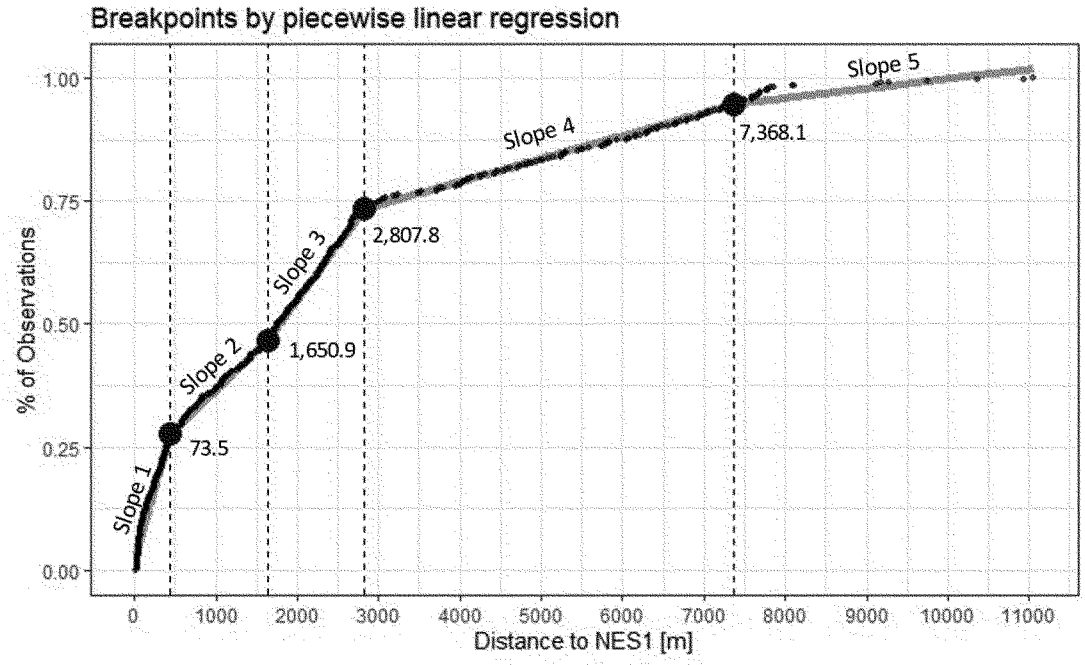

Figure 2 -- Percent of CIBW CPOA Observations in Relation to Distance from the NES1 Project Site and Associated Breakpoints Determined by Piecewise Linear Regression

Piecewise regression is a common tool for modeling ecological thresholds (Lopez *et al.,* 2020; Whitehead *et al.,* 2016; Atwood *et al.,* 2016). In a similar scenario to the one outlined above, Mayette *et al.* (2022) used piecewise regression methods to model the distances between two individual CIBWs in a group in a nearshore and a far shore environment. For the POA's analysis, the breakpoints (*i.e.,* 74, 1,651, 2,808, and 7,369 m) detect a change in the frequency of CIBW groups sighted and the slope of the line between two points indicates the magnitude of change. A greater positive slope indicates a greater accumulation of sightings over the linear distance (x-axis) between the defining breakpoints, whereas a more level slope (*i.e.,* closer to zero) indicates a lower accumulation of sightings over that linear distance (x-axis) between those defining breakpoints (Figure 2; see Table 6–8 in the POA's application for the slope estimates for the empirical cumulative distribution function).

The breakpoints identified by the piecewise regression analysis are in agreement with what is known about CIBW behavior in Knik Arm based on recent monitoring efforts (61N Environmental, 2021, 2022a, 2022b; Easley-Appleyard and Leonard, 2022). Observation location data collected during POA monitoring programs indicate that CIBWs were consistently found in higher numbers in the nearshore areas, along both shorelines, and were found in lower numbers in the center of the Arm. Tracklines of CIBW group movements collected from 2020 to 2022 show that CIBWs displayed a variety of movement patterns that included swimming close to shore past the POA on the east side of Knik Arm (defined by breakpoint 1 at 74 m), with fewer CIBWs swimming in the center of Knik Arm (breakpoints 1 to 2, at 74 to 1,651 m). CIBWs commonly swam past the POA close to shore on the west side of Knik Arm, with no CIBWs able to swim farther from the POA in that area than the far shore (breakpoints 2 to 3, at 1,651 to 2,808 m). Behaviors and locations beyond breakpoint 4 (7,369 m) include swimming past the mouth of Knik Arm between the Susitna River area and Turnagain Arm; milling at the mouth of Knik Arm but not entering the Arm; and milling to the northwest of the POA without exiting Knik Arm. The shallowness of slope 5, at distances greater than 7,369 m, could be due to detection falloff from a proximity (distance) bias, which would occur when PSOs are less likely to detect CIBW groups that are farther away than groups that are closer.

The POA, in collaboration with NMFS, used the distances detected by the breakpoint analysis to define five sighting rate distance bins for CIBWs in the NES1 project area. Each breakpoint (74, 1,651, 2,808, and 7,369 m, and the complete data set of observations [≤ 7,369 m]) was rounded up to the nearest meter and considered the outermost limit of each sighting rate bin, resulting in five identified bins (table 11). All CIBW observations less than each bin's breakpoint distance were used to calculated that bin's respective monthly sighting rates (*e.g.,* all sightings from 0 to 74 m are included in the sighting rates calculated for bin number 1, all sightings from 0 to 1,651 m are included in the sighting rates calculated for bin number 2, and so on). NES1 demolition is anticipated to take place from April through November 2024, therefore monthly sighting rates were only derived for these months (table 11).

TABLE 11—CIBW MONTHLY SIGHTING RATES FOR DIFFERENT SPATIALLY-BASED BIN SIZES

Bin No.	Distance (m)	CIBW/hour [1]							
		April	May	June	July	August	September	October	November
1	≤ 74	0.09	0.06	0.10	0.04	0.83	0.62	0.51	0.11
2	≤ 1,651	0.25	0.14	0.13	0.06	1.43	1.30	1.15	0.70
3	≤ 2,808	0.36	0.22	0.21	0.07	2.08	1.90	2.04	0.73
4	≤ 7,369	0.67	0.33	0.29	0.13	2.25	2.19	2.42	0.73
5	> 7,369	0.71	0.39	0.30	0.13	2.29	2.23	2.56	0.73

[1] Observation hours have been totaled from the PCT 2020 and 2021 programs, the NMFS 2021 data collection effort, and the SFD 2022 program (61N Environmental 2021, 2022a, 2022b; Easley-Appleyard and Leonard, 2022).

Potential exposures (equated with takes) of CIBWs were calculated by multiplying the total number of vibratory installation or removal hours per month for each sized/shaped pile based on the anticipated construction schedule (table 2) with the corresponding sighting rate month and sighting rate distance bin (table 12). For example, the Level B harassment isopleth distance for the vibratory installation of 24-inch (61-cm) piles is 2,247 m, which falls within bin number 3 (table 11). Therefore, take for this activity is calculated by multiplying the total number of hours estimated each month to install 24-inch piles via a vibratory hammer by the monthly CIBW sighting rates calculated for bin number 3 (table 12). The resulting estimated CIBW exposures were totaled for all activities in each month (table 13).

In their calculation of CIBW take, the POA assumed that only 24-inch (61-cm) template piles would be installed (rather than 36-inch, 91-cm) and removed during the project due to the vibratory removal of 24-inch piles having the largest isopleth. If 36-inch (61-cm) piles are used for temporary stability template piles, it would be assumed that the potential impacts of this alternate construction scenario and method on marine mammals are fungible (*i.e.,* that potential impacts of installation and removal of 36-inch (91-cm) steel pipe piles would be similar to the potential impacts of installation and removal of 24-inch (61-cm) steel pipe piles). Using the monthly activity estimates in hours (Table 2) and monthly calculated sighting rates (CIBWs/hour) for the spatially derived distance bins (table 12), the POA estimates that there could be up to 122 (121.1 rounded up to 122) instances of CIBW take where during the NES1 project (table 13).

TABLE 12—ALLOCATION OF EACH LEVEL B HARASSMENT ISOPLETH TO A SIGHTING RATE BIN AND CIBW MONTHLY SIGHTING RATES FOR DIFFERENT PILE SIZES AND HAMMER TYPES

	Level B harassment isopleth distance (m)	Sighting rate bin number and distance	CIBWs/hour							
			April	May	June	July	August	September	October	November
24-inch Vibratory Installation	2,247	3 (2,808 m)	0.36	0.22	0.21	0.07	2.08	1.90	2.04	0.73
24-inch Vibratory Removal	5,968	4 (7,369 m)	0.67	0.33	0.29	0.13	2.25	2.19	2.42	0.73
36-inch Vibratory Installation	4,514	4 (7,369 m)	0.67	0.33	0.29	0.13	2.25	2.19	2.42	0.73
36-inch Vibratory Removal	1,700	3 (2,808 m)	0.36	0.22	0.21	0.07	2.08	1.90	2.04	0.73
Sheet Pile Vibratory Removal	1,954	3 (2,808 m)	0.36	0.22	0.21	0.07	2.08	1.90	2.04	0.73
Observation Hours/ Month [1]:			87.9	615.1	571.6	246.9	224.5	326.2	109.5	132.0

[1] Observation hours have been totaled from the PCT 2020 and 2021 programs, the NMFS 2021 data collection effort, and the SFD 2022 program (61N Environmental, 2021, 2022a, 2022b; Easley-Appleyard and Leonard, 2022).

For the PCT (85 FR 19294, April 6, 2020) and SFD (86 FR 50057, September 7, 2021) projects, NMFS accounted for the implementation of mitigation measures (*e.g.,* shutdown procedures implemented when CIBWs entered or approached the estimated Level B harassment zone) by applying an adjustment factor to CIBW take estimates. This was based on the assumption that some Level B harassment takes would likely be avoided based on required shutdowns for CIBWs at the Level B harassment zones (see the Proposed Mitigation section for more information). For the PCT project, NMFS compared the number of realized takes at the POA to the number of authorized takes for previous projects from 2008 to 2017 and found the percentage of realized takes ranged from 12 to 59 percent with an average of 36 percent (85 FR 19294, April 6, 2020). NMFS then applied the highest percentage of previous realized takes (59 percent during the 2009–2010 season) to ensure potential takes of CIBWs were fully evaluated. In doing so, NMFS assumed that approximately 59 percent of the takes calculated would be realized during PCT and SFD construction (85 FR 19294, April 6, 2020; 86 FR 50057, September 7, 2021) and that 41 percent of the calculated CIBW Level B harassment takes would be avoided by successful

implementation of required mitigation measures.

The POA calculated the adjustment for successful implementation of mitigation measures for NES1 using the percentage of realized takes for the PCT project (see Table 6–12 in the POA's application). The recent data from PCT Phase 1 and PCT Phase 2 most accurately reflect the current marine mammal monitoring program, the current program's effectiveness, and CIBW occurrence in the proposed project area. Between the two phases of the PCT project, 90 total Level B harassment takes were authorized and 53 were potentially realized (*i.e.,* number of CIBWs observed within estimated Level B harassment zones), equating to an overall percentage of 59 percent. The SFD Project, during which only 7 percent of authorized take was potentially realized, represents installation of only 12 piles during a limited time period and does not represent the much higher number of piles and longer construction season anticipated for NES1.2

NMFS proposes that the 59-percent adjustment accurately accounts for the efficacy of the POA's marine mammal monitoring program and required shutdown protocols. NMFS therefore assumes that approximately 59 percent of the takes calculated for NES1 may actually be realized. This adjusts the potential takes by Level B harassment of CIBWs proposed for authorization from 122 to 72 (table 13). Take by Level A harassment is not anticipated or proposed to be authorized because the POA will be required to shutdown activities when CIBWs approach and or enter the Level B harassment zone (see the Proposed Mitigation section for more information).

TABLE 13—POTENTIAL MONTHLY CIBW LEVEL B HARASSMENT EXPOSURES

	April	May	June	July	August	September	October	November	Total
24-inch Vibratory Installation and Removal	2.5	3.0	1.7	0.6	12.5	6.9	3.9	0.2	31.3
Sheet Pile Removal	3.6	9.9	12.5	4.4	27.0	22.8	8.1	1.5	89.8
Total Estimated Level B Harassment Exposures for All Activities (Rounded):									121.1
Total Estimated Level B Harassment Exposures with 59% Correction Factor (Rounded):									71.5 (72)

In summary, the total amount of Level A harassment and Level B harassment proposed to be authorized for each marine mammal stock is presented in table 14.

TABLE 14—AMOUNT OF PROPOSED TAKE AS A PERCENTAGE OF STOCK ABUNDANCE, BY STOCK AND HARASSMENT TYPE

Species	Proposed take			Stock	Percent of stock
	Level A	Level B	Total		
Gray whale	0	6	6	Eastern North Pacific	[1] 0.02
Humpback whale	0	4	4	Hawai'i	[1] 0.04
				Mexico-North Pacific	[2] UNK
Beluga whale	0	72	72	Cook Inlet	21.75
Killer whale	0	6	6	Eastern North Pacific Alaska Resident	[1] 0.31
				Eastern North Pacific Gulf of Alaska, Aleutian Islands and Bering Sea Transient.	1.02[1]
Harbor porpoise	1	17	18	Gulf of Alaska	0.06
Steller sea lion	0	9	9	Western	0.02
Harbor seals	13	234	247	Cook Inlet/Shelikof Strait	0.87

[1] NMFS conservatively assumes that all takes occur to each stock.
[2] NMFS does not have an official abundance estimate for this stock and the minimum population estimate is considered to be unknown (Young *et al.,* 2023).

Proposed Mitigation

In order to issue an IHA under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock for taking for certain subsistence uses (latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or stocks, and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, NMFS considers two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation (probability implemented as planned), and;

(2) The practicability of the measures for applicant implementation, which may consider such things as cost, and impact on operations.

The POA presented mitigation measures in Section 11 of their application that were modeled after the requirements included in the IHAs issued for Phase 1 and Phase 2 PCT construction (85 FR 19294, April 6, 2020) and for SFD construction (86 FR 50057, September 7, 2021), which were designed to minimize the total number, intensity, and duration of harassment events for CIBWs and other marine mammal species during those projects (61N Environmental, 2021, 2022a, 2022b). NMFS concurs that these proposed measures reduce the potential for CIBWs, and other marine mammals, to be adversely impacted by the proposed activity.

The POA must employ the following mitigation measures:

- Ensure that construction supervisors and crews, the monitoring team and relevant POA staff are trained prior to the start of all pile driving, so that responsibilities, communication procedures, monitoring protocols, and operational procedures are clearly understood. New personnel joining during the project must be trained prior to commencing work;
- Employ PSOs and establish monitoring locations as described in Section 5 of the IHA and the POA's Marine Mammal Monitoring and Mitigation Plan (see Appendix B of the POA's application). The POA must monitor the project area to the maximum extent possible based on the required number of PSOs, required monitoring locations, and environmental conditions;
- Monitoring must take place from 30 minutes prior to initiation of pile driving (*i.e.,* pre-clearance monitoring) through 30 minutes post-completion of pile driving;
- Pre-start clearance monitoring must be conducted during periods of visibility sufficient for the lead PSO to determine that the shutdown zones indicated in table 15 are clear of marine mammals. Pile driving may commence following 30 minutes of observation when the determination is made that the shutdown zones are clear of marine mammals or when the mitigation measures proposed specifically for CIBWs (below) are satisfied;
- For all construction activities, shutdown zones must be established following table 15. The purpose of a shutdown zone is generally to define an area within which shutdown of activity would occur upon sighting of a marine mammal (or in anticipation of an animal entering the defined area). In addition to the shutdown zones specified in table 15 and the minimum shutdown zone of 10-m described above, requirements included in NMFS' proposed IHA, the POA plans to implement a minimum 100-m shutdown zone around the active NES1 project work site, including around activities other than pile installation or removal that NMFS has determined do not present a reasonable potential to cause take of marine mammals. Shutdown zones for pile installation and removal would vary based on the type of construction activity and by marine mammal hearing group (table 15). Here, shutdown zones are larger than or equal to the calculated Level A harassment isopleths shown in table 9 for species other than CIBW and are equal to the estimated Level B harassment isopleths for CIBWs;

TABLE 15—PROPOSED SHUTDOWN ZONES DURING PROJECT ACTIVITIES

Activity	Pile type/size	Shutdown zone (m)				PW	OW
		LF cetaceans	Non-CIBW MF cetaceans	CIBWs	HF cetaceans		
Impact Removal	Sheet pile	160	10	900	190	90	10
Vibratory Installation.	24-inch (61-cm)	20	10	2,300	20	10	10
	36-inch (91-cm)	30	10	4,600	40	20	10
Vibratory Removal	Sheet pile	10	10	2,000	20	10	10
	24-inch (61-cm)	40	10	6,000	60	30	10
	36-inch (91-cm)	20	10	1,700	20	10	10

Notes: cm = centimeter(s), m = meter(s).

- Marine mammals observed anywhere within visual range of the PSO must be tracked relative to construction activities. If a marine mammal is observed entering or within the shutdown zones indicated in table 15, pile driving must be delayed or halted. If pile driving is delayed or halted due to the presence of a marine mammal, the activity may not commence or resume until either the animal has voluntarily exited and been visually confirmed beyond the shutdown zone (table 15, or 15 minutes (non-CIBWs) or 30 minutes (CIBWs) have passed without re-detection of the animal;
- The POA must use soft start techniques when impact pile driving. Soft start requires contractors to provide an initial set of three strikes at reduced energy, followed by a 30-second waiting period, then two subsequent reduced energy strike sets. A soft start must be implemented at the start of each day's impact pile driving and at any time following cessation of impact pile driving for a period of 30 minutes or longer. PSOs shall begin observing for marine mammals 30 minutes before ''soft start'' or in-water pile installation or removal begins;
- Pile driving activity must be halted upon observation of either a species for which incidental take is not authorized or a species for which incidental take has been authorized but the authorized number of takes has been met, entering or within the harassment zone; and
- The POA must avoid direct physical interaction with marine mammals during construction activities. If a marine mammal comes within 10 m of such activity, operations shall cease. Should a marine mammal come within 10 m of a vessel in transit, the boat operator will reduce vessel speed to the minimum level required to maintain steerage and safe working conditions. If human safety is at risk, the in-water activity will be allowed to continue until it is safe to stop.

The following additional mitigation measures are proposed by NMFS for CIBWs:

- The POA must make all practicable efforts to complete construction activities between April and July, when CIBWs are typically found in lower numbers near the proposed site;
- Prior to the onset of pile driving, should a CIBW be observed approaching the estimated Level B harassment zone (Table 9) (*i.e.* the CIBWs shutdown zone column in Table 15), pile driving must not commence until the whale(s) moves

at least 100 m past the estimated Level B harassment zone and on a path away from the zone, or the whale has not been re-sighted within 30 minutes;

- If pile installation or removal has commenced, and a CIBW(s) is observed within or likely to enter the estimated Level B harassment zone, pile installation or removal must shut down and not re-commence until the whale has traveled at least 100 m beyond the Level B harassment zone and is on a path away from such zone or until no CIBW has been observed in the Level B harassment zone for 30 minutes; and
- If during installation and removal of piles, PSOs can no longer effectively monitor the entirety of the CIBW Level B harassment zone due to environmental conditions (*e.g.,* fog, rain, wind), pile driving may continue only until the current segment of the pile is driven; no additional sections of pile or additional piles may be driven until conditions improve such that the Level B harassment zone can be effectively monitored. If the Level B harassment zone cannot be monitored for more than 15 minutes, the entire Level B harassment zone will be cleared again for 30 minutes prior to pile driving.

In addition to these additional mitigation measures being proposed by NMFS, NMFS requested that the POA restrict all pile driving and removal work to April to July, when CIBWs are typically found in lower numbers. However, given the safety and environmental concerns of collapse of the Northern Extension once removal work commences, required sequencing of pile installation and removal and fill removal, and uncertainties and adaptive nature of the work, the POA stated that it cannot commit to restricting pile driving and removal to April to July. Instead, as required in the proposed mitigation, NMFS would require the POA to complete as much work as is practicable in April to July to reduce the amount of pile driving and removal activities in August through November.

For previous IHAs issued to the POA (PCT: 85 FR 19294, April 6, 2020; SFD: 86 FR 50057, September 7, 2021), the use of a bubble curtain to reduce noise has been required as a mitigation measure for certain pile driving scenarios. The POA did not propose to use a bubble curtain system during the NES1 project, stating that it is not a practicable mitigation measure for this demolition project. NMFS concurs with this determination. Practicability concerns include the following:

- NES1 construction activities includes installation of round, temporary, stability template piles to shore up the filled NES1 structure while fill material and sheet piles are removed. Stability template piles that would be required for demolition of the sheet pile structure are located in proximity of the sheet piles. A bubble curtain would not physically fit between the sheet piles and the template piles;
- Bubble curtains could not be installed around the sheet piles as they are removed because the structure consists of sheet piles that are connected to one another and used to support fill-material. It would not be possible to place a bubble curtain system along the sheet pile face for similar reasons, including lack of space for the bubble curtain and the structures and equipment that would be needed to install and operate it, and the high likelihood that it could not function or be retrieved; and
- NES1 is a failed structure, and has been deemed ''globally unstable'' and poses significant risk for continued deterioration and structural collapse. If the existing structure were to collapse during deconstruction and sheet pile removal, there is risk of a significant release of impounded fill material into CIBW habitat, the POA's vessel operating and mooring areas, and the USACE Anchorage Harbor Project. Due to the stability risk of the existing impounded material, it is expected that construction and demolition means and methods would be highly adaptive once actual field work commences, and use of a bubble curtain with deconstruction would limit operations in the field and create significant health and safety issues.

The POA also has efficacy concerns about requiring a bubble curtain for NES1 construction activities. Adding a requirement for a bubble curtain may hinder production, due to the time required to install and remove the bubble curtain itself. This has the potential to drive the in-water construction schedule further into the late summer months, which are known for higher CIBW abundance in lower Knik Arm, thus lengthening the duration of potential interactions between CIBW and in-water works. Therefore, NMFS is concerned that use of a bubble curtain may not be an effective measure, given the potential that bubble curtain use could ultimately result in increased impacts to CIBW, in addition to the aforementioned practicability issues.

Based on our evaluation of the applicant's proposed measures, as well as other measures considered by NMFS, NMFS has preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present while conducting the activities. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.,* presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) affected species (*e.g.,* life history, dive patterns); (3) co-occurrence of marine mammal species with the activity; or (4) biological or behavioral context of exposure (*e.g.,* age, calving or feeding areas);
- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
- How anticipated responses to stressors impact either: (1) long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
- Effects on marine mammal habitat (*e.g.,* marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and,
- Mitigation and monitoring effectiveness.

The POA would implement a marine mammal monitoring and mitigation strategy intended to avoid and minimize

impacts to marine mammals (see Appendix B of the POA's application for their Marine Mammal Monitoring and Mitigation Plan). Marine mammal monitoring would be conducted at all times when in-water pile installation and removal is taking place. Additionally, PSOs would be on-site monitoring for marine mammals during in-water cutting of sheet piles with shears or an ultrathermic torch.

The marine mammal monitoring and mitigation program that is planned for NES1 construction would be modeled after the stipulations outlined in the IHAs for Phase 1 and Phase 2 PCT construction (85 FR 19294, April 6, 2020) and the IHA for SFD construction (86 FR 50057, September 7, 2021).

Visual Monitoring

Monitoring must be conducted by qualified, NMFS-approved PSOs, in accordance with the following:

- PSOs must be independent of the activity contractor (*e.g.,* employed by a subcontractor) and have no other assigned tasks during monitoring periods. At least one PSO must have prior experience performing the duties of a PSO during construction activity pursuant to a NMFS-issued IHA or Letter of Concurrence. Other PSOs may substitute other relevant experience, education (degree in biological science or related field), or training for prior experience performing the duties of a PSO. PSOs must be approved by NMFS prior to beginning any activity subject to this IHA;
- The POA must employ PSO stations at a minimum of two locations from which PSOs can effectively monitor the shutdown zones (Table 15). Concerns about the stability of the NES1 project area preclude determination of the exact number and locations of PSO stations until the Construction Contractor develops their Construction Work Plan. PSO stations must be positioned at the best practical vantage points that are determined to be safe. Likely locations include the Anchorage Public Boat Dock at Ship Creek to the south of the proposed project site, and a location to the north of the project site, such as the northern end of POA property near Cairn Point (see North Extension area on Figure 12–1 in the POA's application) or at Port MacKenzie across Knik Arm (see Figure 12–1 in the POA's application for potential locations of PSO stations). A location near the construction activity may not be possible given the risk of structural collapse as outlined in the POA's IHA application. Placing a PSO on the northernmost portion of Terminal 3 would also be considered if deemed safe. Areas near Cairn Point or Port MacKenzie have safety, security, and logistical issues, which would need to be considered. Cairn Point proper is located on military land and has bear presence, and restricted access does not allow for the location of an observation station at this site. Tidelands along Cairn Point are accessible only during low tide conditions and have inherent safety concerns of being trapped by rising tides. Port MacKenzie is a secure port that is relatively remote, creating safety, logistical, and physical staffing limitations due to lack of nearby lodging and other facilities. The roadway travel time between port sites is approximately 2–3 hours. An adaptive management measure is proposed for a monitoring location north of the proposed project site, once the Construction Contractor has been selected and more detailed discussions can occur. Temporary staffing of a northerly monitoring station during peak marine mammal presence time periods and/or when shutdown zones are large would be considered. At least one PSO station must be able to fully observe the shutdown zones (Table 15);
- PSOs stations must be elevated platforms constructed on top of shipping containers or a similar base that is at least 8' 6'' high (*i.e.,* the standard height of a shipping container) that can support up to three PSOs and their equipment. The platforms must be stable enough to support use of a theodolite and must be located to optimize the PSO's ability to observe marine mammals and the harassment zones;
- Each PSO station must have at least two PSOs on watch at any given time; one PSO must be observing, one PSO would be recording data (and observing when there are no data to record). Teams of three PSOs would include one PSO who would be observing, one PSO who would be recording data (and observing when there are no data to record), and one PSO who would be resting. In addition, if POA is conducting non-NES1-related in-water work that includes PSOs, the NES1 PSOs must be in real-time contact with those PSOs, and both sets of PSOs must share all information regarding marine mammal sightings with each other;
- A designated lead PSO must always be on site. The lead observer must have prior experience performing the duties of a PSO during in-water construction activities pursuant to a NMFS-issued incidental take authorization or Letter of Concurrence. Each PSO station must also have a designated lead PSO specific to that station and shift. These lead PSOs must have prior experience working as a PSO during in-water construction activities;
- PSOs would use a combination of equipment to perform marine mammal observations and to verify the required monitoring distance from the project site, including 7 by 50 binoculars, 20x/40x tripod mounted binoculars, 25 by 150 ''big eye'' tripod mounted binoculars, and theodolites;
- PSOs must record all observations of marine mammals, regardless of distance from the pile being driven. PSOs shall document any behavioral reactions in concert with distance from piles being driven or removed;

PSOs must have the following additional qualifications:

- Ability to conduct field observations and collect data according to assigned protocols;
- Experience or training in the field identification of marine mammals, including the identification of behaviors;
- Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;
- Writing skills sufficient to record required information including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates, times, and reason for implementation of mitigation (or why mitigation was not implemented when required); and marine mammal behavior; and
- Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

Reporting

NMFS would require the POA to submit interim weekly and monthly monitoring reports (that include raw electronic data sheets) during the NES1 construction season. These reports must include a summary of marine mammal species and behavioral observations, construction shutdowns or delays, and construction work completed. They also must include an assessment of the amount of construction remaining to be completed (*i.e.,* the number of estimated hours of work remaining), in addition to the number of CIBWs observed within estimated harassment zones to date.

A draft summary marine mammal monitoring report must be submitted to NMFS within 90 days after the completion of all construction activities, or 60 days prior to a requested date of issuance of any future incidental take authorization for projects at the same location, whichever comes first. The

report would include an overall description of work completed, a narrative regarding marine mammal sightings, and associated PSO data sheets. Specifically, the report must include:

- Dates and times (begin and end) of all marine mammal monitoring;
- Construction activities occurring during each daily observation period, including the number and type of piles driven or removed and by what method (*i.e.,* impact or vibratory, the total equipment duration for vibratory installation and removal, and the total number of strikes for each pile during impact driving;
- PSO locations during marine mammal monitoring;
- Environmental conditions during monitoring periods (at beginning and end of PSO shift and whenever conditions change significantly), including Beaufort sea state and any other relevant weather conditions including cloud cover, fog, sun glare, and overall visibility to the horizon, and estimated observable distance;
- Upon observation of a marine mammal, the following information: name of PSO who sighted the animal(s) and PSO location and activity at time of sighting; time of sighting; identification of the animal(s) (*e.g.,* genus/species, lowest possible taxonomic level, or unidentified), PSO confidence in identification, and the composition of the group if there is a mix of species; distance and bearing of each marine mammal observed relative to the pile being driven for each sighting (if pile driving was occurring at time of sighting); estimated number of animals (minimum, maximum, and best estimate); estimated number of animals by cohort (adults, juveniles, neonates, group composition, sex class, *etc.*); animal's closest point of approach and estimated time spent within the harassment zone; group spread and formation (for CIBWs only); description of any marine mammal behavioral observations (*e.g.,* observed behaviors such as feeding or traveling), including an assessment of behavioral responses that may have resulted from the activity (*e.g.,* no response or changes in behavioral state such as ceasing feeding, changing direction, flushing, or breaching);
- Number of marine mammals detected within the harassment zones and shutdown zones, by species;
- Detailed information about any implementation of any mitigation triggered (*e.g.,* shutdowns and delays), a description of specific actions that ensued, and resulting changes in behavior of the animal(s), if any;

If no comments are received from NMFS within 30 days, the draft final report would constitute the final report. If comments are received, a final report addressing NMFS comments must be submitted within 30 days after receipt of comments.

Reporting Injured or Dead Marine Mammals

In the event that personnel involved in the construction activities discover an injured or dead marine mammal, the IHA-holder must immediately cease the specified activities and report the incident to the Office of Protected Resources, NMFS (*PR.ITP.MonitoringReports@noaa.gov*), and to the Alaska Regional Stranding Coordinator as soon as feasible. If the death or injury was clearly caused by the specified activity, the POA must immediately cease the specified activities until NMFS is able to review the circumstances of the incident and determine what, if any, additional measures are appropriate to ensure compliance with the terms of the IHA. The POA must not resume their activities until notified by NMFS. The report must include the following information:

- Time, date, and location (latitude and longitude) of the first discovery (and updated location information if known and applicable);
- Species identification (if known) or description of the animal(s) involved;
- Condition of the animal(s) (including carcass condition if the animal is dead);
- Observed behaviors of the animal(s), if alive;
- If available, photographs or video footage of the animal(s); and
- General circumstances under which the animal was discovered.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through harassment, NMFS considers other factors, such as the likely nature of any impacts or responses (*e.g.,* intensity, duration), the context of any impacts or responses (*e.g.,* critical reproductive time or location, foraging impacts affecting energetics), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS' implementing regulations (54 FR 40338, September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition, this introductory discussion of our analysis applies to all the species listed in Table 14, except CIBWs, given that many of the anticipated effects of this project on different marine mammal stocks are expected to be relatively similar in nature. For CIBWs, there are meaningful differences in anticipated individual responses to activities, impact of expected take on the population, or impacts on habitat; therefore, we provide a separate detailed analysis for CIBWs following the analysis for other species for which we propose take authorization.

NMFS has identified key factors which may be employed to assess the level of analysis necessary to conclude whether potential impacts associated with a specified activity should be considered negligible. These include (but are not limited to) the type and magnitude of taking, the amount and importance of the available habitat for the species or stock that is affected, the duration of the anticipated effect to the species or stock, and the status of the species or stock. The potential effects of the specified actions on gray whales, humpback whales, killer whales, harbor porpoises, Steller sea lions, and harbor seals are discussed below. Some of these factors also apply to CIBWs; however, a more detailed analysis for CIBWs is provided in a separate sub-section below.

Pile driving associated with the project, as outlined previously, has the potential to disturb or displace marine mammals. Specifically, the specified activities may result in take, in the form of Level B harassment and, for some species, Level A harassment, from underwater sounds generated by pile driving. Potential takes could occur if marine mammals are present in zones

ensonified above the thresholds for Level B harassment or Level A harassment, identified above, while activities are underway.

The POA's proposed activities and associated impacts would occur within a limited, confined area of the stocks' range. The work would occur in the vicinity of the NES1 site and sound from the proposed activities would be blocked by the coastline along Knik Arm along the eastern boundaries of the site, and for those harassment isopleths that extend more than 3,000 m (*i.e.,* the vibratory installation of 36-inch (91-cm) piles and vibratory removal of 24-inch (61-inch) piles), directly across the Arm along the western shoreline (see Figure 6–4 in the POA's application)). The intensity and duration of take by Level A and Level B harassment would be minimized through use of mitigation measures described herein. Further the amount of take proposed to be authorized is small when compared to stock abundance (see Table 14). In addition, NMFS does not anticipate that serious injury or mortality will occur as a result of the POA's planned activity given the nature of the activity, even in the absence of required mitigation.

Exposures to elevated sound levels produced during pile driving may cause behavioral disturbance of some individuals. Behavioral responses of marine mammals to pile driving at the proposed project site are expected to be mild, short term, and temporary. Effects on individuals that are taken by Level B harassment, as enumerated in the Estimated Take section, on the basis of reports in the literature as well as monitoring from other similar activities at the POA and elsewhere, will likely be limited to reactions such as increased swimming speeds, increased surfacing time, or decreased foraging (if such activity were occurring; *e.g.,* Ridgway *et al.,* 1997; Nowacek *et al.,* 2007; Thorson and Reyff, 2006; Kendall and Cornick, 2015; Goldbogen *et al.,* 2013b; Piwetz *et al.,* 2021). Marine mammals within the Level B harassment zones may not show any visual cues they are disturbed by activities or they could become alert, avoid the area, leave the area, or display other mild responses that are not observable such as changes in vocalization patterns or increased haul out time (*e.g.,* Tougaard *et al.,* 2003; Carstensen *et al.,* 2006; Thorson and Reyff, 2006; Parks *et al.,* 2007; Brandt *et al.,* 2011; Graham *et al.,* 2017). However, as described in the Potential Effects of Specified Activities on Marine Mammals and Their Habitat section of this notice, marine mammals, excepting CIBWs, observed within Level A and Level B harassment zones related to recent POA construction activities have not shown any acute observable reactions to pile driving activities that have occurred during the PCT and SFD projects (61N Environmental, 2021, 2022a, 2022b).

Some of the species present in the region will only be present temporarily based on seasonal patterns or during transit between other habitats. These temporarily present species will be exposed to even smaller periods of noise-generating activity, further decreasing the impacts. Most likely, individual animals will simply move away from the sound source and be temporarily displaced from the area. Takes may also occur during important feeding times. The project area though represents a small portion of available foraging habitat and impacts on marine mammal feeding for all species should be minimal.

The activities analyzed here are similar to numerous other construction activities conducted in Alaska (*e.g.,* 86 FR 43190, August 6, 2021; 87 FR 15387, March 18, 2022), including the PCT and SFD projects within Upper Knik Arm (85 FR 19294, April 6, 2020; 86 FR 50057, September 7, 2021, respectively) which have taken place with no known long-term adverse consequences from behavioral harassment. Any potential reactions and behavioral changes are expected to subside quickly when the exposures cease and, therefore, no such long-term adverse consequences should be expected (*e.g.,* Graham *et al.,* 2017). For example, harbor porpoises returned to a construction area between pile-driving events within several days during the construction of offshore wind turbines near Denmark (Carstensen *et al.,* 2006). The intensity of Level B harassment events would be minimized through use of mitigation measures described herein, which were not quantitatively factored into the take estimates. The POA would use PSOs stationed strategically to increase detectability of marine mammals during in-water construction activities, enabling a high rate of success in implementation of shutdowns to avoid or minimize injury for most species. Further, given the absence of any major rookeries and haulouts within the estimated harassment zones, we assume that potential takes by Level B harassment would have an inconsequential short-term effect on individuals and would not result in population-level impacts.

As stated in the mitigation section, the POA will implement shutdown zones that equal or exceed the Level A harassment isopleths shown in Table 9. Take by Level A harassment is proposed for authorization for some species (harbor seals and harbor porpoises) to account for the potential that an animal could enter and remain within the Level A harassment zone for a duration long enough to incur PTS. Any take by Level A harassment is expected to arise from, at most, a small degree of PTS because animals would need to be exposed to higher levels and/or longer duration than are expected to occur here in order to incur any more than a small degree of PTS.

Due to the levels and durations of likely exposure, animals that experience PTS will likely only receive slight PTS, *i.e.,* minor degradation of hearing capabilities within regions of hearing that align most completely with the frequency range of the energy produced by POA's proposed in-water construction activities (*i.e.,* the low-frequency region below 2 kHz), not severe hearing impairment or impairment in the ranges of greatest hearing sensitivity. If hearing impairment does occur, it is most likely that the affected animal will lose a few dBs in its hearing sensitivity, which in most cases is not likely to meaningfully affect its ability to forage and communicate with conspecifics. There are no data to suggest that a single instance in which an animal accrues PTS (or TTS) and is subject to behavioral disturbance would result in impacts to reproduction or survival. If PTS were to occur, it would be at a lower level likely to accrue to a relatively small portion of the population by being a stationary activity in one particular location. Additionally, and as noted previously, some subset of the individuals that are behaviorally harassed could also simultaneously incur some small degree of TTS for a short duration of time. Because of the small degree anticipated, though, any PTS or TTS potentially incurred here is not expected to adversely impact individual fitness, let alone annual rates of recruitment or survival.

Theoretically, repeated, sequential exposure to pile driving noise over a long duration could result in more severe impacts to individuals that could affect a population (via sustained or repeated disruption of important behaviors such as feeding, resting, traveling, and socializing; Southall *et al.,* 2007). Alternatively, marine mammals exposed to repetitious construction sounds may become habituated, desensitized, or tolerant after initial exposure to these sounds (reviewed by Richardson *et al.,* 1995; Southall *et al.,* 2007). Given that marine mammals still frequent and use Knik Arm despite being exposed to pile

driving activities across many years, these severe population level of impacts are not anticipated. The absence of any pinniped haulouts or other known non-CIBW home-ranges in the proposed action area further decreases the likelihood of severe population level impacts.

The NES1 project is also not expected to have significant adverse effects on any marine mammal habitat. The project activities would occur within the same footprint as existing marine infrastructure, and when construction is complete, subtidal and intertidal habitats previously lost at the project site would be restored. Impacts to the immediate substrate are anticipated, but these would be limited to minor, temporary suspension of sediments, which could impact water quality and visibility for a short amount of time but which would not be expected to have any effects on individual marine mammals. While the area is generally not high quality habitat, it is expected to be of higher quality to marine mammals and fish after NES1 construction is complete as the site returns to its natural state and is colonized by marine organisms. Further, there are no known BIAs near the project zone, except for CIBWs, that will be impacted by the POA's planned activities.

Impacts to marine mammal prey species are also expected to be minor and temporary and to have, at most, short-term effects on foraging of individual marine mammals, and likely no effect on the populations of marine mammals as a whole. Overall, the area impacted by the NES1 project is very small compared to the available surrounding habitat, and does not include habitat of particular importance. The most likely impact to prey would be temporary behavioral avoidance of the immediate area. During construction activities, it is expected that some fish and marine mammals would temporarily leave the area of disturbance, thus impacting marine mammals' foraging opportunities in a limited portion of their foraging range. But, because of the relatively small area of the habitat that may be affected, and lack of any habitat of particular importance, the impacts to marine mammal habitat are not expected to cause significant or long-term negative consequences. Further, as described above, additional habitat for marine mammal prey will be available after the completion of the proposed construction activities likely providing additional foraging, migrating, and rearing habitats to fish and foraging habitat to marine mammals.

In summary and as described above, the following factors support our preliminary negligible impact determinations for the affected stocks of gray whales, humpback whales, killer whales, harbor porpoises, Steller sea lions, and harbor seals:

- No takes by mortality or serious injury are anticipated or authorized;
- Any acoustic impacts to marine mammal habitat from pile driving (including to prey sources as well as acoustic habitat, and including resulting behavioral impacts *e.g.,* from masking) are expected to be temporary and minimal;
- Take would not occur in places and/or times where take would be more likely to accrue to impacts on reproduction or survival, such as within ESA-designated or proposed critical habitat, BIAs, or other habitats critical to recruitment or survival (*e.g.,* rookery);
- The project area represents a very small portion of the available foraging area for all potentially impacted marine mammal species;
- Take will only occur within upper Cook Inlet—a limited, confined area of any given stock's home range;
- Monitoring reports from similar work in Knik Arm have documented little to no observable effect on individuals of the same species impacted by the specified activities;
- The required mitigation measures (*i.e.,* soft starts, pre-clearance monitoring, shutdown zones) are expected to be effective in reducing the effects of the specified activity by minimizing the numbers of marine mammals exposed to injurious levels of sound, and by ensuring that any take by Level A harassment is, at most, a small degree of PTS and of a lower degree that would not impact the fitness of any animals; and
- The intensity of anticipated takes by Level B harassment is low for all stocks consisting of, at worst, temporary modifications in behavior, and would not be of a duration or intensity expected to result in impacts on reproduction or survival.

Cook Inlet Beluga Whales. For CIBWs, we further discuss our negligible impact findings in the context of potential impacts to this endangered stock based on our evaluation of the take proposed for authorization (Table 14).

As described in the Recovery Plan for the CIBW (NMFS, 2016b), NMFS determined the following physical or biological features are essential to the conservation of this species: (1) Intertidal and subtidal waters of Cook Inlet with depths less than 9 m mean lower low water and within 8 km of high and medium flow anadromous fish streams; (2) Primary prey species consisting of four species of Pacific salmon (Chinook, sockeye, chum, and coho), Pacific eulachon, Pacific cod, walleye pollock, saffron cod, and yellowfin sole, (3) Waters free of toxins or other agents of a type and amount harmful to CIBWs, (4) Unrestricted passage within or between the critical habitat areas, and (5) Waters with in-water noise below levels resulting in the abandonment of critical habitat areas by CIBWs. The NES1 project will not impact essential features 1–3 listed above. All construction will be done in a manner implementing best management practices to preserve water quality, and no work will occur around creek mouths or river systems leading to prey abundance reductions. In addition, no physical structures will restrict passage; however, impacts to the acoustic habitat are relevant and discussed here.

Monitoring data from the POA suggest pile driving does not discourage CIBWs from entering Knik Arm and traveling to critical foraging grounds such as those around Eagle Bay (*e.g.,* 61N Environmental, 2021, 2022a, 2022b; Easley-Appleyard and Leonard, 2022). As described in the Potential Effects of Specified Activities on Marine Mammals and Their Habitat section of this notice, sighting rates were not different in the presence or absence of pile driving (Kendall and Cornick, 2015). In addition, large numbers of CIBWs have continued to use Knik Arm and pass through the area during pile driving projects that have taken place at the POA during the past two decades (Funk *et al.,* 2005; Prevel-Ramos *et al.,* 2006; Markowitz and McGuire, 2007; Cornick and Saxon-Kendall, 2008, 2009; ICRC, 2009, 2010, 2011, 2012; Cornick *et al.,* 2010, 2011; Cornick and Pinney, 2011; Cornick and Seagars, 2016; POA, 2019), including during the recent PCT and SFD construction projects (61N Environmental, 2021, 2022a, 2022b; Easley-Appleyard and Leonard, 2022). These findings are not surprising as food is a strong motivation for marine mammals. As described in Forney *et al.* (2017), animals typically favor particular areas because of their importance for survival (*e.g.,* feeding or breeding), and leaving may have significant costs to fitness (reduced foraging success, increased predation risk, increased exposure to other anthropogenic threats). Consequently, animals may be highly motivated to maintain foraging behavior in historical foraging areas despite negative impacts (*e.g.,* Rolland *et al.,* 2012). Previous monitoring data indicates CIBWs are

responding to pile driving noise, but not through abandonment of critical habitat, including primary foraging areas north of the port. Instead, they travel more often and faster past the POA, more quietly, and in tighter groups (Kendall and Cornick, 2015; 61N Environmental, 2021, 2022a, 2022b).

During PCT and SFD construction monitoring, little variability was evident in the behaviors recorded from month to month, or between sightings that coincided with in-water pile installation and removal and those that did not (61N Environmental, 2021, 2022a, 2022b; Easley-Appleyard and Leonard, 2022). Of the 386 CIBWs groups sighted during PCT and SFD construction monitoring, 10 groups were observed during or within minutes of in-water impact pile installation and 56 groups were observed during or within minutes of vibratory pile installation or removal (61N Environmental, 2021, 2022a, 2022b). In general, CIBWs were more likely to display no reaction or to continue to move towards the PCT or SFD during pile installation and removal. In the situations during which CIBWs showed a possible reaction (six groups during impact driving and 13 groups during vibratory driving), CIBWs were observed either moving away immediately after the pile driving activities started or were observed increasing their rate of travel.

NMFS funded a visual marine mammal monitoring project in 2021 (described in the Potential Effects of Specified Activities on Marine Mammals and Their Habitat) to supplement sighting data collected by the POA monitoring program during non-pile driving days in order to further evaluate the impacts of anthropogenic activities on CIBWs (Easley-Appleyard and Leonard, 2022). Preliminary results suggest that group size ranged from 1 to 34 whales, with an average of 3 to 5.6, depending on the month. September had the highest sighting rate with 4.08 whales per hour, followed by October and August (3.46 and 3.41, respectively). Traveling was recorded as the primary behavior for 80 percent of the group sightings and milling was the secondary behavior most often recorded. Sighting duration varied from a single surfacing lasting less than 1 minute to 380 minutes. Preliminary findings suggest these results are consistent with the results from the POA's PCT and SFD monitoring efforts. For example, group sizes ranged from 2.38 to 4.32 depending on the month and the highest sighting rate was observed in September (1.75). In addition, traveling was the predominant behavior observed for all months and categories of construction activity (*i.e.,* no pile driving, before pile driving, during pile driving, between pile driving, or after pile driving), being recorded as the primary behavior for 86 percent of all sightings, and either the primary or secondary behavior for 95 percent of sightings.

Easley-Appleyard and Leonard (2022) also asked PSOs to complete a questionnaire post-monitoring that provided NMFS with qualitative data regarding CIBW behavior during observations. Specifically during pile driving events, the PSOs noted that CIBW behaviors varied; however, multiple PSOs noted seeing behavioral changes specifically during impact pile driving (which would only be used when necessary to loosen piles for vibratory removal or direct pulling during the NES1 project) and not during vibratory pile driving. CIBWs were observed sometimes changing direction, turning around, or changing speed during impact pile driving. There were numerous instances where CIBWs were seen traveling directly towards the POA during vibratory pile driving before entering the Level B harassment zone (POA was required to shutdown prior to CIBWs entering the Level B harassment zone), which is consistent with findings during the POA's PCT and SFD monitoring efforts (61N Environmental, 2021, 2022a, 2022b). The PSOs also reported that it seemed more likely for CIBWs to show more cryptic behavior during pile driving (*e.g.,* surfacing infrequently and without clear direction), though this seemed to vary across months (Easley-Appleyard and Leonard, 2022).

We anticipate that disturbance to CIBWs will manifest in the same manner when they are exposed to noise during the NES1 project: whales would move quickly and silently through the area in more cohesive groups. We do not believe exposure to elevated noise levels during transit past the POA has adverse effects on reproduction or survival as the whales continue to access critical foraging grounds north of the POA, even if having shown a potential reaction during pile driving, and tight associations help to mitigate the potential for any contraction of communication space for a group. We also do not anticipate that CIBWs will abandon entering or exiting Knik Arm, as this is not evident based on previous years of monitoring data (*e.g.,* Kendall and Cornick, 2015; 61N Environmental, 2021, 2022a, 2022b; Easley-Appleyard and Leonard, 2022), and the pre-pile driving clearance mitigation measure is designed to further avoid any potential abandonment. Finally, as described previously, both telemetry (tagging) and acoustic data suggest CIBWs likely stay in upper Knik Arm (*i.e.,* north of the NES1 project site) for several days or weeks before exiting Knik Arm. Specifically, a CIBW instrumented with a satellite link time/depth recorder entered Knik Arm on August 18, 1999 and remained in Eagle Bay until September 12, 1999 (Ferrero *et al.,* 2000). Further, a recent detailed re-analysis of the satellite telemetry data confirms how several tagged whales exhibited this same movement pattern: whales entered Knik Arm and remained there for several days before exiting through lower Knik Arm (Shelden *et al.,* 2018). This longer-term use of upper Knik Arm will avoid repetitive exposures from pile driving noise.

There is concern that exposure to pile driving at the POA could result in CIBWs avoiding Knik Arm and thereby not accessing the productive foraging grounds north of POA such as Eagle River flats thus, impacting essential feature number five above. Although the data previously presented demonstrate CIBWs are not abandoning the area (*i.e.,* no significant difference in sighting rate with and without pile driving), results of an expert elicitation (EE) at a 2016 workshop, which predicted the impacts of noise on CIBW survival and reproduction given lost foraging opportunities, helped to inform our assessment of impacts on this stock. The 2016 EE workshop used conceptual models of an interim population consequences of disturbance (PCoD) for marine mammals (NRC, 2005; New *et al.,* 2014; Tollit *et al.,* 2016) to help in understanding how noise-related stressors might affect vital rates (survival, birth rate and growth) for CIBW (King *et al.,* 2015). NMFS (2016b) suggests that the main direct effects of noise on CIBW are likely to be through masking of vocalizations used for communication and prey location and habitat degradation. The 2016 workshop on CIBWs was specifically designed to provide regulators with a tool to help understand whether chronic and acute anthropogenic noise from various sources and projects are likely to be limiting recovery of the CIBW population. The full report can be found at *https://www.smruconsulting.com/publications/* with a summary of the expert elicitation portion of the workshop below.

For each of the noise effect mechanisms chosen for EE, the experts provided a set of parameters and values that determined the forms of a relationship between the number of days of disturbance a female CIBW experiences in a particular period and the effect of that disturbance on her

energy reserves. Examples included the number of days of disturbance during the period April, May, and June that would be predicted to reduce the energy reserves of a pregnant CIBW to such a level that she is certain to terminate the pregnancy or abandon the calf soon after birth, the number of days of disturbance in the period April-September required to reduce the energy reserves of a lactating CIBW to a level where she is certain to abandon her calf, and the number of days of disturbance where a female fails to gain sufficient energy by the end of summer to maintain themselves and their calves during the subsequent winter. Overall, median values ranged from 16 to 69 days of disturbance depending on the question. However, for this elicitation, a ''day of disturbance'' was defined as any day on which an animal loses the ability to forage for at least one tidal cycle (*i.e.,* it forgoes 50–100 percent of its energy intake on that day). The day of disturbance considered in the context of the report is notably more severe than the Level B harassment expected to result from these activities, which as described is expected to be comprised predominantly of temporary modifications in the behavior of individual CIBWs (*e.g.,* faster swim speeds, more cohesive group structure, decreased sighting durations, cessation of vocalizations). Also, NMFS proposes to authorize 72 instances of takes, with the instances representing disturbance events within a day—this means that either 72 different individual CIBWs are disturbed on no more than 1 day each, or some lesser number of individuals may be disturbed on more than 1 day, but with the product of individuals and days not exceeding 72. Given the overall anticipated take, it is unlikely that any one CIBW will be disturbed on more than a few days. Further, the mitigation measures NMFS has prescribed for the NES1 project are designed to avoid the potential that any animal will lose the ability to forage for one or more tidal cycles should they be foraging in the proposed action area, which is not known to be a particularly important feeding area for CIBWs. While Level B harassment (behavioral disturbance) would be authorized, the POA's mitigation measures will limit the severity of the effects of that Level B harassment to behavioral changes such as increased swim speeds, tighter group formations, and cessation of vocalizations, not the loss of foraging capabilities. Regardless, this elicitation recognized that pregnant or lactating females and calves are inherently more at risk than other animals, such as males. NMFS has determined all CIBWs warrant pile driving shutdown to be protective of potential vulnerable life stages, such as pregnancy, that could not be determined from observations, and to avoid more severe behavioral reaction.

POA proposed and NMFS has prescribed mitigation measures to minimize exposure to CIBWs, specifically, shutting down pile driving should a CIBW approach or enter the Level B harassment zone. These measures are designed to ensure CIBWs will not abandon critical habitat and exposure to pile driving noise will not result in adverse impacts on the reproduction or survival of any individuals. The location of the PSOs would allow for detection of CIBWs and behavioral observations prior to CIBWs entering the Level B harassment zone. Further, impact driving appeared to cause behavioral reactions more readily than vibratory hammering (61N Environmental, 2021, 2022a, 2022b), which would only be used in situations where sheet piles remain seized in the sediments and cannot be loosened or broken free with a vibratory hammer, which is expected to be uncommon during the NES1 project. If impact driving does occur, the POA must implement soft starts, which ideally allows animals to leave a disturbed area before the full-power driving commences (Tougaard *et al.,* 2012). Although NMFS does not anticipate CIBWs will abandon entering Knik Arm in the presence of pile driving with the required mitigation measures, PSOs will be integral to identifying if CIBWs are potentially altering pathways they would otherwise take in the absence of pile driving. Finally, take by mortality, serious injury, or Level A harassment of CIBWs is not anticipated or proposed to be authorized.

In summary and as described above, the following factors primarily support our preliminary determination that the impacts resulting from this activity are not expected to adversely affect the CIBWs through effects on annual rates of recruitment or survival:

- No mortality is anticipated or proposed to be authorized;
- The area of exposure would be limited to habitat primarily used as a travel corridor. Data demonstrates Level B harassment of CIBWs typically manifests as increased swim speeds past the POA, tighter group formations, and cessation of vocalizations, rather than through habitat abandonment;
- No critical foraging grounds (*e.g.,* Eagle Bay, Eagle River, Susitna Delta) would be impacted by pile driving; and
- While animals could be harassed more than once, exposures are not likely to exceed more than a few per year for any given individual and are not expected to occur on sequential days; thereby decreasing the likelihood of physiological impacts caused by chronic stress or masking.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the required monitoring and mitigation measures, NMFS preliminarily finds that the total marine mammal take from the specified activity will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted previously, only take of small numbers of marine mammals may be authorized under sections 101(a)(5)(A) and (D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. When the predicted number of individuals to be taken is fewer than one-third of the species or stock abundance, the take is considered to be of small numbers. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

For all stocks, except for the Mexico-North Pacific stock of humpback whales whose abundance estimate is unknown, the amount of taking is less than one-third of the best available population abundance estimate (in fact it is less than 2 percent for all stocks, except for CIBWs whose proposed take is 22 percent of the stock; Table 14). The number of animals proposed for authorization to be taken from these stocks would be considered small relative to the relevant stock's abundances even if each estimated take occurred to a new individual. The amount of take authorized likely represents smaller numbers of individual harbor seals and Steller sea lions. Harbor seals tend to concentrate near Ship Creek and have small home ranges. It is possible that a single individual harbor seal may linger near the POA, especially near Ship Creek, and be counted multiple times each day as it moves around and resurfaces in

different locations. Previous Steller sea lion sightings identified that if a Steller sea lion is within Knik Arm, it is likely lingering to forage on salmon or eulachon runs and may be present for several days. Therefore, the amount of take authorized likely represents repeat exposures to the same animals. For all species, PSOs would count individuals as separate unless they cannot be individually identified.

Abundance estimates for the Mexico-North Pacific stock of humpback whales are based upon data collected more than 8 years ago and, therefore, current estimates are considered unknown (Young *et al.,* 2023). The most recent minimum population estimates (N_{MIN}) for this population include an estimate of 2,241 individuals between 2003 and 2006 (Martinez-Aguilar, 2011) and 766 individuals between 2004 and 2006 (Wade, 2021). NMFS' Guidelines for Assessing Marine Mammal Stocks suggest that the N_{MIN} estimate of the stock should be adjusted to account for potential abundance changes that may have occurred since the last survey and provide reasonable assurance that the stock size is at least as large as the estimate (NMFS, 2023). The abundance trend for this stock is unclear; therefore, there is no basis for adjusting these estimates (Young *et al.,* 2023). Assuming the population has been stable, the 4 takes of this stock proposed for authorization represents small numbers of this stock (0.18 percent of the stock assuming a N_{MIN} of 2,241 individuals and 0.52 percent of the stock assuming an N_{MIN} of 766 individuals).

Based on the analysis contained herein of the proposed activity (including the proposed mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS preliminarily finds that small numbers of marine mammals would be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

In order to issue an IHA, NMFS must find that the specified activity will not have an ''unmitigable adverse impact'' on the subsistence uses of the affected marine mammal species or stocks by Alaskan Natives. NMFS has defined ''unmitigable adverse impact'' in 50 CFR 216.103 as an impact resulting from the specified activity: (1) That is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by: (i) Causing the marine mammals to abandon or avoid hunting areas; (ii) Directly displacing subsistence users; or (iii) Placing physical barriers between the marine mammals and the subsistence hunters; and (2) That cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

While no significant subsistence activity currently occurs within or near the POA, Alaska Natives have traditionally harvested subsistence resources, including marine mammals, in upper Cook Inlet for millennia. CIBWs are more than a food source; they are important to the cultural and spiritual practices of Cook Inlet Native communities (NMFS, 2008b). Dena'ina Athabascans, currently living in the communities of Eklutna, Knik, Tyonek, and elsewhere, occupied settlements in Cook Inlet for the last 1,500 years and have been the primary traditional users of this area into the present.

NMFS estimated that 65 CIBWs per year (range 21–123) were killed between 1994 and 1998, including those successfully harvested and those struck and lost. NMFS concluded that this number was high enough to account for the estimated 14 percent annual decline in population during this time (Hobbs *et al.,* 2008); however, given the difficulty of estimating the number of whales struck and lost during the hunts, actual mortality may have been higher. During this same period, population abundance surveys indicated a population decline of 47 percent, although the reason for this decline should not be associated solely with subsistence hunting and likely began well before 1994 (Rugh *et al.,* 2000).

In 1999, a moratorium was enacted (Pub. L. 106–31) prohibiting the subsistence harvest of CIBWs except through a cooperative agreement between NMFS and the affected Alaska Native organizations. NMFS began working cooperatively with the Cook Inlet Marine Mammal Council (CIMMC), a group of tribes that traditionally hunted CIBWs, to establish sustainable harvests. CIMMC voluntarily curtailed its harvests in 1999. In 2000, NMFS designated the Cook Inlet stock of beluga whales as depleted under the MMPA (65 FR 34590, May 31, 2000). NMFS and CIMMC signed Co-Management of the Cook Inlet Stock of Beluga Whales agreements in 2000, 2001, 2002, 2003, 2005, and 2006. CIBW harvests between 1999 and 2006 resulted in the strike and harvest of five whales, including one whale each in 2001, 2002, and 2003, and two whales in 2005 (NMFS, 2008b). No hunt occurred in 2004 due to higher-than-normal mortality of CIBWs in 2003, and the Native Village of Tyonek agreed to not hunt in 2007. Since 2008, NMFS has examined how many CIBWs could be harvested during 5-year intervals based on estimates of population size and growth rate and determined that no harvests would occur between 2008 and 2012 and between 2013 and 2017 (NMFS, 2008b). The CIMMC was disbanded by unanimous vote of the CIMMC member Tribes' representatives in June 2012, and a replacement group of Tribal members has not been formed to date. There has been no subsistence harvest of CIBWs since 2005 (NMFS, 2022d).

Subsistence harvest of other marine mammals in upper Cook Inlet is limited to harbor seals. Steller sea lions are rare in upper Cook Inlet; therefore, subsistence use of this species is not common. However, Steller sea lions are taken for subsistence use in lower Cook Inlet. Residents of the Native Village of Tyonek are the primary subsistence users in the upper Cook Inlet area. While harbor seals are hunted for subsistence purposes, harvests of this for traditional and subsistence uses by Native peoples have been low in upper Cook Inlet (*e.g.,* 33 harbor seals were harvested in Tyonek between 1983 and 2013; see Table 8–1 in the POA's application), although these data are not currently being collected and summarized. As the POA's proposed project activities will take place within the immediate vicinity of the POA, no activities will occur in or near Tyonek's identified traditional subsistence hunting areas. As the harvest of marine mammals in upper Cook Inlet is historically a small portion of the total subsistence harvest, and the number of marine mammals using upper Cook Inlet is proportionately small, the number of marine mammals harvested in upper Cook Inlet is expected to remain low.

The potential impacts from harassment on stocks that are harvested in Cook Inlet would be limited to minor behavioral changes (*e.g.,* increased swim speeds, changes in dive time, temporary avoidance near the POA, *etc.*) within the vicinity of the POA. Some PTS may occur; however, the shift is likely to be slight due to the implementation of mitigation measures (*e.g.,* shutdown zones, pre-clearance monitoring, soft starts) and the shift would be limited to lower pile driving frequencies which are on the lower end of phocid and otariid hearing ranges. In summary, any impacts to harbor seals would be limited to those seals within Knik Arm (outside of any hunting area) and the very few takes of Steller sea lions in Knik Arm would be far removed in time and space from any hunting in lower Cook Inlet.

The POA will communicate with representative Alaska Native subsistence users and Tribal members to identify and explain the measures that have been taken or will be taken to minimize any adverse effects of NES1 on the availability of marine mammals for subsistence uses. In addition, the POA will adhere to the following procedures during Tribal consultation regarding marine mammal subsistence use within the Project area:

(1) Send letters to the Kenaitze, Tyonek, Knik, Eklutna, Ninilchik, Salamatof, and Chickaloon Tribes informing them of the proposed project (*i.e.,* timing, location, and features). Include a map of the proposed project area; identify potential impacts to marine mammals and mitigation efforts, if needed, to avoid or minimize impacts; and inquire about possible marine mammal subsistence concerns they have.

(2) Follow up with a phone call to the environmental departments of the seven Tribal entities to ensure that they received the letter, understand the proposed project, and have a chance to ask questions. Inquire about any concerns they might have about potential impacts to subsistence hunting of marine mammals.

(3) Document all communication between the POA and Tribes.

(4) If any Tribes express concerns regarding proposed project impacts to subsistence hunting of marine mammals, propose a Plan of Cooperation between the POA and the concerned Tribe(s).

The proposed project features and activities, in combination with a number of actions to be taken by the POA during project implementation, should avoid or mitigate any potential adverse effects on the availability of marine mammals for subsistence uses. Furthermore, although construction will occur within the traditional area for hunting marine mammals, the proposed project area is not currently used for subsistence activities. In-water pile installation and removal will follow mitigation procedures to minimize effects on the behavior of marine mammals, and impacts will be temporary.

The POA has expressed, if desired, regional subsistence representatives may support project marine mammal biologists during the monitoring program by assisting with collection of marine mammal observations and may request copies of marine mammal monitoring reports.

Based on the description of the specified activity, the measures described to minimize adverse effects on the availability of marine mammals for subsistence purposes, and the proposed mitigation and monitoring measures, NMFS has preliminarily determined that there will not be an unmitigable adverse impact on subsistence uses from the POA's proposed activities.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA; 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS Office of Protected Resources (OPR) consults internally whenever we propose to authorize take for endangered or threatened species, in this case with the NMFS Alaska Regional Office.

NMFS OPR is proposing to authorize take of Mexico-North Pacific humpback whales (including individuals from the Mexico DPS), CIBWs, and western DPS Steller sea lions, which are listed under the ESA. NMFS OPR has requested initiation of section 7 consultation with the issuance of this IHA. NMFS will conclude the ESA consultation prior to reaching a determination regarding the proposed issuance of the authorization.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to the POA for conducting construction and demolition activities in Anchorage Alaska from April 1, 2024 through March 31, 2025, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. A draft of the proposed IHA can be found at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities*.

Request for Public Comments

We request comment on our analyses, the proposed authorization, and any other aspect of this notice of proposed IHA for the proposed construction and demolition activities. We also request comment on the potential renewal of this proposed IHA as described in the paragraph below. Please include with your comments any supporting data or literature citations to help inform decisions on the request for this IHA or a subsequent renewal IHA.

On a case-by-case basis, NMFS may issue a one-time, 1-year renewal IHA following notice to the public providing an additional 15 days for public comments when (1) up to another year of identical or nearly identical activities as described in the Description of Proposed Activity section of this notice is planned or (2) the activities as described in the Description of Proposed Activity section of this notice would not be completed by the time the IHA expires and a renewal would allow for completion of the activities beyond that described in the *Dates and Duration* section of this notice, provided all of the following conditions are met:

- A request for renewal is received no later than 60 days prior to the needed renewal IHA effective date (recognizing that the renewal IHA expiration date cannot extend beyond 1 year from expiration of the initial IHA).
- The request for renewal must include the following:

(1) An explanation that the activities to be conducted under the requested renewal IHA are identical to the activities analyzed under the initial IHA, are a subset of the activities, or include changes so minor (*e.g.,* reduction in pile size) that the changes do not affect the previous analyses, mitigation and monitoring requirements, or take estimates (with the exception of reducing the type or amount of take).

(2) A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized.

Upon review of the request for renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures will remain the same and appropriate, and the findings in the initial IHA remain valid.

Dated: October 30, 2023.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

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