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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 985

[Doc. No. AMS–SC–17–0073; SC18–985–1A FR]

Marketing Order Regulating the Handling of Spearmint Oil Produced in the Far West; Revision of the Salable Quantity and Allotment Percentage for Class 3 (Native) Spearmint Oil for the 2018–2019 Marketing Year

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule implements a recommendation from the Far West Spearmint Oil Administrative Committee (Committee) to increase the quantity of Class 3 (Native) spearmint oil that handlers may purchase from, or handle on behalf of, producers during the 2018–2019 marketing year. The Committee recommended this action to ensure that the Native spearmint oil market is adequately supplied through the end of the current marketing year.

DATES: Effective April 25, 2019.

FOR FURTHER INFORMATION CONTACT: Barry Broadbent, Senior Marketing Specialist, or Gary D. Olson, Regional Director, Northwest Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (503) 326–2724, Fax: (503) 326–7440, or Email: *Barry.Broadbent@ams.usda.gov* or *GaryD.Olson@ams.usda.gov.*

Small businesses may request information on complying with this regulation by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202)720–8938, or Email: *Richard.Lower@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This final rule, pursuant to 5 U.S.C. 553, amends regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This rule is issued under Marketing Order No. 985 (7 CFR part 985), as amended, regulating the handling of spearmint oil produced in the Far West (Washington, Idaho, Oregon, and designated parts of Nevada and Utah). Part 985 (referred to as ''the Order'') is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' The Committee locally administers the Order and is comprised of spearmint oil producers operating within the area of production, and a public member.

The Department of Agriculture (USDA) is issuing this final rule in conformance with Executive Orders 13563 and 13175. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review. Additionally, because this rule does not meet the definition of a significant regulatory action, it does not trigger the requirements contained in Executive Order 13771. See OMB's Memorandum titled ''Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, titled 'Reducing Regulation and Controlling Regulatory Costs' '' (February 2, 2017).

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the provisions of the Order now in effect, salable quantities and allotment percentages may be established for classes of spearmint oil produced in the Far West. This rule increases the quantity of Native spearmint oil produced in the Far West that handlers may purchase from, or handle on behalf of, producers during the 2018–2019 marketing year, which ends on May 31, 2019.

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

This rule revises the quantity of Native spearmint oil that handlers may purchase from, or handle on behalf of, producers during the 2018–2019 marketing year. The salable quantity and allotment percentage for Native spearmint oil for the 2018–2019 marketing year was initially established at 1,307,947 pounds and 53 percent, respectively, in a final rule published in the **Federal Register** on July 24, 2018 (83 FR 34935). This rule increases the Native spearmint oil salable quantity from 1,307,947 pounds to 1,431,350 pounds and the allotment percentage from 53 percent to 58 percent.

Under the volume regulation provisions of the Order, the Committee meets each year to adopt a marketing policy for the ensuing year. When the Committee's marketing policy considerations indicate a need to limit the quantity of spearmint oil available to the market to establish or maintain orderly marketing conditions, the Committee submits a recommendation to the Secretary of Agriculture for volume regulation.

Volume regulation under the Order is effectuated through the establishment of a salable quantity and allotment percentage applicable to each class of spearmint oil handled in the production area during a marketing year. The salable quantity is the total quantity of each class of oil that handlers may purchase from, or handle on behalf of, producers during a given marketing year. The allotment percentage for each class of oil is derived by dividing the salable quantity by the total industry allotment base for that same class of oil. The total industry allotment base is the aggregate of all allotment base held individually by producers. Producer allotment base is the quantity of each class of spearmint oil that the Committee has determined is representative of a producer's spearmint oil production. Each producer is allotted a pro rata share of the total salable quantity of each class of spearmint oil

each marketing year. Each producer's annual allotment is determined by applying the allotment percentage to the producer's individual allotment base for each applicable class of spearmint oil.

The full Committee met on October 25, 2017, to consider its marketing policy for the 2018–2019 marketing year. At that meeting, the Committee determined that marketing conditions indicated a need for volume regulation of both classes of spearmint oil (Scotch and Native) for the 2018–2019 marketing year. The Committee recommended salable quantities of 760,660 pounds and 1,307,947 pounds, and allotment percentages of 35 percent and 53 percent, respectively, for Scotch and Native spearmint oil. A proposed rule to that effect was published in the **Federal Register** on April 6, 2018 (83 FR 14766). Comments on the proposed rule were solicited from interested persons until June 5, 2018. No comments were received. Subsequently, a final rule establishing the salable quantities and allotment percentages for Scotch and Native spearmint oil for the 2018–2019 marketing year was published in the **Federal Register** on July 24, 2018 (83 FR 34935).

Pursuant to authority contained in §§ 985.50, 985.51, and 985.52, the full eight-member Committee met again on July 18, 2018, to evaluate the current year's volume control regulation. At the meeting, the Committee assessed the current market conditions for spearmint oil in relation to the salable quantities and allotment percentages established for the 2018–2019 marketing year. The Committee considered a number of factors, including the current and projected supply and the estimated future demand for all classes of spearmint oil. The Committee determined that the established salable quantity and allotment percentage in effect for Native spearmint oil for the 2018–2019 marketing year should be increased to accommodate a rise in market demand for that class of spearmint oil.

At the July 18, 2018, meeting, the Committee staff reported that estimated demand for Native spearmint oil for the 2018–2019 marketing year was greater than previously anticipated. The Committee initially estimated the trade demand for Native spearmint oil for the 2018–2019 marketing year to be 1,306,625. In a unanimous vote, the Committee revised its estimated trade demand for the 2018–2019 marketing year from 1,306,625 pounds to 1,400,000 pounds. In addition, the Committee recommended increasing the 2018–2019 marketing year Native spearmint oil salable quantity from 1,307,947 pounds to 1,357,315 pounds and the allotment percentage from 53 percent to 55 percent. The motion to recommend to the Secretary to increase the salable quantity and allotment percentage also passed unanimously.

A proposed rule concerning this action was published in the **Federal Register** on October 9, 2018 (83 FR 50527). A 60-day comment period ending December 10, 2018, was provided to allow interested persons to respond to the proposal.

During the proposed rule comment period, the Committee met again on October 17, 2018, to further discuss the changing Native spearmint oil market environment. The Order requires that producers and handlers report to the Committee all production and disposition of spearmint oil within the Order's production area. Using the information collected for the 2018–2019 and prior marketing years, the Committee staff reported that current marketing year trade statistics indicate demand for Native spearmint oil is greater than previously estimated. Further, the industry consensus of those in attendance at the meeting was that trade demand should remain strong throughout the year.

As such, in a unanimous action, the Committee again revised its 2018–2019 marketing year estimated trade demand for Native spearmint oil from 1,400,000 pounds to 1,450,000 pounds. Accordingly, the Committee also voted unanimously to recommend to USDA, via a public comment on the proposed rule (83 FR 50527), to increase the salable quantity and allotment percentage to 1,431,350 pounds and 58 percent, respectively. These numbers were derived by recalculating the salable quantity and allotment percentage to incorporate the increase in Native allotment base revealed by the updated industry data. These calculations are fully discussed below. The Committee recommended this quantity to fully supply anticipated demand (1,450,000 pounds) for the rest of the 2018–2019 marketing year and to carry-out an estimated 8,005 pounds of salable oil into the 2019–2020 marketing year.

After receiving the Committee's recommendation to amend the original proposal (submitted via public comment) and the other comments submitted during the comment period, USDA reviewed the updated industry information on the price, supply, and demand of Native spearmint oil supplied by the Committee and determined that additional oil, in excess of the level specified in the proposed rule, is necessary to fully supply the market for the 2018–2019 marketing year. As such, this final rule makes additional amounts of Native spearmint oil available to the market by increasing the salable quantity and allotment percentage previously established under the Order for the 2018–2019 marketing year. This rule increases the Native spearmint oil salable quantity by 123,403 pounds to 1,431,350 pounds and raises the allotment percentage 5 percentage points to 58 percent.

The additional Native spearmint oil will be made available from the release of oil held by producers in the reserve pool. As of May 31, 2018, the Committee records show that the reserve pool for Native spearmint oil contained 1,020,583 pounds of oil. This action will help reduce the quantity of Native spearmint oil held in reserve. The Committee considers the level of Native spearmint oil currently held in reserve to be excessive relative to market conditions.

The increased quantity of Native spearmint oil (123,403 pounds) that will be made available to the market as a result of this rule will ensure that market demand is fully satisfied in the current year and approximately 8,005 pounds of Native spearmint oil salable inventory will be available to carry-over for the start of the 2019–2020 marketing year, which begins on June 1, 2019.

In making the recommendation to increase the salable quantity and allotment percentage of Native spearmint oil for the 2018–2019 marketing year, the Committee considered newly gathered price, supply, and demand information collected through industry producer and handler reports and comments provided by those in attendance at the October 17, 2018, meeting. USDA has also reviewed the newly reported data and has concluded that the proposed increase would meet the needs of the industry.

This rule increases the 2018–2019 marketing year Native spearmint oil salable quantity by 123,403 pounds to a total of 1,431,350 pounds. Actual sales of Native spearmint oil for the 2017–2018 marketing year totaled 1,565,515 pounds. The 5-year average of Native spearmint oil sales is 1,365,377 pounds.

The Committee estimates that this action will result in 8,005 pounds of salable Native spearmint oil being carried into the 2019–2020 marketing year which begins June 1, 2019. While 8,005 pounds is a relatively low quantity of salable Native spearmint oil to begin the marketing year, reserve pool oil could be released into the market under a future relaxation of the volume regulation should it be necessary to

adequately supply the market prior to the beginning of the 2019–2020 marketing year. The Committee estimates that a total of 1,082,257 pounds of Native spearmint oil (1,020,583 currently in reserve and an estimated 61,674 pounds of excess oil produced during the 2018 crop year) will be available from the reserve pool, if needed.

As mentioned previously, when the 2018–2019 marketing policy statement was drafted, handlers estimated the demand for Native spearmint oil for the 2018–2019 marketing year to be 1,306,625 pounds. The Committee's initial recommendation for the establishment of the Native spearmint oil salable quantity and allotment percentage for the 2018–2019 marketing year was based on that estimate. The Committee did not anticipate the level of demand that the Native spearmint oil market is currently experiencing and did not account for it when the marketing policy for the 2018–2019 marketing year was adopted.

At the July 18, 2018, meeting, the Committee revised its estimate of Native spearmint oil trade demand to 1,400,000 pounds. The Committee further revised its estimate of trade demand to 1,450,000 at its October 17, 2018, meeting. The Committee believes that the supply of Native spearmint oil available to the market under the initially established salable quantity and allotment percentage would be insufficient to satisfy the current level of demand for oil at reasonable price levels. The Committee further believes that the increase in the salable quantity and allotment percentage established by this action is vital to ensuring an adequate supply of Native spearmint oil is available to the market moving forward.

The Committee's stated intent in the use of the Order's volume control regulation is to keep adequate supplies of spearmint oil available to meet market needs and to maintain orderly marketing conditions. With that in mind, the Committee developed its recommendation for increasing the Native spearmint oil salable quantity and allotment percentage for the 2018–2019 marketing year based on the information discussed above, as well as the summary data outlined below.

(A) *Initial estimated 2018–2019 Native allotment base—2,467,825 pounds.* This is the allotment base estimate upon which the original 2018–2019 marketing year salable quantity and allotment percentage was based.

(B) *Revised 2018–2019 Native allotment base—2,467,845 pounds.* This is 20 pounds more than the initial estimated allotment base of 2,467,825 pounds. The difference is the result of annual adjustments made to the allotment base at the beginning of the marketing year in accordance with the provisions of the Order.

(C) *Initial 2018–2019 Native allotment percentage—53 percent.* This was unanimously recommended by the Committee on October 25, 2017.

(D) *Initial 2018–2019 Native salable quantity—1,307,947 pounds.* This figure is 53 percent of the original estimated 2018–2019 marketing year allotment base of 2,467,825 pounds.

(E) *Adjusted initial 2018–2019 Native salable quantity—1,307,958 pounds.* This figure reflects the salable quantity actually available at the beginning of the 2018–2019 marketing year. This quantity is derived by applying the initial 53 percent allotment percentage to the revised allotment base of 2,467,845.

(F) *Revision to the 2018–2019 Native salable quantity and allotment percentage:*

(1) *Proposed increase in the 2018–2019 Native allotment percentage—2 percentage points.* The Committee initially recommended an increase of 2 percentage points over the initial Native allotment percentage at its July 17, 2018, meeting.

(2) *Proposed 2018–2019 Native allotment percentage—55 percent.* This number was derived by adding the increase of 2 percentage points to the initially established 2018–2019 allotment percentage of 53 percent.

(3) *Increase in the 2018–2019 Native allotment percentage established by this final rule—a total of 5 percentage points.* The Committee initially recommended an increase of 2 percentage points over the initial Native allotment percentage at its July 17, 2018, meeting. At its October 17, 2018, meeting, the Committee voted unanimously to recommend to USDA, via a public comment on the proposed rule (83 FR 50527), to increase the salable quantity and allotment percentage to 1,431,350 pounds and 58 percent, respectively. Based on comments received, including the Committee's recommendation, and a thorough review of all information presented, USDA is increasing the Native spearmint oil allotment percentage by a total of 5 percentage points.

(4) *Final revised 2018–2019 Native allotment percentage—58 percent.* This number was derived by adding the increase of 5 percentage points to the initially established 2018–2019 allotment percentage of 53 percent.

(5) *Final revised 2018–2019 Native salable quantity—1,431,350 pounds.* This amount is 58 percent of the revised 2018–2019 allotment base of 2,467,845 pounds.

(6) *Computed increase in the 2018–2019 Native salable quantity as a result of this revision—123,403 pounds.* This figure represents the difference between the initially established salable quantity of 1,307,947 pounds and the increased salable quantity of 1,431,350 pounds effectuated by this final rule.

Scotch spearmint oil is also regulated by the Order. As mentioned previously, a salable quantity and allotment percentage for Scotch spearmint oil for the 2018–2019 marketing year was established in a final rule published in the **Federal Register** on July 24, 2018 (83 FR 34935). At the July 18, 2018, meeting, the Committee considered the projected production, inventory, and marketing conditions for Scotch spearmint oil for the 2018–2019 marketing year. After receiving reports from the Committee staff and comments from the industry, the consensus of the Committee was that the established salable quantity and allotment percentage for Scotch spearmint oil was appropriate for the current market conditions. Therefore, the Committee recommended no further action with regard to Scotch spearmint oil for the 2018–2019 marketing year.

This final rule relaxes the volume regulation of Native spearmint oil and will allow producers to meet market demand and improve producer returns. In conjunction with the issuance of this rule, the Committee's revised marketing policy statement for the 2018–2019 marketing year has been reviewed by USDA.

The increase in the Native spearmint oil salable quantity and allotment percentage is expected to account for the anticipated market needs for that class of oil. In determining anticipated market needs, the Committee considered changes and trends in historical sales, production, and demand.

Final Regulatory Flexibility Analysis

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

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened.

Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are eight spearmint oil handlers subject to regulation under the Order, and approximately 43 producers of Scotch spearmint oil and approximately 95 producers of Native spearmint oil in the regulated production area. Small agricultural service firms are defined by the Small Business Administration (SBA) as those having annual receipts of less than $7,500,000, and small agricultural producers are defined as those having annual receipts of less than $750,000 (13 CFR 121.201).

Based on the SBA's definition of small entities, the Committee estimates that only two of the eight handlers regulated by the Order could be considered small entities. Most of the handlers are large corporations involved in the international trading of essential oils and the products of essential oils. In addition, the Committee estimates that 12 of the 43 Scotch spearmint oil producers and 31 of the 95 Native spearmint oil producers could be classified as small entities under the SBA definition. Thus, the majority of handlers and producers of Far West spearmint oil may not be classified as small entities.

The use of volume control regulation allows the spearmint oil industry to fully supply spearmint oil markets while avoiding the negative consequences of over-supplying these markets. Without volume control regulation, the supply and price of spearmint oil would likely fluctuate widely. Periods of oversupply could result in low producer prices and a large volume of oil stored and carried over to future crop years. Periods of undersupply could lead to excessive price spikes and drive end users to source flavoring needs from other markets, potentially causing long-term economic damage to the domestic spearmint oil industry. The Order's volume control provisions have been successfully implemented in the domestic spearmint oil industry since 1980 and provide benefits for producers, handlers, manufacturers, and consumers.

This rule increases the quantity of Native spearmint oil that handlers may purchase from, or handle on behalf of, producers during the 2018–2019 marketing year, which ends May 31, 2019. The 2018–2019 marketing year Native spearmint oil salable quantity was initially established at 1,307,947 pounds, and the allotment percentage initially set at 53 percent, in a final rule published in the **Federal Register** on July 24, 2018 (83 FR 34935). This final rule increases the Native spearmint oil salable quantity to 1,431,350 pounds and the allotment percentage to 58 percent.

Based on the information and market projections presented at the July 18 and October 17, 2018, meetings, the Committee considered several alternatives to this increase. The Committee considered leaving the salable quantity and allotment percentage unchanged and also considered other potential levels of increase. The Committee initially recommended increasing the salable quantity to 1,357,315 pounds and the allotment percentage to 55 percent. After further consideration, the Committee recommended, via a comment submitted during the rulemaking process, establishing the salable quantity at 1,431,350 pounds and the allotment percentage at 58 percent.

The Committee reached its final recommendation to increase the salable quantity and allotment percentage for Native spearmint oil after careful consideration of all available information and input from all interested industry participants. The Committee believes that the volume regulation levels effectuated herein will achieve the desired objectives. Without the increase, the Committee believes the industry will not be able to satisfactorily meet market demand at reasonable prices.

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

This final rule relaxes the volume regulation requirements established under the Order for the 2018–2019 marketing year. This action will not impose any additional reporting or recordkeeping requirements on either small or large spearmint oil handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

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

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

The Committee's July 18 and October 17, 2018, meetings were widely publicized throughout the Far West spearmint oil industry, and all interested persons were invited to attend the meetings and participate in Committee deliberations on all issues. The meetings were public, and all entities, both large and small, were able to express views on this issue.

A proposed rule concerning this action was published in the **Federal Register** on October 9, 2018 (83 FR 50527). Copies of the proposed rule were sent via email to all Committee members and Far West spearmint oil handlers. The proposed rule was made available through the internet by USDA and the Office of the **Federal Register**. A 60-day comment period ending December 10, 2018, was provided to allow interested persons to respond to the proposal. Three comments were received, including a comment submitted by the Committee manager on behalf of the Committee.

All three comments submitted were in support of increasing the salable quantity and allotment percentage of Native spearmint oil for the 2018–2019 marketing year. Further, the commenters recommended increasing the salable quantity and allotment percentage to a higher level than the one published in the proposed rule. Specifically, the commenters recommended establishing a salable quantity and allotment percentage of 1,431,350 pounds and 58 percent, respectively. The increased salable quantity and allotment percentage level recommended by the commenters for Native spearmint oil was 74,035 pounds and 3 percentage points higher than the level of increase proposed in the proposed rule. USDA considered the comments and updated Committee price, production and demand data submitted, and agrees that the recommended increased volume regulation is justified by current market conditions and is consistent with the requirements of the Order. Therefore, the salable quantity and allotment percentage, as proposed, have been revised accordingly in this final rule.

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

at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

USDA has determined that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register**. This final rule increases the saleable quantity and allotment percentage of Native spearmint oil for the 2018–2019 marketing year. Because this final rule relaxes the volume regulation requirements established under the Order for Native spearmint oil for the 2018–2019 marketing year, good cause exists to not delay the effective date of this rule.

List of Subjects in 7 CFR Part 985

Marketing agreements, Oils and fats, Reporting and recordkeeping requirements, Spearmint oil.

For the reasons set forth in the preamble, 7 CFR part 985 is amended as follows:

PART 985—MARKETING ORDER REGULATING THE HANDLING OF SPEARMINT OIL PRODUCED IN THE FAR WEST

■ 1. The authority citation for part 985 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. In § 985.233, revise paragraph (b) to read as follows:

§ 985.233 Salable quantities and allotment percentages.

* * * * *

(b) Class 3 (Native) oil—a salable quantity of 1,431,350 pounds and an allotment percentage of 58 percent.

Dated: April 18, 2019.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2019–08180 Filed 4–23–19; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1209

[Document Number AMS–SC–18–0009]

Mushroom Promotion, Research, and Consumer Information Order; Reallocation of Council Membership

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule reallocates the membership of the Mushroom Council (Council) under the Agricultural Marketing Service's (AMS) regulations regarding a national research and promotion program for mushrooms. The Council administers the regulations with oversight by the U.S. Department of Agriculture (USDA). This rule was recommended by the Council after a review of the geographic distribution of the volume of mushroom production throughout the United States and the volume of imports. This rule revises the number of Council members in two of the four geographic regions under the program. This action is necessary to provide for equitable representation of producers and importers on the Council.

DATES: *Effective Date:* May 24, 2019.

FOR FURTHER INFORMATION CONTACT: Marlene Betts, Marketing Specialist, Promotion and Economics Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, Room 1406–S, Stop 0244, Washington, DC 20250–0244; telephone: (202) 720–9915; facsimile (202) 205–2800; or electronic mail: *Marlene.Betts@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This rule affecting 7 CFR part 1209 is authorized under the Mushroom Promotion, Research, and Consumer Information Act of 1990 (Act) (7 U.S.C. 6101–6112).

Executive Orders 12866, 13563, and 13771

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules and promoting flexibility. This rulemaking has been determined to be not significant for purposes of Executive Order 13563. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review. Additionally, because this rule does not meet the definition of a significant regulatory action it does not trigger the requirements contained in Executive Order 13771. See OMB's Memorandum titled ''Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, titled 'Reducing Regulation and Controlling Regulatory Costs' '' (February 2, 2017).

Executive Order 13175

This action has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation would not have substantial and direct effects on Tribal governments and would not have significant Tribal implications.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. Section 1930 of the Act (7 U.S.C. 6109) provides that it shall not affect or preempt any other Federal or State law authorizing promotion or research relating to mushrooms.

Under section 1927 of the Act (7 U.S.C. 6106), a person subject to an order issued under the Act may file a written petition with USDA stating that an order, any provision of the order, or any obligation imposed in connection with the order, is not established in accordance with the law, and request a modification of the order or an exemption from the order. Any petition filed challenging an order, any provision of an order, or any obligation imposed in connection with the order, shall be filed within two years after the effective date of an order, provision, or obligation subject to challenge in the petition. The petitioner will have the opportunity for a hearing on the petition. Thereafter, USDA will issue a ruling on the petition. The Act provides that the district court of the United States for any district in which the petitioner resides or conducts business shall have the jurisdiction to review a final ruling on the petition, if the petitioner files a complaint for that purpose not later than 20 days after the date of the entry of USDA's final ruling.

Background

This rule reallocates the membership of the Council established under the Mushroom Promotion, Research, and Consumer Information Order (Order). The Order (7 CFR part 1209) is administered by the Council with oversight by USDA. This action was recommended by the Council after a review of the geographic distribution of the volume of mushroom production throughout the United States and the volume of imports. This rule revises the number of Council members representing two of the four regions under the program. This action is necessary to provide for equitable representation of producers and importers on the Council.

Section 1209.30(a) specifies that the Council shall consist of not less than four or more than nine members who are mushroom producers and importers. Pursuant to § 1209.30(b), for purposes of nominating and appointing producers to the Council, the United States is divided into three geographic regions and the number of Council members from each region are currently as follows: (1) Region 1: All other States including the District of Columbia and the Commonwealth of Puerto Rico except for Pennsylvania and California—two members; (2) Region 2: Pennsylvania—four members; and (3) Region 3: California—two members. Pursuant to § 1209.30(c), importers are represented by a single, separate region, referred to as Region 4, when imports, on average, equal or exceed 50,000,000 pounds of mushrooms annually.

Section 1209.30(d) prescribes that, at least every five years, and not more than every three years, the Council must review changes in the geographic distribution of mushroom production volume throughout the United States and import volume, using the average annual mushroom production and imports over the preceding four years. The Council must recommend to the Secretary reapportionment of the regions and/or modification of the number of members from such regions as necessary to best reflect the geographic distribution of mushroom production volume in the United States and representation of imports, if applicable.

Section 1209.30(e) prescribes a procedure to be used to determine the number of members for each region to serve on the Council, subject to the nine-member maximum limitation. Each region that produces, on average, at least 50,000,000 pounds of mushrooms annually is entitled to one representative on the Council. Importers are represented by a single, separate region, which is entitled to one representative, if the region imports, on average, at least 50,000,000 pounds of mushrooms annually. If the annual production of a region is greater than 110,000,000 pounds, but less than or equal to 180,000,000 pounds, the region must be represented by one additional member. If the annual production of a region is greater than 180,000,000 pounds, but less than or equal to 260,000,000 pounds, the region must be represented by two additional members. If the annual production of a region is greater than 260,000,000 pounds, the region must be represented by three additional members. Finally, if in the aggregate, regions are entitled to levels of representation that would exceed the nine-member limit on the Council, the seat or seats assigned shall be assigned to that region or those regions with greater on-average production or import volume than the other regions otherwise eligible at that increment level.[1]

The Council met in February 2018 and reviewed the geographic distribution of mushroom production volume throughout the United States and import volume to assess whether reapportionment of the current regions or modification of the number of members from such regions, or both, were warranted. Table 1 below is based on Council assessment data for the preceding four years (2014 through 2017).

TABLE 1—ANALYSIS OF COUNCIL REPRESENTATION BASED ON ASSESSMENT DATA

Region	Current council representation	2014 pounds	2015 pounds	2016 pounds	2017 pounds	4-year average	New council representation
		In millions					
1 (All other States)	2	202.7	205	203.8	196	201.9	3
2 (PA)	4	480.6	488	477.8	502.6	487.3	4
3 (CA)	2	109.5	102.3	106.7	91.2	102.4	1
4 (Imports)	1	98.8	110.1	119.3	132	115.1	1
	9	.....	.....	.....	.....	.....	9

Table 2 below provides a similar analysis based on U.S. production data from USDA's National Agricultural Statistics Service (NASS) and import data from USDA's Global Agricultural Trade System (GATS).[2]

TABLE 2—ANALYSIS OF COUNCIL REPRESENTATION BASED ON NASS AND GATS DATA

Region	Current council representation	2014 pounds	2015 pounds	2016 pounds	2017 pounds	4-year average	New council representation
			In millions				
1 (All other States)	2	208.8	217.5	221.6	223.9	218.0	3
2 (PA)	4	571.7	584.0	587.4	577.6	580.2	4
3 (CA)	2	101.5	105.6	109.9	101.7	104.7	1
4 (Imports)	1	80.6	89.5	102.0	111.3	98.5	1
	9	.....	.....	.....	.....	.....	9

[1] *On average* means a rolling average of production or imports during the last two fiscal years, or such other period as may be determined by the Secretary.

[2] NASS United States Department of Agriculture (USDA) (2018) Quick Stats. U.S. Department of Agriculture, National Agricultural Statistics Service, Washington DC. *https://quickstats.nass.usda.gov/*.

GATS United States Department of Agriculture (USDA) (2018) Global Agricultural Trade System. U.S. Department of Agriculture, Foreign Agricultural Service, Washington DC. *https://apps.fas.usda.gov/gats/*.

Council Recommendation

Based on its analysis, the Council unanimously recommended increasing the number of members in Region 1 by one and decreasing the number of members in Region 3 by one. This action is necessary to provide for equitable representation of producers and importers on the Council. No changes are necessary to the number of members in Regions 2 and 4 or to the make-up of any of the regions. Section 1209.230 which is currently reserved, will be added accordingly.

Final Regulatory Flexibility Act Analysis

In accordance with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS is required to examine the impact of the proposed rule on small entities. Accordingly, AMS has considered the economic impact of this action on such entities.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions so that small businesses will not be disproportionately burdened. The Small Business Administration (SBA) defines, in 13 CFR part 121, small agricultural producers as those having annual receipts of no more than $750,000 and small agricultural service firms (importers) as those having annual receipts of no more than $7.5 million.

It is estimated that there are about 120 mushroom producers in the United States and about 20 importers eligible to serve on the Council. The majority of these producers and importers would be considered small entities as defined by the SBA. Persons who produce or import organic mushrooms or who produce or import 500,000 pounds or less on average of mushrooms annually for the fresh market are exempt from the requirements of the Order.

This rule reallocates the membership of the Council under the Order. The Order is administered by the Council with oversight by USDA. This action was recommended by the Council after a review of the geographic distribution of the volume of mushroom production throughout the United States and the volume of imports. The rule revises the number of Council members in two of the four regions under the program. This action is necessary to provide for equitable representation of producers and importers on the Council. Section 1209.230 which is currently reserved, is being added accordingly. Authority for this action is provided in § 1209.30(d) of the Order and section 6104 of the Act (7 U.S.C. 6104).

Regarding the economic impact of this rule on affected entities, revising the number of members in Regions 1 and 3 will impose no additional costs on industry members. Eligible producers and importers interested in serving on the Council will have to complete a background questionnaire. Those requirements are addressed in the section below titled Reporting and Recordkeeping Requirements. The changes are necessary to provide for the equitable representation of producers and importers on the Council.

Regarding alternatives, one option to the action regarding revising the number of Council members in two of four regions would be to maintain the status quo and not revise the number of Council members representing Regions 1 and 3. However, the Council's analysis of the assessment data and NASS and GATS data support the changes. USDA concludes that the changes are necessary and appropriate.

Reporting and Recordkeeping Requirements

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the background form, which represents the information collection and recordkeeping requirements that are imposed under the program, have been approved previously under OMB number 0581–0093. The mushroom Order requires that two nominees be submitted for each vacant position. With regard to information collection requirements, producers and importers interested in serving on the Council must submit a background form (Form AD–755) to USDA to verify their eligibility for appointment to the Council. However, serving on the Council is voluntary, and the burden of submitting the background form would be offset by the benefits of serving on the Council.

As with all Federal promotion programs, reports and forms are periodically reviewed to reduce information collection requirements and duplication by industry and public sector agencies. USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this proposed rule. AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Regarding outreach efforts, this action was discussed by the Council at its meeting held in February 2018 where the Council unanimously made its recommendation. All of the Council's meetings are open to the public and interested persons are invited to participate and express their views.

A proposed rule concerning this action was published in the **Federal Register** on February 11, 2019 (84 FR 3114). A 30-day comment period ending March 13, 2019, was provided to allow interested persons to submit comments.

Analysis of Comment

Eight comments were received in response to the proposed rule. Of those eight comments, four comments supported the reallocation of Council members in two regions to more accurately represent the volume of production, one comment was opposed, and three comments were outside the scope of the rulemaking.

The comments that supported the proposed changes agreed with reallocating the number of members in two regions in order to more accurately represent the volume of production. Specifically, the comments supported increasing the number of member seats by one in Region 1 and decreasing the number of member seats by one in Region 3. In addition, the supporters recommended that the length of term for the new member in Region 1 be for a two-year term instead of the standard three-year term for the purpose of staggering the terms of the members representing Region 1. According to section 1925 of the Act (7 U.S.C. 6104) and § 1209.34 of the Order, members of the Council shall serve for terms of three years, except for members appointed to the initial Council. Since this is not the ''initial'' Council, members of the Council shall serve terms of three years, and therefore, the recommendation for a two-year term is not accepted.

One comment disagreed with the Council membership being determined based on geographic production volume. The commenter wants more diversification by type of mushroom growing method and suggests consideration of seats for growers specializing in farmers market distribution and those using sustainable agricultural practices. Section 1925 of the Act (7 U.S.C. 6104) and § 1209.30 of the Order state that the establishment and membership of the Council shall consider the geographical distribution of mushroom production throughout the U.S. and the comparative volume of mushrooms imported into the U.S. In addition, the Council has a diverse membership and has a policy to continuously pursue diverse representation in size of operations, experience of members, methods of production, and other factors to bring individuals with different perspectives to the Council. Further, the Council's

meetings are open to the public and interested persons are invited to participate and express their views.

No changes have been made to the proposed rule based on the comments received.

After consideration of all relevant matters presented, including the information and recommendations submitted by the Council, the comments received, and other available information, it is hereby found that this rule, as hereinafter set forth, is consistent with and will effectuate the purposes of the Act.

List of Subjects in 7 CFR Part 1209

Administrative practice and procedure, Advertising, Consumer information, Marketing agreements, Mushroom promotion, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 1209 is hereby amended as follows:

PART 1209—MUSHROOM PROMOTION, RESEARCH AND CONSUMER INFORMATION ORDER

■ 1. The authority citation for 7 CFR part 1209 continues to read as follows:

Authority: 7 U.S.C. 6101–6112 and 7 U.S.C. 7401.

■ 2. Revise the heading for subpart B to read as follows:

Subpart B—Administrative Requirements

■ 3. Section 1209.230 is added to read as follows:

§ 1209.230 Reallocation of Council members.

Pursuant to § 1209.30, the number of members on the Council shall be as follows:

(a) Region 1: All other States including the District of Columbia and the Commonwealth of Puerto Rico except for Pennsylvania and California—3 Members.

(b) Region 2: The State of Pennsylvania—4 Members.

(c) Region 3: The State of California—1 Member.

(d) Region 4: Importers—1 Member.

Dated: April 18, 2019.

Bruce Summers,

Administrator.

[FR Doc. 2019–08177 Filed 4–23–19; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–0522; Product Identifier 2015–SW–068–AD; Amendment 39–19621; AD 2019–07–10]

RIN 2120–AA64

Airworthiness Directives; Northrop Grumman LITEF GmbH LCR–100 Attitude and Heading Reference System Units

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for Northrop Grumman LITEF GmbH LCR–100 Attitude and Heading Reference System (AHRS) units installed on various aircraft. This AD requires removing certain LCR–100 AHRS units from service. This AD was prompted by test results showing loss of or invalid data. The actions of this AD are intended to prevent an unsafe condition on these products.

DATES: This AD is effective May 29, 2019.

ADDRESSES: For service information identified in this final rule, contact Northrop Grumman LITEF GmbH, Customer Service—Commercial Avionics, Loerracher Str. 18, 79115 Freiburg, Germany; telephone +49 (761) 4901–142; fax +49 (761) 4901–773; email *ahrs.support@ng-litef.de.* You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0522; 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 AD, the European Aviation Safety Agency (EASA) AD, the economic evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations Office, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Nick Rediess, Aviation Safety Engineer, Boston ACO Branch, Compliance and Airworthiness Division, 1200 District Avenue, Burlington, Massachusetts 01803; telephone (781) 238–7763; email *nicholas.rediess@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

On June 5, 2017, at 82 FR 25742, the **Federal Register** published our notice of proposed rulemaking (NPRM), which proposed to amend 14 CFR part 39 by adding an AD that would apply to airplanes and helicopters with a Northrop Grumman LITEF GmbH LCR–100 AHRS unit part number (P/N) 145130–2000, 145130–2001, 145130–7000, 145130–7001, or 145130–7100 installed that uses analog outputs for primary flight information display or autopilot functions without automatic output comparison. A primary flight information display includes any device that displays to the pilot primary flight information such as attitude, airspeed, and altitude. Such displays include primary flight displays, standby instruments, and multifunction displays that provide a secondary display of primary flight information. The NPRM proposed to require removing these LCR–100 AHRS units from service and to prohibit installing them on any aircraft.

These units are often used to supply attitude and heading data to Primary Flight Displays (PFDs), autopilots, and other avionics. Northrop Grumman LITEF GmbH discovered erroneous behavior of an AHRS unit when the unit's continuous built-in test detects a failure and then does not correctly reset. When this occurs, the analog outputs of attitude and heading data freeze and the transmission of digital outputs of attitude and heading stops. The effect of the errors (display of misleading information, providing an alert if the attitude and heading data is frozen) depends on how the AHRS unit outputs are used in a particular installation. For instance, if the AHRS unit analog outputs are used by a PFD without any automatic comparison with another source of data, the PFD will display misleading information, which could lead to loss of control of the aircraft. Other installations using the analog outputs might include an automatic comparison feature that detects and provides an alert if the attitude and heading data is frozen. A similar situation would occur in installations that use the digital outputs since the erroneous behavior would be detected. The NPRM proposed to only apply to installations of the AHRS units using analog outputs for the display of

primary flight information or for input to an autopilot without automatic output comparison since these installations do not provide any warning indication of the erroneous behavior.

The proposed requirements were intended to prevent an AHRS unit's analog outputs of attitude and heading data freezing without detection or warning, which could result in misleading attitude and heading information, anomalous autopilot behavior, and loss of control of the aircraft.

The NPRM was prompted by AD No. 2015–0093, dated May 27, 2015, issued by EASA, which is the Technical Agent for the Member States of the European Union, to correct an unsafe condition for the Northrop Grumman LITEF GmbH LCR–100 AHRS units. EASA advises that laboratory tests of the AHRS units discovered that when the built-in test detects failures and resets the system, the units are not executing the system reset properly, which results in a freeze of analog attitude and heading output data without detection or warning to the pilot. EASA states that installations vary, but if there is no automatic comparison of analog output to detect unit failure, this condition, if not corrected, could lead to undetected attitude and heading errors, possibly resulting in loss of control of the aircraft.

The NPRM also advised that the proposed AD would affect AD 2010–26–09 (75 FR 81424, December 28, 2010) (''AD 2010–26–09''), which applies to Sikorsky Model S–76A, B, and C helicopters with an AHRS unit P/N 145130–7100 installed. Since the NPRM proposed to require the removal of P/N 145130–7100, compliance with the proposed would make AD 2010–26–09 no longer valid for those Sikorsky helicopters.

Since the NPRM was issued, the FAA's Aircraft Certification Service has changed its organizational structure. The new structure replaces product directorates with functional divisions. We have revised some of the office titles and nomenclature throughout this Final rule to reflect the new organizational changes. Additional information about the new structure can be found in the Notice published on July 25, 2017 (82 FR 34564).

Comments

After our NPRM was published, we received comments from one commenter.

Request

The commenter suggested we made an error in the Discussion section where it states, ''A similar situation would occur in installations that use the digital outputs since the erroneous behavior would be detected.'' The commenter states the loss of digital data would be detected, and therefore the sentence should state instead that a similar situation would not occur.

We disagree. The commenter is correct that an installation that uses digital outputs would detect the erroneous behavior and provide an alert. The ''similar situation'' referred to is the alert provided by installations that use analog outputs with automatic comparison, which also detect the attitude and heading data becoming frozen. Because both types of installations detect the erroneous behavior, they result in a similar situation. We did not change the AD based on this comment.

FAA's Determination

We have reviewed the relevant information, considered the comment received, and determined that an unsafe condition exists and is likely to exist or develop on other products of these same type designs and that air safety and the public interest require adopting the AD requirements as proposed.

Differences Between This AD and the EASA AD

This AD only applies to certain part-numbered AHRS units that use analog outputs for primary flight information display or autopilot functions without automatic output comparison. The EASA AD applies to all of these part-numbered units regardless of the type of installation. The EASA AD requires inserting a temporary revision into the flight manual for analog without automatic output comparison installations until the AHRS unit is replaced with a modified unit. This AD does not require temporarily revising the flight manual. The EASA AD requires replacing the AHRS units with particular part-numbered modified units, while this AD requires removing the AHRS units from service instead.

Related Service Information

We reviewed Northrop Grumman LITEF GmbH Service Bulletin No. 145130–0017–845, Revision D, dated April 1, 2015 (SB 145130–0017–845). SB 145130–0017–845 specifies returning the applicable part numbered AHRS units to certain repair stations for modification. The modified AHRS units, which have new part numbers, have an additional watchdog circuit in the electronic board that eliminates frozen analog outputs and digital output interruptions.

Costs of Compliance

We estimate that this AD affects 50 aircraft of U.S. Registry. We estimate that operators may incur the following costs in order to comply with this AD. Labor costs are estimated at $85 per work-hour, and typical installations consist of two AHRS units. Replacing two AHRS units takes about 4 work-hours and $62,630 for required parts, for a total cost of $62,970 per aircraft and $3,148,500 for the U.S. fleet.

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.

We are 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) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and

(4) 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.

We prepared an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

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

Adoption of 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 (AD):

2019–07–10 Northrop Grumman LITEF GmbH LCR–100 Attitude and Heading Reference System: Amendment 39–19621; Docket No. FAA–2017–0522; Product Identifier 2015–SW–068–AD.

(a) Applicability

This AD applies to airplanes and helicopters, certificated in any category, with a Northrop Grumman LITEF GmbH LCR–100 Attitude and Heading Reference System (AHRS) unit part number (P/N) 145130–2000, 145130–2001, 145130–7000, 145130–7001, or 145130–7100 installed using analog outputs for primary flight information display or autopilot functions without automatic output comparison. Aircraft known to have the subject AHRS units installed include but are not limited to the following:

(1) Dornier Luftfahrt GmbH Model 228–100, 228–101, 228–200, 228–201, 228–202, and 228–212 airplanes;

(2) Learjet Inc. Model 31A airplanes;

(3) Pilatus Aircraft Ltd. Model PC12, PC–12/45, and PC–12/47 airplanes;

(4) Polskie Zaklady Lotnicze Sp. z o.o. Model PZL M28 05 airplanes;

(5) Textron Aviation Inc. (type certificate previously held by Cessna Aircraft Company) Model 560XL airplanes;

(6) Bell Helicopter Textron Canada Limited Model 407 helicopters;

(7) Bell Helicopter Textron Inc. Model 412 and 412EP helicopters; and

(8) Sikorsky Aircraft Corporation Model S–76A, S–76–B, and S–76C helicopters.

(b) Unsafe Condition

This AD defines the unsafe condition as the AHRS unit's analog outputs of attitude and heading data freezing without detection or warning. This condition could result in misleading attitude and heading information, anomalous autopilot behavior, and loss of control of the aircraft.

(c) Affected ADs

This AD affects AD 2010–26–09, Amendment 39–16548 (75 FR 81424, December 28, 2010) (''AD 2010–26–09''). Accomplishing a certain requirement of this AD terminates the requirements of AD 2010–26–09.

(d) Effective Date

This AD becomes effective May 29, 2019.

(e) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(f) Required Actions

(1) Within 25 hours time-in-service (TIS), remove the AHRS unit from service.

(2) Removal from service of P/N 145130–7100 terminates the requirements of AD 2010–26–09 (75 FR 81424, December 28, 2010).

(3) Do not install an AHRS unit P/N 145130–2000, 145130–2001, 145130–7000, 145130–7001, or 145130–7100 on any aircraft.

(g) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Boston ACO Branch, FAA, may approve AMOCs for this AD. Send your proposal to: Nick Rediess, Aviation Safety Engineer, Boston ACO Branch, Compliance and Airworthiness Division, 1200 District Avenue, Burlington, Massachusetts 01803; telephone (781) 238–7763; email *nicholas.rediess@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office, before operating any aircraft complying with this AD through an AMOC.

(h) Additional Information

(1) Northrop Grumman LITEF GmbH Service Bulletin No. 145130–0017–845, Revision D, dated April 1, 2015, which is not incorporated by reference, contains additional information about the subject of this AD. For service information identified in this AD, contact Northrop Grumman LITEF GmbH, Customer Service—Commercial Avionics, Loerracher Str. 18, 79115 Freiburg, Germany; telephone +49 (761) 4901–142; fax +49 (761) 4901–773; email *ahrs.support@ng-litef.de.* You may review a copy of the service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

(2) The subject of this AD is addressed in European Aviation Safety Agency (EASA) AD No. 2015–0093, dated May 27, 2015. You may view the EASA AD on the internet at *http://www.regulations.gov* in Docket No. FAA–2017–0522.

(i) Subject

Joint Aircraft Service Component (JASC) Code: 3420, Attitude and Directional Data System.

Issued in Fort Worth, Texas, on April 16, 2019.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2019–08157 Filed 4–23–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 7

[Docket No. RM19–6–000; Order No. 858]

Hydroelectric Licensing Regulations Under the America's Water Infrastructure Act of 2018

AGENCY: Federal Energy Regulatory Commission.

ACTION: Final rule.

SUMMARY: In this final rule, the Federal Energy Regulatory Commission (Commission) is establishing an expedited process for issuing original licenses for qualifying facilities at existing nonpowered dams and for closed-loop pumped storage projects, pursuant to sections 3003 and 3004 of the America's Water Infrastructure Act of 2018. Under the expedited licensing process, the Commission will seek to ensure that a final decision is issued no later than two years after the Commission receives a completed license application. The final rule will be codified in a new part that will be added to the Commission's regulations.

DATES: The rule is effective July 23, 2019.

FOR FURTHER INFORMATION CONTACT:

Shana Wiseman (Technical Information), Office of Energy Projects, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–8736, *shana.wiseman@ferc.gov.*

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Order No. 858

Final Rule

(Issued April 18, 2019)

1. On October 23, 2018, the America's Water Infrastructure Act (AWIA) [1] was signed into law. The AWIA requires the Federal Energy Regulatory Commission (Commission or FERC) to establish an expedited process for issuing and amending licenses for qualifying facilities at existing nonpowered dams and for closed-loop pumped storage projects. Under the expedited process, the Commission will seek to ensure that a final decision on a license application is issued no later than two years after the Commission receives a completed license application.

2. To comply with the AWIA, the Commission issues this final rule to amend its regulations governing hydroelectric licensing under the Federal Power Act (FPA) by establishing an expedited licensing process for qualifying facilities at existing nonpowered dams and for closed-loop pumped storage projects. The final rule will be codified in a new part 7 that will be added to Title 18 of the Code of Federal Regulations.

I. Background

3. Sections 3003 and 3004 of the AWIA amended the FPA by adding new sections 34 and 35. Section 34 of the FPA gives the Commission discretion to issue or amend licenses, as appropriate, for any facility that the Commission determines is a qualifying facility at an existing nonpowered dam. Section 35 of the FPA gives the Commission discretion to issue or amend licenses, as appropriate, for closed-loop pumped storage projects. Congress directed the Commission to issue a rule, no later than 180 days after October 23, 2018, establishing an expedited licensing process for issuing and amending licenses for projects covered by FPA sections 34 and 35. In establishing the expedited licensing process, Congress directed the Commission to convene an interagency task force (ITF), with appropriate federal and state agencies and Indian Tribes represented, to coordinate the regulatory processes associated with the authorizations required to construct and operate qualifying facilities at nonpowered dams and closed-loop pumped storage projects.

4. On November 13, 2018, the Commission issued a notice inviting federal agencies, state agencies, and Indian Tribes to participate on the ITF.[2] The notice directed interested agencies and Indian Tribes to file a statement of interest with the Commission by November 29, 2018. On December 6, 2018, the Commission issued a notice identifying 28 federal agencies, state agencies, and Indian Tribes as ITF participants.[3]

5. On December 12, 2018, the Commission convened a meeting with the ITF participants at the Commission's headquarters to discuss the Commission's preliminary proposal to coordinate the regulatory processes associated with the authorizations required to construct and operate qualifying facilities at nonpowered dams and closed-loop pumped storage projects. At the meeting, Commission staff presented for the ITF participants' consideration and comment a flowchart illustrating a draft expedited licensing process.[4] In addition to soliciting comments at the meeting, Commission staff invited ITF participants to file comments on the process in Docket No. RM19–6–000 by December 26, 2018. Seven post-session comments were filed. The Commission's coordination and discussion with appropriate federal and state agencies and Indian Tribes, as part of the ITF, have informed this final rule.

II. Notice of Proposed Rulemaking

6. On January 31, 2019, the Commission issued a Notice of Proposed Rulemaking proposing to promulgate rules to establish an

[1] Public Law 115–270, 132 Stat. 3765.

[2] *See Notice Inviting Federal and State Agencies and Indian Tribes to Request Participation in the Interagency Task Force Pursuant to America's Water Infrastructure Act of 2018,* 83 FR 58,245 (Nov. 19, 2018).

[3] *See* Notice of Interagency Task Force (Dec. 6, 2018); *see also* FERC, Office of Energy Projects, Summary of Interagency Task Force Activities (Jan. 10, 2019) (Appendix A identifies the ITF participants).

[4] *See* Commission staff's Letter to ITF Participants, Summary of Interagency Task Force Activities (Jan. 10, 2019).

expedited process to license eligible projects at existing nonpowered dams and closed-loop pumped storage projects.[5] In response to the NOPR, the Commission received 11 comments. Consumers Energy Company (Consumers),[6] Daybreak Power, Inc. (Daybreak),[7] Dominion Energy Services, Inc. (Dominion),[8] the U.S. Department of Agriculture's Forest Service (Forest Service), the U.S. Department of the Interior (Interior),[9] the National Hydropower Association (NHA),[10] the National Marine Fisheries Service (NMFS), the Oregon Department of Fish and Wildlife (Oregon DFW), the Nature Conservancy, the Pennsylvania State Historic Preservation Office (PA SHPO), and Rye Development, LLC (Rye Development) filed comments.[11] The proposal set forth in the NOPR, the comments received in response to the NOPR, and the Commission's determinations are discussed below.

III. Discussion

A. Scope of the Expedited Licensing Process

7. The NOPR explained that the Commission's current regulations provide three pre-filing process options for hydropower developers to use in preparing license applications: (i) the integrated licensing process (ILP), which is the default process, as described in part 5;[12] (ii) the traditional licensing process (TLP), as described in part 4, subparts D to H;[13] or (iii) the alternative procedures (*i.e.,* the alternative licensing process (ALP)), as described in section 4.34(i) of part 4.[14] The NOPR did not propose to alter these existing licensing processes. Rather, the NOPR proposed to establish procedures for the Commission to determine, on a case-by-case basis, whether original license applications for qualifying hydropower projects at nonpowered dams or for closed-loop pumped storage projects, as defined in sections 34 and 35 of the FPA and the eligibility criteria below, qualify for expedited processing.

8. As stated in the NOPR, the use of the expedited licensing process is voluntary. To apply for consideration under the expedited process, an applicant for an original license for a qualifying hydropower project or closed-loop pumped storage project must supplement its license application with a request for authorization to use the expedited licensing process.

9. The NOPR proposed that the expedited licensing process would begin with the receipt of a completed license application. Consistent with the statute, the proposed expedited licensing process envisioned a two-year framework that did not include the pre-filing stages of application development (*i.e.,* all process milestones and consultation to obtain necessary authorizations that must occur before an applicant files a license application). For pre-filing activities, the NOPR explained that any applicant interested in pursuing authorization to use the expedited licensing process must use the default ILP, or request authorization to the use TLP or ALP, as required under our current regulations.

10. Finally, the scope of the NOPR was limited to original license applications. However, the Commission requested comments on whether the expedited licensing process should apply to applications for a new or subsequent license for a project that was originally licensed under the expedited licensing process.[15]

1. Pre-filing Process

11. NHA, Consumers, Dominion, and Rye Development encourage the Commission to improve the overall process to authorize hydroelectric facilities, which includes streamlining the pre-filing process.[16] Rye Development estimates that the NOPR may not reduce the overall licensing time, which it calculates to be at least three years for the pre-filing process and two years for the post-filing process for a total of at least five years, because the NOPR does not address the pre-filing process time.[17] This, it alleges, is contrary to Congressional intent.[18] Rye Development explains that a shorter and more certain licensing schedule, which includes pre-filing process ''reforms'' and allows for off-ramps for more problematic projects, would allegedly make hydroelectric generation cost competitive with other types of power generation and help attract investors.[19]

12. NHA proposes, and Dominion supports, an alternative two-step pre-filing process that NHA posits will allow the Commission to determine, during pre-filing, whether a project would be eligible for the expedited licensing process.[20] If the Commission finds a project eligible, NHA recommends that the Commission also grant preliminary approval of draft study plans and establish milestones and a schedule for the expedited licensing process during pre-filing.[21] Noting that the success of the expedited licensing process depends on the cooperation of all parties to the process, NHA and Dominion also encourage other federal and state agencies to align their policies and regulations with the expedited licensing process and urge consideration of an interagency memorandum of understanding.[22]

13. The Commission understands the importance of a clear process schedule. It is for this reason that the Commission has made publicly available on its website diagrammatic representations of the ILP and TLP.[23] We will provide the same for the expedited licensing process under the new part 7.[24] This rulemaking, however, is limited to the post-filing period as mandated by the AWIA. Congress required the Commission to issue a rule establishing a two-year expedited licensing process that begins from the receipt of a

[5] *Hydroelectric Licensing Regulations Under the America's Water Infrastructure Act of 2018,* 84 FR 2469, 166 FERC ¶ 61,083 (2019) (NOPR).

[6] Consumers is a public utility that owns and operates thirteen FERC-licensed hydroelectric projects.

[7] Daybreak is a developer of pumped storage projects.

[8] Dominion holds a preliminary permit for the proposed Tazewell Hybrid Energy Center Project No. 14854, and states that it is currently investigating whether the Tazewell Project, or a similar project, could be configured as a closed-loop pumped storage project.

[9] Interior represents the U.S. Bureau of Reclamation, the National Park Service, and U.S. Fish and Wildlife Service in its comment.

[10] NHA represents the Edison Electric Institute, the National Rural Electric Cooperative Association, the American Public Power Association, and the Northwest Hydropower Association in its comment.

[11] Rye Development is developing a number of hydroelectric projects, including one that was licensed under the Commission's Two-Year Pilot Licensing Process, *FFP Project 92, LLC,* 155 FERC ¶ 62,089 (2016).

[12] 18 CFR part 5 (2018).

[13] 18 CFR part 4, subpt. D–H (2018).

[14] *Id.* 4.34(i).

[15] NOPR, 166 FERC ¶ 61,083 at P 7.

[16] *See* NHA's March 11, 2019 Comment at 4–6; Consumers' March 11, 2019 Comment at 2; Dominion's March 11, 2019 Comment at 1–2; Rye Development's March 8, 2019 Comment at 2.

[17] *See* Rye Development's Comment at 2.

[18] *See id.* at 2–3.

[19] *See id.* at 3–4.

[20] *See* NHA's Comment at 6–9 (proposing a two-step pre-filing eligibility determination that would culminate in Commission action on a request for authorization to use the expedited licensing following issuance of the Scoping Document 1); Dominion's Comment at 2–4.

[21] NHA's Comment at 6–7; Dominion's Comment at 4.

[22] NHA's Comment at 7–8; Dominion's Comment at 4.

[23] *See* FERC, the Integrated Licensing Process (ILP)—Tutorial, *https://www.ferc.gov/industries/hydropower/gen-info/licensing/ilp/ilp-tutorial/overview.asp* (updated Oct. 10, 2012); FERC, Processes for Hydropower Licenses—Traditional Licensing Process (Applicant's Pre-Filing Process), *https://www.ferc.gov/resources/processes/flow/hydro-1.asp;* FERC, Processes for Hydropower Licenses—Traditional Licensing Process (FERC Application Process), *https://www.ferc.gov/resources/processes/flow/hydro-2.asp.*

[24] Commission staff will provide a flowchart on the Commission's website shortly after the final rule is issued.

completed license application.[25] Completion of the pre-filing process is necessary to develop a completed application. We therefore decline to revise the established pre-filing schedule in our existing regulations in this rulemaking. Furthermore, the Commission's existing ALP framework provides the flexibility that could accommodate, on a case by case basis, the type of pre-filing schedule NHA has proposed.[26]

14. While we encourage federal and state agencies to cooperate with the Commission's licensing schedules, we have no authority to require other agencies to modify their own regulations or policies to suit our licensing process as encouraged by NHA and Dominion. Nor will we dictate to other agencies how their regulations or policies should be interpreted. Expedited processing is possible when applicants and stakeholders work closely during pre-filing to gather information, conduct studies, and address information gaps. Expedited licensing is further aided by well-developed license applications that provide a detailed project proposal, a comprehensive summary of existing facilities and natural resources, and a thorough examination of the resource issues at hand and study needs.

2. Relicense Proceedings

15. The NOPR requested comments on whether the expedited licensing process should be available for applications for new or subsequent licenses,[27] provided that the project was originally licensed under the expedited licensing process.[28]

16. Daybreak and Consumers recommend that the proposed rule be expanded to include relicensing of projects licensed under the expedited licensing process.[29] NHA did not explicitly express opposition or support in response to the Commission's relicensing inquiry, but observed that the first new or subsequent license applications for projects originally licensed under the expedited licensing process would not be filed for another 40 years.[30] Absent a significant change in the regulatory landscape, NHA finds it highly unlikely that future relicensing of a project that was originally licensed under the expedited licensing process could not be completed within two years.[31]

17. The AWIA's eligibility criteria for qualifying facilities at existing nonpowered dams exclude facilities that are already licensed or exempted from license requirements in the FPA.[32] Thus, future new or subsequent license applications for projects at existing nonpowered dams that were originally licensed under the expedited process would be ineligible to participate in the expedited process. Furthermore, we agree with NHA's observation that, in most cases, a relicense proceeding for a project that was originally licensed under the expedited licensing process should be completed within an average of two years under the Commission's existing regulations. Accordingly, the expedited licensing process set forth in this final rule remains limited in scope to original license applications for projects at qualifying facilities at existing nonpowered dams and for closed-looped pumped storage projects.

3. Amendment Proceedings

18. The NOPR explained that FPA sections 34(a)(1) and 35(a)(1) give the Commission discretion to amend licenses, as appropriate, for any facility that the Commission determines is a qualifying facility. As part of this rulemaking, the Commission is required to establish an expedited process for amending licenses for qualifying facilities. FPA sections 34(a)(4) and 35(a)(4) explicitly define the expedited process for license applications as a two-year process for the Commission to issue a final decision on a license application once it receives a completed license application. These sections, however, are silent on the length of time to process applications to amend licenses.

19. Because the Commission already processes the majority of amendments within two years, the NOPR proposed to process applications to amend licenses for projects located at qualifying nonpowered dams and for closed-loop pumped storage projects under the Commission's existing regulations for amendments in 18 CFR part 4, subpart L.[33]

20. NHA contends that once a project is licensed, there is no reason that applications to amend licenses issued under the expedited licensing process should receive preferential treatment over applications to amend licenses issued under the ILP, TLP, or ALP framework.[34] No other comments addressed or advocated for an expedited amendment process separate and apart from the Commission's existing procedures for license amendment applications.

21. Therefore, we are satisfied that the Commission's existing procedures will continue to result in expeditious action on any application to amend a license originally licensed under the expedited process, well within the two-year benchmark established in the AWIA. Accordingly, the final rule does not establish a separate process for acting on applications to amend licenses issued under the expedited licensing process.

B. Expedited Licensing Process

1. Section 7.1—Applicability and Definitions

22. In § 7.1(c)(3) of the NOPR, the Commission restated the Commission's current definition of a closed-loop pumped storage project as ''a pumped storage project that is not continually connected to a naturally-flowing water feature.'' [35] The NOPR also incorporated the statutorily-defined ''qualifying criteria,'' ''qualifying nonpowered dam,'' and ''qualifying facility.''

23. We received several comments that the key terms, such as ''continually,'' ''connected,'' and ''naturally-flowing water features'' are unclear, which could potentially result in the expeditious licensing of an environmentally-harmful pumped storage project.[36] Some commenters argue that a pumped storage project may not be ''continually'' connected to a naturally-flowing water feature, but those intermittent periods when the

[25] *See* 16 U.S.C.A. 823e(a)(4), 823f(a)(4) (West 2019).

[26] The ALP framework was designed to be flexible in order for an applicant to tailor the pre-filing consultation process to the circumstances of each case. *See Regulations for the Licensing of Hydroelectric Projects,* Order No. 596, FERC Stats & Regs ¶ 31,057, at P 6 (1997) (cross-referenced at 81 FERC ¶ 61,103).

[27] A new license is a license that is issued under FPA section 15(a) after an original license expires. A subsequent license is a license that is issued under FPA Part I after a minor or minor-part license that was not subject to FPA sections 14 and 15 expires. Both new and subsequent licenses are considered relicenses. *See* 18 CFR 16.2(a), (d) (2018).

[28] NOPR, 166 FERC ¶ 61,083 at P 7.

[29] Daybreak's February 25, 2019 Comment at 1; Consumers' Comment at 1–2.

[30] *See* NHA's Comment at 17.

[31] *Id.* at 17. NHA further states that a new or subsequent license application for a project previously licensed at an existing dam would not qualify for the expedited licensing process because it would not satisfy the requirement set forth in section 34(e)(1)(A) of the FPA that the project not already be licensed.

[32] *See* 16 U.S.C.A. 823e(e)(1)(A) (West 2019).

[33] NOPR, 166 FERC ¶ 61,083 at PP 42–44 (estimating that about 98 percent of amendment-related filings were processed in two years during the past five years).

[34] NHA's Comment at 18.

[35] NOPR, 166 FERC ¶ 61,083 at PP 21 & 36. The NOPR's preamble mistakenly used ''continuously'' instead of ''continually'' to describe the Commission's current definition of closed-loop pumped storage.

[36] *See* Interior's March 8, 2019 Comment at 2–3, Forest Service's March 8, 2019 Comment at 2, Oregon DFW's March 11, 2019 Comment at 1–2.

project is connected to the naturally-flowing water feature could result in substantial resource impacts.[37] On the other hand, NHA, Consumers, and Dominion encourage the Commission to generously interpret terms, such as closed-loop pumped storage, in order to allow more projects to be eligible for the expedited process.[38]

24. In addition, commenters contend that the term ''connected'' is ambiguous as to whether the connection only refers to a physical hydraulic connection or includes a separate and independent hydrologic connection.[39] Some commenters suggest that for a project to qualify for expedited processing as a closed-loop pumped storage project, there should be no hydrologic connection between the project and surface or groundwater features.[40] Interior notes that subsurface or surface hydrologic connections might adversely affect lake levels and associated recreational use and access on lakes which would lead to longer processing times.[41] NHA and Dominion allege that excluding projects from eligibility based on a mere physical hydraulic or a hydrologic connection to surface waters or groundwater would disqualify almost all closed-loop pumped storage projects, and therefore request that our definition focus on how the water would be used by the project rather than how the project is connected to the water feature.[42]

25. As for ''naturally-flowing water features,'' the Forest Service asks whether such water features include groundwater aquifers, existing lakes, or other isolated waterbodies.[43] Commenters note that although flow is generally not significant in the hydrologic mass balance of lakes or other isolated, surface water features,[44] use of the term ''naturally-*flowing*'' could result in eligibility for projects that would significantly adversely affect lakes, endorheic basins,[45] and other isolated surface water features,[46] as well as wildlife that inhabit these areas.[47]

26. We received several proposed alternative definitions of a closed-loop pumped storage project.

27. The Forest Service recommends that a closed-loop pumped storage project be defined as a pumped storage project ''whose operation causes little to no change in discharge, flow, water quality, or other hydrologic characteristics of naturally-occurring surface or groundwater features, or the species and habitats that depend on these features.'' [48] Oregon DFW suggests defining closed-loop pumped storage as ''projects that utilize artificial reservoirs that have been constructed and operated for purposes authorized in the original license; that rely on temporary connections to flowing water features or groundwater for initial fill and periodic recharge; and whose construction and operation causes little to no change in discharge, flow, water quality, or other hydrologic characteristics of naturally occurring surface or groundwater features, or to the fish and wildlife and their habitats associated with these features.'' [49] NHA and Dominion encourage the Commission to expand its definition, and suggest that the Commission define a closed-loop pumped storage project as: ''a pumped storage project that: (1) does not obtain its principal water supply from a naturally-flowing water feature; (2) obtains its water from a naturally-flowing surface water feature only for the purpose of initial fill and periodic replenishment, or (3) is not located on a navigable waterway.'' [50]

28. As noted by the resource agencies, we recognize that use of the term ''not continually connected'' in our definition might capture pumped storage projects that would potentially require additional time and agency resources to determine their environmental effects, and may not be appropriate for expedited processing. Therefore, in the final rule, we adopt a definition of a closed-loop pumped storage project that focuses on the extent and type of a project's use of surface waters or groundwater rather than on its physical, hydraulic connection to such features. Further, we agree with the resource agencies that the term ''naturally-flowing water features'' in terms of a connected use is overly narrow and does not account for the environmental significance of water withdrawals from such features as groundwater, lakes, and wetlands. We see the benefit in specifying in our definition how we expect closed-loop pumped storage projects would utilize water from these water features (*i.e.,* initial fill and periodic recharge), as suggested by many commenters.[51]

29. In addition, as required by section 35(g)(2) of the FPA, a request to use the expedited licensing process must demonstrate that a closed-loop pumped storage project will cause little to no change to existing surface and groundwater flows and uses, and is unlikely to adversely affect species listed as threatened or endangered under the Endangered Species Act of 1973 (ESA).[52] If the proposed project does not meet these two aforementioned statutory criteria, then the project will not qualify under the AWIA for use of the expedited process. Therefore, we have incorporated these criteria into the final rule's definition of a closed-loop pumped storage project.

30. As to the statutory requirement that the project cause little to no change to the existing surface flows and uses, the mere presence of a pumped storage project reservoir on a surface water feature, such as a natural waterway, lake, or wetland would undeniably change existing surface water flows and uses in direct contravention of FPA section 35(g)(2)(A). For this reason and for clarification, the revised definition requires closed-loop pumped storage projects to use reservoirs that are not located on natural surface water features.

31. Therefore, informed by the comments received on the NOPR, and for the purposes of expediting processing under the AWIA, § 7.1(c)(3) is revised, as follows: ''pumped storage projects that: (1) cause little to no change to existing surface and groundwater flows and uses; (2) are unlikely to adversely affect species listed as a threatened species or endangered species, or designated critical habitat of such species, under the Endangered Species Act of 1973; (3) utilize only reservoirs situated at locations other than natural waterways, lakes, wetlands, and other natural surface water features; and (4) rely only on temporary withdrawals from surface

[37] *See* Forest Service's Comment at 2; Interior's Comment at 3; Oregon DFW's Comment at 1.

[38] *See* NHA's Comment at 10–15; Consumers' Comment at 2; Dominion's Comment at 4–8.

[39] *See, e.g.,* Forest Service's Comment at 2.

[40] *See* Oregon DFW's Comment at 2; Nature Conservancy's March 11, 2019 Comment at 4; Forest Service's Comment at 2.

[41] *See* Interior's Comment at 3.

[42] *See* NHA's Comment at 14; Dominion's Comment at 7.

[43] *See* Forest Service's Comment at 2.

[44] *See id.*

[45] Endorheic basins are hydrologically-landlocked drainage basins that do not discharge to other bodies of water.

[46] *See* Forest Service's Comment at 2; Interior's Comment at 3; Oregon DFW's Comment at 2.

[47] *See* Oregon DFW's Comment at 2.

[48] Forest Service's Comment at 1.

[49] Oregon DFW's Comment at 2.

[50] NHA's Comment at 15; *see* Dominion's Comment at 7. NHA contends that the location of a proposed project on non-navigable waterways (*e.g.,* small creeks or streams which do not contain or affect significant environmental resources) should not disqualify the project from the expedited licensing process.

[51] *See, e.g.,* NHA's Comment at 11, 14–15; Dominion's Comment at 5; Oregon DFW's Comment at 2.

[52] 16 U.S.C. 1531–1544 (2012).

waters or groundwater for the sole purposes of initial fill and periodic recharge needed for project operation.''

2. Section 7.2—Use of Expedited Licensing Process

32. Section 7.2 of the NOPR described the information that an applicant must include in any license application that accompanies a request to use the expedited licensing process. The information includes design and environmental criteria mandated by sections 34 and 35 of the FPA and documentation demonstrating early consultation with relevant agencies, Indian Tribes, and dam owners.[53]

a. Statutory Criteria for Qualifying Facilities at Nonpowered Dams

33. FPA section 34(e)(1) sets forth the ''qualifying criteria'' that a proposed project at an existing ''qualifying nonpowered dam'' must meet in order to be considered a ''qualifying facility'' [54] eligible to apply for the expedited licensing process. Section 34(e)(1) states that such a facility must: (A) As of October 23, 2018, not be licensed under, or exempted from, the license requirements contained in Part I of the FPA; (B) be associated with a qualifying nonpowered dam; (C) be constructed, operated, and maintained for the generation of electric power; (D) generate electricity by using any withdrawals, diversions, releases, or flows from the associated qualifying nonpowered dam, including its associated impoundment or other infrastructure; and (E) not result, due to operation of the facility, in any material change to the storage, release, or flow operations of the associated qualifying nonpowered dam.[55]

34. Section 34(e)(3) defines ''qualifying nonpowered dam'' as any dam, dike, embankment, or other barrier, constructed on or before October 23, 2018, that is or was operated for the control, release, or distribution of water for agricultural, municipal, navigational, industrial, commercial, environmental, recreational, aesthetic, drinking water, or flood control purposes, and that, as of October 23, 2018, is not generating electricity with hydropower generating works licensed under, or exempted from, the license requirements of Part I of the FPA.[56]

35. NHA and the Nature Conservancy ask the Commission to define the term ''material change'' contained in FPA section 34(e)(1)(E).[57] Concerned that the Commission's interpretation of this statutory qualifying criterion might unnecessarily preclude from the expedited process projects that would have only minor effects on existing dam operations,[58] NHA proposes to define a ''material change'' as a change that would ''(1) significantly modify the pre-license storage, release, or flow operations of the associated qualifying nonpowered dam, or (2) would impair the ability of the dam owner to control operation of the dam.'' [59] The Nature Conservancy proposes an alternative definition: ''little or no change to the subdaily, daily, seasonal and interannual operations, or to the sediment, nutrient, dissolved oxygen, and temperature components of water quality upstream and downstream of the facility, unless it is clearly demonstrated that such changes will not conflict with the existing public uses and will also result in a new ecological benefit.'' [60]

36. NHA also requests that the final rule identify operational regimes, such as ''run-of-river'' or ''run-of-release,'' that would categorically not rise to the level of a ''material change'' to the storage, release, or flow operations.[61]

37. We decline to define ''material change'' as requested by NHA and the Nature Conservancy. The statute provides sufficiently clear guidance, such that a further definition is unnecessary. The term ''material'' is well understood to mean significant or consequential. Further, we do not believe that it would be possible to develop a definition of ''material'' that could be applied in all cases. We will examine the facts of any case in which the materiality of changes that be may caused by a proposed project is at issue, and make a case-by-case decision.

38. Rye Development recommends that we create alternative eligibility criteria for projects at nonpowered dams, to include projects that will (i) add new generating capacity to nonpowered dams, (ii) not include new dams or impoundments, (iii) not materially change any existing storage and release regimes, (iv) not include federal lands except for those associated with an existing federal dam, and (v) not require more than one environmental study season.[62] Nature Conservancy recommends that an eligible facility not materially change water quality and that qualifying nonpowered dams exclude those that it terms ''obsolete.'' [63] Because section 34 of the FPA does not authorize the Commission to replace or revise the statutory eligibility criteria that Congress established for qualifying facilities at nonpowered dams, we will not make the additions recommended by Rye Development and Nature Conservancy.

b. Qualifying Criteria for Closed-Loop Pumped Storage Projects

39. FPA section 35(g)(1) directs the Commission to establish criteria that a pumped storage project must meet to be eligible for the expedited licensing process. FPA section 35(g)(2) further instructs the Commission to include criteria that an eligible closed-loop pumped storage project cause little to no change to existing surface and groundwater flows and uses, and is unlikely to adversely affect species listed as threatened or endangered under the ESA.

40. We received several comments requesting that the final rule include additional or revised qualifying criteria for closed-loop pumped storage projects to be eligible for the expedited licensing process under FPA section 35(g)(2). Specifically, we received recommendations that the final rule include additional qualifying criteria to ensure that a closed-loop pumped storage project eligible for the expedited licensing process will: (i) Not be hydrologically connected to natural water bodies; [64] (ii) cause little to no change to existing aquatic habitats, water quality, and water quantity; [65] (iii) cause little to no change to river, lacustrine, and groundwater-dependent ecosystems; [66] (iv) cause little to no change to existing recreational access and uses; [67] (v) meet the intent of

[53] *See* NOPR, 166 FERC ¶ 61,083 at PP 15–17 (CWA), PP 18–22 (ESA), PP 23–24 (NHPA).

[54] FPA section 34(e)(2) defines ''qualifying facility'' as any facility that is determined to meet the ''qualifying criteria'' under section 34(e)(1).

[55] 16 U.S.C.A. 823e(e)(1) (West 2019).

[56] *Id.* section 823e(e)(3).

[57] FPA section 34(e)(1)(E) states that ''the operation of the facility will not result in any *material change* to the storage, release, or flows from the associated qualifying nonpowered dam, including associated impoundment or other infrastructure.'' 16 U.S.C.A. 823e(e)(1)(E) (emphasis added).

[58] NHA's and Dominion's comments generally advocate that the Commission interpret statutory language generously and broadly in order to capture more projects in the expedited licensing process. *See, e.g.,* NHA's Comment at 11; Dominion Comment at 5 (interpret ''cause little to no change'' in FPA section 35(g)(2)(A) broadly).

[59] NHA's Comment at 10.

[60] Nature Conservancy's Comment at 3.

[61] NHA's Comment at 10.

[62] Rye Development's Comment at 7.

[63] *See* Nature Conservancy's Comment at 3 (recommending the addition of a criterion to ensure that an associated nonpowered dam actively serves a public purpose).

[64] *See* Oregon DFW's Comment at 2; Nature Conservancy's Comment at 4.

[65] *See* Oregon DFW's Comment at 2; Nature Conservancy's Comment at 4; NMFS' February 15, 2019 Comment at 2; Forest Service's Comment at 2–3; Interior's Comment at 3.

[66] *See* Forest Service's Comment at 3; Oregon DFW's Comment at 2.

[67] *See* Interior's Comment at 3.

comprehensive land management plans for all applicable resources if the project will be located on federal reservations; [68] and (vi) not degrade or act as a source of contaminants to surface or groundwater features if the project will use abandoned mines as storage reservoirs.[69]

41. We believe that the Commission's revised definition of a ''closed-loop pumped storage project,'' [70] in combination with the Commission's existing licensing requirements, will ensure that only projects meeting the Congressional criteria qualify for expedited treatment, and that therefore no additional definition is needed.

42. With regard to the qualifying criteria, we also received requests to clarify the statutory language. NMFS, Interior, and Oregon DFW recommend that the qualifying criteria set forth in FPA section 35(g)(2)(i) be revised to specify ''the construction and operation'' of the project will cause little to no change to existing surface and groundwater flows and uses.[71]

43. We cannot revise the criteria established by Congress. However, we note that Congress did not exclude project construction and operation from the criteria in section 35(g)(2)(i).

44. Pursuant to the authority in FPA section 35(g)(2) that directs the Commission to establish additional qualifying criteria for closed-loop pumped storage projects, we proposed in the NOPR to add ''designated critical habitat of species of [threatened or endangered] species'' in § 7.2(b)(2)(ii) to ensure the qualifying criterion conforms with the ESA.[72]

45. NHA does not oppose this additional criterion because it assumes that an applicant would be unlikely to request use of the expedited licensing process if a proposed project would require preparation of a Biological Opinion.[73] Forest Service endorses the addition.[74] We therefore have retained the additional critical habitat criterion in § 7.2(b)(2)(ii) of the final rule.

c. Commission-Defined Criteria for the Expedited Licensing Process

46. The NOPR established criteria for applications to be eligible for the new expedited licensing process. The FERC-defined criteria for the expedited process, as set forth in §§ 7.2(b)(3) to 7.2(b)(7), modify the timing of existing licensing requirements by requiring an applicant interested in pursuing the expedited process to submit certain documentation of consultation at the same time that an application is filed.

i. Early Consultation With Agencies

47. Several commenters recommended early and frequent consultation with federal and state agencies. The Nature Conservancy recommends that § 7.2(b) include a requirement that applicants engage in early coordination with mandatory conditioning agencies and any resource agencies with jurisdiction over resources that may be affected by the proposed project.[75] Interior also requests additional guidance on the form and content of the required pre-filing documentation.[76]

48. Consultation with agencies will be crucial to the success of the expedited licensing process. Moreover, the consultation criteria discussed below are designed to promote early engagement between applicants and agencies. However, because the Commission's existing regulations already require applicants to consult with these agencies prior to filing a license application,[77] we decline to include Nature Conservancy's suggested requirement in § 7.2(b) of the final rule.

ii. Clean Water Act Documentation

49. In the NOPR, § 7.2(b)(3) proposed to require an applicant, as part of its application, to provide its request for certification under section 401(a)(1) of the Clean Water Act, including proof of the date on which the certifying agency received the request; and one of the following: (1) A copy of water quality certification, (2) evidence of a waiver of the certification, or (3) documentation from the state certifying agency that the water quality certification application is complete, or in the event a certifying agency denies certification, a copy of the denial within 30 days after the applicant receives it.

50. Daybreak contends that section 401 of the Clean Water Act does not require that a state certify a water quality certification application is complete in order to start the clock on the one-year statutory deadline for a state to act on an application.[78]

51. Daybreak is correct. Section 401(a)(1) of the Clean Water Act states that ''[i]f the State . . . fails or refuses to act on a request for certification, within a reasonable period of time (which shall not exceed one year) after receipt of such request, the certification requirements . . . shall be waived with respect to such Federal application.'' [79] A state's one-year review period begins when the applicable state agency receives the request for water quality certification, not when the state agency deems an application ''complete.'' [80]

52. The purpose of proposed § 7.2(b)(3)(iii) was not to inform the Commission when to start the one-year clock for state action on a section 401 application. Rather, proposed § 7.2(b)(3)(iii) sought to ensure that all of the necessary authorizations, including water quality certification, could be obtained in a timely enough manner so as to enable the Commission to act on a license application within two years from the date of application filing.

53. However, recognizing that requiring applicants to submit documentation from a state certifying agency that the water quality certification application is ''complete'' may prove difficult, we have revised § 7.2(b)(3)(iii) to remove this requirement. Accordingly, at the time of application filing, an applicant will be required to submit a copy of the request for certification, including proof of the date on which the certifying agency received the request; a copy of water quality certification; or evidence of waiver of water quality certification. This information will still enable us to assess the likelihood that a water quality certification will be obtained in a timely enough manner so as to facilitate Commission action on a license application within two years from the date of application filing.

iii. ESA Documentation

54. NMFS recommends that the Commission require that applicants, in proposed § 7.2(b)(4), begin early coordination with NMFS during pre-

[68] *See* Forest Service's Comment at 3; Interior's Comment at 3; Nature Conservancy's Comment at 4. Nature Conservancy also recommends a qualifying criterion that the project not be located on a river reach protected under the National Wild and Scenic Rivers Act, or similar state statute. However, pursuant to section 7(a) of the Wild and Scenic Rivers Act, the Commission is already prohibited from licensing the construction of any ''dam, water conduit, reservoir, powerhouse, transmission line, or other project works . . . on or directly affecting'' a river segment that Congress has designated as component of the National Wild and Scenic Rivers System. 16 U.S.C. 1278(a) (2012).

[69] *See* Forest Service's Comment at 3; Nature Conservancy's Comment at 4.

[70] *See supra* PP 28–31.

[71] *See* NMFS' Comment at 2; Interior's Comment at 3; Oregon DFW's Comment at 2.

[72] NOPR, 166 FERC ¶ 61,083 at P 22 (explaining that section 7(a)(2) of the ESA, 16 U.S.C. 1536(a)(2) (2012), requires agencies to ensure that their actions are not likely to result in the destruction or adverse modification of designated critical habitat of such species).

[73] NHA's Comment at 13.

[74] *See* Forest Service's Comment at 3.

[75] *See* Nature Conservancy's Comment at 5.

[77] *See* 18 CFR 4.38, 4.34(i), 5.1(d).

[78] Daybreak's Comment at 2.

[79] 33 U.S.C. 1341(a)(1) (2012).

[80] *N.Y. State Dep't of Environmental Conservation* v. *FERC,* 884 F.3d 450, 455–456 (2d Cir. 2018).

filing if the project would affect resources protected under the ESA or Magnuson-Stevens Fishery Conservation and Management Act (MSA).[81] NMFS states that the benefits of early coordination include improved license applications, efficient environmental reviews, and a higher likelihood of a settlement.[82] Interior requests that the same requirement be added with regard to early coordination with FWS and lists similar benefits.[83]

55. Pursuant to § 4.38 of the Commission's regulations, a potential applicant must consult with the relevant federal, state, and interstate resource agencies, including NMFS and FWS, prior to filing an application for an original license. We agree with NMFS and Interior that early consultation on resources protected under the ESA or MSA would allow applicants to avoid or minimize effects to listed species by negotiating protection, mitigation, and enhancement measures. However, this request for pre-filing consultation does not differ from the Commission's existing licensing requirements. Moreover, in the NOPR,[84] the Commission proposed to require that any application filed with a request for authorization to use the expedited licensing process include: A no-effect determination that includes documentation that no listed species or critical habitat are present at the proposed project site; (ii) documentation of concurrence from FWS and NMFS, as necessary, on a not likely to adversely affect determination; or (iii) a draft biological assessment that includes documentation of consultation with FWS and NMFS, as necessary. Therefore, we find it unnecessary to add NMFS and Interior's request as a requirement of the expedited licensing process.[85]

56. Interior recommends that the applicant file concurrently with its application written concurrence from applicable stakeholders concerning potential project impacts on natural, cultural, or recreation resources.[86]

57. After a license application is filed and accepted as complete, the Commission will issue a Ready for Environmental Analysis (REA) notice to seek input from stakeholders on an applicant's license application in advance of preparing the Environmental Assessment (EA) or Environmental Impact Statement (EIS) required by the National Environmental Policy Act of 1969 (NEPA). In terms of the licensing process, seeking input from stakeholders at the time of the REA notice does not delay or slow down the license process timeline. Therefore, we find the recommendation that the applicant include with its application written concurrence from applicable stakeholders concerning potential project impacts on natural, cultural, or recreation resources unduly burdensome and unnecessary to expedite the licensing process.

58. To conform to ESA regulations, NMFS and Interior recommend that the Commission revise § 7.2(b)(4)(i) to replace ''at the proposed project site'' with ''in the action area, as defined by the ESA regulations at 50 CFR 402.02.'' [87] Interior explains that limiting evaluation to a ''proposed project site'' would not adequately consider impacts to National Park Services (NPS) resources and recreational use.[88] All aspects of the project, Interior suggests, should be evaluated, such as staging and construction laydown areas, roads and other conduits and/or transmission line or interconnections.[89] Interior recommends that the Commission evaluate a proposal and determine the impacts in ''action areas'' under the ESA and/or ''area of potential effects'' under the National Historic Preservation Act (NHPA) [90] in order to identify the potential adverse effects on natural and recreational resources near a NPS unit.[91]

59. We accept NMFS' and Interior's recommendation and replace the term ''at the proposed project site'' with the term ''in the action area'' in § 7.2(b)(4)(i) to bring the language into accord with the ESA. With respect to commenters' other concerns about the Commission's responsibilities under the ESA and the NHPA, the expedited licensing process does not change the Commission's responsibilities under existing federal laws, such as the ESA and the NHPA, and Commission staff will continue to comply with all pertinent federal laws during the review of a license application.

60. NMFS and Interior request that the Commission clarify in § 7.2(b)(4)(i) that the Commission has the responsibility to determine whether ESA consultation is necessary under section 7 of the ESA.[92] Both assert that the Commission has the ultimate responsibility to ensure compliance with section 7 of the ESA.[93]

61. Section 7 of the ESA speaks for itself and there is thus no need for the requested clarification in § 7.2(b)(4)(i).

62. NMFS and Interior request that the Commission clarify in § 7.2(b)(4)(ii) that the Commission will designate an applicant to be a non-federal representative under ESA regulations [94] at the beginning of the expedited process in order for the applicant to participate in informal ESA consultation.[95]

63. Section 5.5(e) of the Commission's regulations [96] provides that a potential license applicant may, as early as the same time it files its notification of intent and distributes its pre-application document (PAD) at the beginning of the pre-filing period, request to be designated as the Commission's non-federal representative for purposes of consultation under section 7 of the ESA and the joint agency regulations thereunder at 50 CFR part 402, section 305(b) of the MSA and the implementing regulations at 50 CFR 600.902. Even if it chooses not to request such designation at the time of the filing of the notification of intent, an applicant could make such a request at any time later in the pre-filing period. The Commission typically grants such requests as a routine process matter. Therefore, there is no need for the requested clarification to § 7.2(b)(4)(ii).

64. NMFS recommends that the Commission, with the assistance of NMFS, develop guidance on informal ESA consultations and preparation of biological assessments to provide to the designated non-federal representative.[97] NMFS and Interior further recommend that we provide a template letter for the Commission to use to designate a non-federal representative to conduct consultation or prepare a draft biological assessment.[98]

65. Commission staff typically prepares guidance documents for use by prospective license applicants, federal and state resource agencies, and the public regarding various aspects of the

[81] 16 U.S.C. 1801 *et seq.* (2012); *See* NMFS' Comment at 2.

[82] *See id.*

[83] *See* Interior's Comment at 3.

[84] NOPR, 166 FERC ¶ 61,083 at P 11.

[85] We also decline to issue guidance pertaining to how to consult with the FWS or how to interpret FWS's or NMFS' regulations and policies, as requested by Interior and NMFS.

[86] Interior's Comment at 1–2.

[87] NMFS' Comment at 2; Interior's Comment at 4.

[88] *See* Interior's Comment at 2.

[89] *See id.*

[90] 36 CFR 800.16(d) (2018).

[91] *See* Interior's Comment at 2 and n.2.

[92] NMFS' Comment at 2; Interior's Comment at 4.

[93] NMFS' Comment at 3; Interior's Comment at 4.

[94] *See* 50 CFR 402.02, 402.08, 402.13 (2018).

[95] NMFS' Comment at 2; Interior's Comment at 3.

[96] 18 CFR 5.5(e).

[97] *See* NMFS' Comment at 3.

[98] NMFS' Comment at 3 and Attachment 1 (providing a sample template letter); Interior's Comment at 3–4 and Attachment 1 (providing a sample template letter).

licensing process.[99] We will instruct our staff to review the license process guidance material to determine what modifications and additional guidance are needed to facilitate the efficient implementation of the new part 7 regulations.

66. Interior recommends that proposed § 7.2(b)(4)(ii) should require consultation documentation ''that the action is not likely to adversely affect ESA-listed species or critical habitat.'' [100] We agree that Interior's recommended revision is more precise, and have revised § 7.2(b)(4)(ii) accordingly.

67. NMFS requests clarification of the language ''documentation of consultation with the Service(s)'' in proposed § 7.2(b)(4)(iii). NMFS explains that the Commission must be involved with the applicant's ESA consultation with NMFS, as required by ESA regulations.[101] Interior requests that the phrase should be revised to ''documentation of communication.'' [102]

68. We decline to make this change. As the ESA regulations allow, the intent here is that the applicant will act as our designated non-federal representative in seeking the documentation of consultation specified by § 7.2(b)(4)(iii).

69. NHA submits that Commission action on the request to use the expedited process comes too late in the process if it coincides with the REA notice.[103] Instead, NHA contends, a request for expedited processing should be approved during the pre-filing process if an applicant is able to provide, concurrent with its Notice of Intent to File a License Application and PAD submittal, a no effect determination, FWS and/or NMFS concurrence on a not likely to adversely affect determination, or a draft biological assessment with documentation of consultation and draft mitigation measures.[104]

70. As noted above, the clear mandate of the AWIA is that the expedited licensing process begin with the filing of a completed license application, and therefore, we make no changes to the existing pre-filing processes. If an applicant requesting to use the expedited licensing process is able to demonstrate that its project satisfies the eligibility criteria and submits a complete license application without the need for Commission staff to request additional information or correct deficiencies, then Commission staff will be able to approve the request sooner than 180 days from the date the application was filed. Generally, Commission staff issues an REA notice when it determines that the contents of a license application meet the Commission's requirements and no additional information is needed to process the application.[105] In the context of the expedited licensing process, if Commission staff determines a request and application are satisfactory, then we will issue an REA notice no later than 180 days from the date of receipt of a completed application.

iv. NHPA Documentation

71. PA SHPO contends that the requirement in proposed § 7.2(b)(5) that an applicant provide documentation demonstrating that consultation with a SHPO or Tribal Historic Preservation Office has been initiated is insufficient to satisfy section 106 of the NHPA.[106] In addition to consultation, PA SHPO requests that the Commission provide guidance to applicants regarding the consultation procedures for each state SHPO. PA SHPO recommends hiring consultants that meet Interior's standards.[107] PA SHPO further encourages applicants to initiate consultation early and to identify potentially affected historic properties as soon as possible.[108] PA SHPO also notes some projects may be more likely to affect historic properties, which would require more consultation time under section 106 and may warrant exclusion from the expedited process.[109] PA SHPO also requests that we consider the impacts on historic properties of transmission lines associated with projects eligible for the expedited process.[110]

72. PA SHPO states that existing nonpowered dams may be eligible to be listed as historic properties in the National Register.[111] For a dam to be eligible in Pennsylvania, PA SHPO explains that the dam must have engineering significance or retain its historic setting and integrity in a surrounding historic district.[112] PA SHPO also recommends that applicants should begin, and if possible finish, locating National Register significant archaeological properties during pre-filing.[113]

73. PA SHPO recommends that the Commission, with the intent to improve efficiency, provide guidance on the anticipated effects and alternatives to adverse effects typically caused by projects located at nonpowered dams and closed-loop pumped storage projects.[114]

74. As we acknowledged in the NOPR,[115] the requirement that a part 7 applicant provide documentation demonstrating that section 106 consultation has been initiated does not differ from the Commission's existing licensing requirements.[116] We expect our applicants, as the project proponents, to work collaboratively with a SHPO and any affected tribes to conduct information gathering and to complete any studies the Commission determines necessary to support its section 106 decision-making as the Commission will make the final determination. However, because consultation practices vary, we do not believe this rulemaking is the appropriate forum to provide guidance on each state SHPO's section 106 consultation procedures and preferences. Moreover, because projects at nonpowered dams and closed-loop pumped storage projects can vary drastically in size and scope, the Commission prefers to analyze anticipated impacts on historic properties and resolution of any adverse impacts on a project-by-project basis, rather than providing a generalized or over-simplistic forecast of anticipated effects and alternatives for projects to be proposed at nonpowered dams and for closed-loop pumped storage projects.

v. Dam Owner Documentation

75. The NOPR proposed to require an applicant to provide confirmation that the federal or non-federal dam owner is not opposed to hydropower development at the dam if the proposed project would be located at an existing nonpowered dam.[117]

76. The Forest Service requests clarification concerning the requirement in proposed § 7.2(b)(6)(ii) that an applicant provide confirmation that the federal entity is not opposed to hydropower development at the

[99] Commission staff's licensing guidance material is available on the Commission's website at *http://www.ferc.gov/industries/hydropower/gen-info/licensing.asp.*

[100] Interior's Comment at 4.

[101] NMFS' Comment at 3 (citing 50 CFR 402.08).

[102] Interior's Comment at 4.

[103] NHA's Comment at 13.

[104] NHA's Comment at 13; Dominion's Comment at 6.

[105] 18 CFR 5.22.

[106] PA SHPO's March 5, 2019 Comment at 1.

[107] *Id.* (citing Secretary of Interior, *Archeology and Historic Preservation; Secretary of the Interior's Standards and Guidelines,* 48 FR 44738–39 (1983)).

[108] PA SHPO's Comment at 1.

[109] *Id.*

[110] *Id.*

[111] *Id.* at 2.

[112] *See id.*

[113] *See id.*

[114] *Id.*

[115] NOPR, 166 FERC ¶ 61,083 at PP 23–24.

[116] *See* 18 CFR 4.41(f)(4), 5.18(b)(3)(v).

[117] *See* NOPR, 166 FERC ¶ 61,083 at P 25.

location.[118] The Forest Service recommends that the documentation include confirmation that the applicant and federal entity discussed the possible license conditions that may be required by the federal entity, as well as confirmation of discussions about planning, permitting, and management issues related to all aspects of the development and operation of a hydropower facility, not only the location.[119] According to the Forest Service, the requirement should also apply to applicants for closed-loop pumped storage projects.[120]

77. In contrast, Rye Development recommends that the final rule exclude the proposed requirement in § 7.2(b)(6)(ii) that the federal dam owner must state the project is feasible.[121] Rye Development states that the U.S. Army Corps of Engineers' (Army Corps) practice is to refuse to provide such documentation and it does not favor projects at its facilities.[122] In effect, Rye Development contends the requirement would exclude many projects from the expedited process.[123]

78. NHA also opposes the requirement that an applicant must submit documentation demonstrating that the federal dam owner does not oppose project development.[124] NHA states that the federal dam owner's opposition to the project should not be determinative, but also notes that the federal entity could prevent project development even after issuance of a Commission license by denying necessary authorizations under its purview.[125] According to NHA, a federal dam owner's concerns about a proposed project should be addressed by the applicant outside of the Commission's licensing process.[126] Moreover, NHA observes that if the federal agency opposes the project, it is unlikely that an application will ever be filed.[127]

79. Dominion supports the NOPR's proposal to require applicants to provide documentation of consultation with a non-federal dam owner that confirms the owner is not opposed to project development.[128] Dominion notes that allowing a developer to obtain an expedited license at an existing non-federal dam without the owner's consent could impair the intended use of the dam and water resource.[129]

80. The Commission's intent is to avoid significant staff expenditures of time and effort that would be needed to shepherd an application through the expedited licensing process to ensure a license decision can be made two years from application filing, only to have a project stalled by a federal dam owner's general opposition to hydropower development at its facility. The required documentation must demonstrate a preliminary confirmation that the federal dam owner is not opposed to use of the facility for hydropower development; there is no need for the federal entity to agree to specific design components or specifications at the time of application filing. We also note that neither the Army Corps nor Interior (on behalf the Bureau of Reclamation) commented on this documentation requirement.

81. Accordingly, the final rule retains the requirement that an applicant provide documentation demonstrating that the dam owner, whether a federal or non-federal entity, is not opposed to project development.

vi. Public Parks, Recreation Areas, and Wildlife Areas Documentation

82. If a proposed project would use any public park, recreation area, or wildlife refuge established under state or local law, the NOPR proposed in § 7.2(b)(7) to require an expedited licensing applicant to provide, at the time of application filing, documentation from the managing entity demonstrating that it is not opposed to use of the park, area, or wildlife refuge for hydropower development.[130]

83. Referencing § 7.2(b)(7) as proposed in the NOPR, Interior recommends that any license application submitted alongside a request to use the expedited licensing process address the following areas of interest to the National Park Service (NPS): (1) NPS areas; (2) Wild and Scenic Rivers; (3) Nationwide Rivers Inventory and eligible/suitable rivers; (4) recreation grant programs, and (5) recreation management.[131] Specifically, Interior requests that if the project or any appurtenant structure or conduit is located in the vicinity of a NPS unit, consultation with NPS should begin as soon as possible and an application should include a concurrence from the NPS that the project is not likely to adversely affect NPS-managed lands, or natural, cultural, or recreational resources.[132] Interior also reminds the Commission that it must comply with the Wild and Scenic Rivers Act if a project is proposed to be located in the proximity of a designated Wild and Scenic River or Congressionally-authorized study segments.[133] Further, if the project would require a conversion under various NPS-administered recreation grant programs, Interior recommends that an application identify a suitable replacement property approved by NPS.[134] Lastly, Interior recommends that an application include an explanation of a recreation strategy, a draft or final recreation management plan, and documentation of consultation with interested stakeholders.[135]

84. Pursuant to § 4.38 of the Commission's regulations,[136] a potential applicant must consult with the relevant federal, state, and interstate resource agencies, including NPS, prior to filing an application for an original license. Further, §§ 4.41 and 5.18 of our regulations require an application to include documentation of consultation; describe existing recreation facilities, existing and potential recreational use, and any new recreation development proposed by the applicant (*e.g.,* recreation management plan); and identify any designated waters and lands including any areas within or in the vicinity of the proposed project boundary that are included in, or have been designated for the study for inclusion in, the National Wild and Scenic Rivers System, or that have been designated as wilderness area, recommended for such designation, or designated as a wilderness study area under the Wilderness Act.[137] Therefore, with the exception of the need for an application to identify suitable replacement property under NPS-administered grant programs, Interior's requests do not differ from the Commission's existing requirements

[118] Forest Service's Comment at 3.

[119] *See id.*

[120] *See id.*

[121] Rye Development's Comment at 7.

[122] *See id.*

[123] *See id.*

[124] NHA's Comment at 16.

[125] *See id.*

[126] *See id.*

[127] *See id.*

[128] Dominion's Comment at 8.

[129] *See id.*

[130] NOPR, 166 FERC ¶ 61,083 at P 26 (explaining that section 21 of the FPA, as amended by the Energy Policy Act of 1992, limits the use of eminent domain to acquire any lands included within any public park, recreation area, or wildlife refuge established under state or local law).

[131] Interior's Comment at 5–6.

[132] *Id.* at 5.

[133] *Id.* Interior also recommends that an application for a project proposed to be located on eligible or suitable wild and scenic rivers, including Nationwide Rivers Inventory, should include a determination from the NPS as to whether the project would preclude Wild and Scenic Rivers designation for Nationwide Rivers Inventory segments and other eligible and suitable river segments.

[134] *Id.* at 5–6 (citing 36 CFR 59.3, 72.72, and 40 U.S.C. 550(b) and (e)).

[135] Interior's Comment at 6.

[136] 18 CFR 4.38.

[137] *See* 18 CFR 4.41, 5.18.

with respect to the recreation-related content of a license application. Identifying suitable replacement property under NPS-administered grant programs is not a prerequisite for issuance of a Commission license. The Commission does not anticipate that this information, or the lack thereof, will preclude the Commission's expedited processing of the license application. Therefore, we will not require the additional information requested by Interior.

3. Section 7.3—Adequacy Review of Application

85. In the NOPR, the Commission proposed to review a license application that is accompanied by a request to use the expedited licensing process under part 4 (TLP or ALP) or part 5 (ILP) of the Commission's regulations, depending on the applicant's elected licensing process. If the application is deemed deficient and rejected under part 4 or 5, the NOPR explained that the request to use the expedited licensing process would likewise be rejected.

86. We received no comments on this aspect of the NOPR. The final rule retains § 7.3 as originally proposed.

4. Section 7.4—Additional Information

87. In the NOPR, the Commission proposed to include § 7.4, requiring an applicant under part 7 to submit additional information or documentation to the Commission in the form and time frame prescribed by the Commission. As proposed, § 7.4 would also allow the Commission to direct a part 7 applicant to submit copies of the application or other filed materials to any person, agency, Indian Tribe, or other entity specified by the Commission. Failure to provide the requested information or documentation as specified may result in dismissal or abeyance of the license application.

88. We received no comments on this aspect of the NOPR. The final rule retains § 7.4 as originally proposed.

5. Section 7.5—Decision on Request To Use Expedited Licensing Process

89. In the NOPR, the Commission proposed that the Director of the Office of Energy Projects (OEP) would act on a request to use the expedited licensing process within six months from the date of application filing. If Commission staff is unable to find that the application meets the requirements of parts 4, 5, and 7, deficiencies remain, or additional information is still needed six months after the date the application is filed, the Director will deny the request to use the expedited licensing process. If the expedited licensing request is denied, proposed § 7.5 explained that the license application would be processed pursuant to a standard processing schedule under parts 4 or 5 of the Commission's regulations, as appropriate.

90. Daybreak recommends that the Director of OEP should only have 60 to 90 days, not six months as proposed in § 7.5, to review a request to use the expedited process to determine whether the project is eligible for the expedited process.[138] Similarly, NMFS recommends 30 to 60 days to make this determination,[139] while the Nature Conservancy recommends 60 days.[140] If an application is complete, NMFS recommends that the Commission issue a Notice of Acceptance and Ready for Environmental Analysis immediately and not wait for the six-month period to run.[141] Alternatively, Daybreak recommends that the time for the applicants to respond to the Commission staff's deficiency requests should not be counted toward the two-year deadline.[142]

91. The Nature Conservancy asks the Commission to clarify whether the two-year timeframe begins once the Director of OEP determines whether the use of the expedited licensing process is appropriate.[143]

92. To clarify, the Director of OEP will act on a request to use the expedited licensing process no later than 180 days after an application and request to use the expedited process has been filed. However, earlier action by the Director of OEP is possible if an application clearly demonstrates compliance with the expedited licensing eligibility criteria. The timeliness of the Director's action on such a request will also be directly tied to the completeness of the license application as well as the applicant's prompt resolution of any deficiencies and additional information requests. If an applicant is unable to correct all deficiencies within 180 days after the application filing date, the Director will deny the request to use the expedited licensing process, and processing of the application will proceed under the Commission's standard licensing process.

93. If the Director approves a request to use the expedited licensing process, the two-year process will be deemed to have begun on the date the application was filed. Therefore, whether the Director approves an expedited licensing request within 30 days or 180 days from the date the application was filed, the two-year schedule commences on the date the application was filed. For the sake of precision, we have revised §§ 7.5 and 7.6 in the final rule to replace ''6 months'' with ''180 days.''

6. Section 7.6—Notice of Acceptance and Ready for Environmental Analysis

94. As proposed in the NOPR, section 7.6 explained that if the Director of OEP approves a request to use the expedited licensing process, the Commission will issue a public notice no later than six months from the application filing date. The notice will accept the application and confirm the acceptance date as the application filing date; find the application ready for environmental analysis; request comments, protests, and interventions; request recommendations, preliminary terms and conditions, and preliminary fishway prescriptions; and establish a schedule for the application's expedited processing.

95. The expedited schedule will include date estimates for: (i) The filing of recommendations, preliminary terms and conditions, and fishway prescriptions; (ii) issuance of the draft NEPA document, or an EA not preceded by a draft; (iii) filing of responses, if applicable, to requests for concurrence or formal consultation under ESA, or to other Commission staff requests to agencies or Indian Tribes under other federal laws, including the MSA and the NHPA; (iv) filing of comments on a draft NEPA document, if applicable; (v) filing of modified recommendations, mandatory terms and conditions, and fishway prescriptions in response to a draft NEPA document or, if no draft NEPA document is issued, to an EA; and (vi) issuance of a final NEPA document, if applicable.

96. NMFS and Interior request that the Commission, prior to issuing public notice of the application, seek concurrence on the proposed schedule from the agencies responsible for the various environmental reviews and authorizations.[144] NMFS and Interior also request that the Commission issue a final decision on an application as soon as possible after the issuance of the final NEPA document to allow resource agencies sufficient time within the two-year expedited process to complete the requisite environmental reviews and authorizations.[145]

[138] Daybreak's Comment at 3.

[139] NMFS' Comment at 3.

[140] Nature Conservancy's Comments at 5.

[141] NMFS' Comment at 3.

[142] Daybreak's Comment at 3.

[143] Nature Conservancy's Comment at 5.

[144] NMFS' Comment at 3; Interior's Comment at 4.

[145] NMFS' Comment at 3; Interior's Comment at 4.

97. The expedited processing schedule provided for in § 7.6(e) will be determined on case-by-case basis. Agencies should memorialize any anticipated timing or scheduling concerns during pre-filing correspondence with the applicant. In addition, once an application with a request for expedited processing is filed with the Commission, agencies should strive to promptly notify the Commission of any schedule-related concerns or requests. The Commission will consider any such agency input prior to issuing the public notice containing a project's expedited licensing schedule.

7. Section 7.7—Amendment of Application

98. Section 7.7 of the NOPR proposed a process for amending a pending part 7 application following the Commission's issuance of the notice accepting the application and finding it ready for environmental analysis.

99. The Forest Service recommends that amendments to a license application filed under part 7 only be permitted before the Commission issues a notice of acceptance of the application.[146] Permitting amendments after a notice of acceptance has been issued would not allow sufficient time for the applicant and agencies to negotiate and modify license terms and conditions.[147]

100. We agree that a request to amend a part 7 license application after the acceptance of the application and issuance of the expedited processing schedule may interfere with the Commission's ability to act on a license application within two years from the date of application filing. Therefore, we have revised § 7.7 to allow the Director of OEP to remove an application from the expedited licensing process if the applicant files a significant amendment to its application. If an application is removed from the expedited licensing process, Commission staff will continue to process the application under the Commission's standard licensing process.

8. Section 7.8—Other Provisions

101. Section 7.8, as proposed in the NOPR, authorized the Director of OEP to waive or modify provisions of part 7 for good cause. Proposed § 7.8 also explained that the Commission may consider late-filed recommendations by authorized fish and wildlife agencies under the Fish and Wildlife Coordination Act [148] and FPA section 10(j),[149] and late-filed FPA section 4(e) [150] terms and conditions or FPA section 18 [151] prescriptions as cause to remove the application from the expedited licensing process under this part. In addition, proposed § 7.8(c)(5) stated that ''[t]he Commission will require the construction, maintenance, and operation of such fishways as may be *timely* prescribed by the Secretary of Commerce or the Secretary of the Interior, as appropriate, pursuant to section 18 of the [FPA].'' [152]

102. NMFS and Interior recommend that the Commission expand or generalize the circumstances listed in proposed § 7.8 that would cause the Commission to remove a project from the expedited process.[153] NMFS provides two examples, one in which the an applicant fails to provide sufficient information to complete ESA or essential fish habitat (EFH) consultation due to unanticipated delays, and another in which the scope of the project changes unexpectedly.[154]

103. Once an applicant has received approval to use the expedited licensing process, circumstances such as late-filed recommendations, terms and conditions, or prescriptions that may cause a project to be removed from the expedited licensing process will be evaluated on a case-by-case basis. The scenarios posed by NMFS (*i.e.,* insufficient information to complete ESA or EFH consultation and unanticipated changes to the scope of the project) could impact the aspirational two-year processing timeline, but depending on the circumstances, may not be cause to remove the project from the expedited licensing process. In the alternative, rather than removing the project from the expedited licensing process, Commission staff may instead choose to document the reason for the delay and issue a revised processing schedule that may extend the original two year timeline.

104. NMFS and Interior state that the Commission lacks the authority to reject a mandatory license condition prescribed by an agency under section 4(e) of the FPA or a fishway prescription prescribed by agency under section 18 of the FPA based on a deadline set forth by the Commission.[155] Therefore, NMFS recommends that the word ''timely'' be removed from proposed § 7.8(c)(5).[156]

105. As NMFS and Interior correctly observe, the Commission has no authority to reject mandatory conditions filed under FPA section 4(e) or fishway prescriptions filed under FPA section 18 even if the mandatory condition or prescription is filed late.[157] Accordingly, we have deleted the word ''timely'' from § 7.8(c)(5).

9. Section 7.9—Transition Provision

106. The NOPR proposed including a transition provision to clarify that the new part 7 would only apply to original license applications filed on or after the effective date of the final rule.

107. The Commission received no comments on this aspect of the NOPR. The final rule retains § 7.9 as originally proposed.

C. Other Matters

1. Projects That Require an EIS

108. The NOPR requested comments on whether the expedited licensing process should be available for projects that otherwise meet the eligibility criteria, but will require the preparation of an EIS.[158]

109. The Forest Service, Oregon DFW, Interior, and the Nature Conservancy support excluding projects that would require the preparation of an EIS from the expedited process because the expedited process should only be available for projects that would have limited environmental impacts.[159]

110. In contrast, Daybreak believes that an expedited process that would exclude closed-loop pumped storage projects that would require an EIS would be overly restrictive.[160] Daybreak warns that ''virtually'' no closed-loop pumped storage project would qualify for the expedited process and would violate the purpose of the statute.[161]

111. Rather than categorically excluding projects that will require preparation of an EIS, NHA suggests that the Commission should make a case-by-case determination at the conclusion of the pre-filing NEPA scoping on whether the particular

[146] Forest Service's Comment at 4.

[147] Forest Service's Comment at 4.

[148] 16 U.S.C. 661–666c (2012).

[149] *Id.* section 803(j).

[150] *Id.* section 797(e).

[151] *Id.* section 811.

[152] NOPR, 166 FERC ¶ 61,083 at § 7.8(c)(5) (emphasis added).

[153] NMFS' Comment at 4; Interior's Comment at 4.

[154] NMFS' Comment at 4.

[155] NMFS' Comment at 4; Interior's Comment at 2 and 5.

[156] NMFS' Comment at 4.

[157] *See City of Tacoma, WA* v. *FERC,* 460 F.3d 53, 64–65 (D.C. Cir. 2006).

[158] NOPR, 166 FERC ¶ 61,083 at PP 45–47.

[159] Forest Service's Comment at 4; Oregon DFW's Comment at 2; Interior's Comment at 7; Nature Conservancy's Comment at 2.

[160] Daybreak's Comment at 2–3.

[161] *Id.*

circumstances warrant approval of the expedited licensing process.[162]

112. As further described in the discussion regarding the One Federal Decision process,[163] the final rule will not categorically exclude applications for projects that would require the preparation of an EIS.[164] In light of NHA's recommendation, Commission staff will decide, on a case-by-case basis, whether to approve a request to use the expedited process after completing pre-filing scoping. By waiting until more information about a proposal's possible environmental effects is available, we ensure that EIS projects that can be licensed within two years are not unreasonably excluded from the expedited process. Yet, we would also be able to exclude from expedited processing EIS projects that would require more resources, thereby ensuring that these projects are not hastily licensed under the expedited process. Accordingly, the final rule will not restrict part 7 eligibility to only projects that require preparation of an EA.

113. The Forest Service and NMFS request clarification on the processing timeline for an application for a project that would be eligible for both the expedited licensing process and the One Federal Decision process.[165]

114. By signing a Memorandum of Understanding Implementing One Federal Decision Under Executive Order 13807,[166] federal agencies, including the Commission, committed to completing within an average of two years all required environmental reviews and authorization decisions for ''major infrastructure projects.'' [167] In general for hydropower projects, this two-year timeframe starts on the date the Commission publishes a Notice of Intent to prepare an EIS and ends with the issuance of all federal environmental reviews and authorization decisions.[168]

115. Projects that qualify as ''major infrastructure projects'' and receive approval to use the expedited licensing process will be processed under the two-year expedited licensing process set forth in part 7 of the Commission's regulations. The two-year timeframe for the expedited licensing process will begin on the date of application filing, and will follow the procedures set forth in part 7 of the Commission's regulations. Under the expedited licensing process, the Commission will strive to ensure that a final order is issued within two years from the date of application filing, as directed by the AWIA. We believe this outcome fulfills the spirit of the One Federal Decision MOU.

2. FPA Section 35(c) Exceptions

116. When issuing or amending a license for a closed-loop pumped storage project under the expedited licensing process, FPA section 35(c) gives the Commission discretion to ''grant an exception from any other requirement of [FPA Part I] with respect to any part of the closed-loop pumped storage project (not including any dam or other impoundment).'' [169] The NOPR did not propose regulations implementing this section of the AWIA.

117. NHA notes that the NOPR did not discuss FPA section 35(c), and asks the Commission to provide guidance on the kinds of exceptions to the FPA Part I requirements that it will adopt or consider.[170] NHA posits that section 35(c) allows the Commission to ease the burden of license conditions for closed-loop pumped storage projects that qualify for expedited processing, noting that the Commission could refrain from requiring recreation improvements or could ease monitoring and reporting requirements unrelated to dam and project safety for these types of projects.[171]

118. Pursuant to section 35(c) of the FPA, any applicant interested in pursuing the expedited licensing process may request an exception from any of the requirements of Part I of the FPA with respect to any part of the applicant's proposed closed-loop pumped storage project (not including any dam or other impoundment). An applicant may request a section 35(c) exception concurrently with a license application and the request for authorization to use the expedited licensing process. A request for a section 35(c) exception should clearly identify the requirement under Part I of the FPA from which the applicant is seeking to be excepted and provide reasoned justification for the request.

IV. Regulatory Requirements

A. Information Collection Statement

119. The Paperwork Reduction Act [172] requires each federal agency to seek and obtain the Office of Management and Budget's (OMB) approval before undertaking a collection of information directed to ten or more persons or contained in a rule of general applicability. OMB regulations require approval of certain information collection requirements contained in final rules published in the **Federal Register**.[173] Upon approval of a collection of information, OMB will assign an OMB control number and an expiration date. Respondents subject to the filing requirements of a rule will not be penalized for failing to respond to the collection of information unless the collection of information displays a valid OMB control number.

120. *Public Reporting Burden:* In this final rule, the Commission establishes an expedited process for issuing original licenses for qualifying facilities at nonpowered dams and for closed-loop pumped storage projects, as directed by Congress in the AWIA.

121. This final rule modifies certain reporting and recordkeeping requirements included in FERC–500 (OMB Control No. 1902–0058) [174] and FERC–505 (OMB Control No. 1902–0115).[175]

122. The revisions to the Commission's regulations, associated with the FERC–500 and FERC–505 information collections, are intended to comply with the requirements of the AWIA. While the information to be included in the license application and the required federal and state authorizations would remain the same under the expedited licensing process,

[162] NHA's Comment at 18.

[163] *See infra* PP 114–115.

[164] Under the Commission's existing regulations, an EIS is normally prepared for licenses for construction of any unconstructed water power projects. 18 CFR 380.6(a)(4) (2018). If, however, the Commission finds a license application may not significantly affect the quality of the human environment, an EIS may not be required to be prepared. *Id.* 380.6(b).

[165] Forest Service's Comment at 4; NMFS' Comment at 1.

[166] *Establishing Discipline and Accountability in the Environmental Review and Permitting Process for Infrastructure Projects,* Exec. Order No. 13,807, 82 FR 40,463 (Aug. 15, 2017); Memorandum of Understanding Implementing the One Federal Decision under Executive Order 13807, *https://www.ferc.gov/legal/mou/2018/MOU-One-Federal-Decision.pdf* (One Federal Decision MOU).

[167] A major infrastructure project is defined as an infrastructure project for which multiple authorizations by Federal agencies will be required to proceed with construction, the lead Federal agency has determined that it will prepare an EIS, and the project sponsor has identified the reasonable availability of funds sufficient to complete the project. Exec. Order No. 13,807, section 3(e).

[168] FERC's One Federal Decision Implementation Plan, Attachment C. Under our One Federal Decision Implementation Plan, we will issue NOIs to prepare an EIS in post-filing for hydropower projects.

[169] 16 U.S.C.A. 823f(c) (West 2019).

[170] NHA's Comment at 19.

[171] NHA's Comment at 19.

[172] 44 U.S.C. 3501–3521 (2012).

[173] *See* 5 CFR 1320.12 (2018).

[174] FERC–500 includes the reporting and recordkeeping requirements for ''Application for License/Relicense for Water Projects with More than 5 Megawatt (MW) Capacity.''

[175] FERC–505 includes the reporting and recordkeeping requirements for ''Small Hydropower Projects and Conduit Facilities including License/Relicense, Exemption, and Qualifying Conduit Facility Determination.''

consultation documentation regarding these authorizations will need to be submitted to the Commission at an earlier point in the licensing process. Therefore, preparing the request to use the expedited licensing process represents a slight increase in the reporting requirements and burden information for FERC–500 and FERC–505.

123. The estimated burden and cost for the requirements contained in this final rule follow.

REVISIONS DUE TO THE FINAL RULE IN DOCKET NO. RM19–6–000

	Number of respondents (1)	Number of responses per respondent (2)	Total number of responses (1) × (2) = (3)	Average burden hours & cost per response [176] (4)	Total annual burden hours & total annual cost (3) × (4) = 5
FERC–500	5	1	5	40; $3,160	200 hrs.; $15,800.
FERC–505	5	1	5	40; $3,160	200 hrs.; $15,800.
Total			10		400 hrs.; $31,600.

124. *Titles:* FERC–500 (Application for License/Relicense for Water Projects with More than 5 Megawatt (MW) Capacity) and FERC–505 (Small Hydropower Projects and Conduit Facilities including License/Relicense, Exemption, and Qualifying Conduit Facility Determination).

125. *Action:* Revisions to information collections FERC–500 and FERC–505.

126. *OMB Control Nos.:* 1902–0058 (FERC–500) and 1902–0115 (FERC–505).

127. *Respondents:* Municipalities, businesses, private citizens, and for-profit and not-for-profit institutions.

128. *Frequency of Information:* Ongoing.

129. *Necessity of Information:* The revised regulations implement the AWIA's directive to establish an expedited licensing process for two types of hydropower projects—qualifying facilities at existing nonpowered dams and closed-loop pumped storage projects. The revised regulations would affect only those entities that opt to request authorization to use the expedited process at the time they file a license application proposing one of the two aforementioned project types. The revised regulations would impose a new, albeit slight, information collection requirement.

130. The new requirement for an applicant to file a request for authorization to use the expedited process concurrently with its license application is necessary for the Commission to carry out its responsibilities under the FPA, as amended by the AWIA. The information provided by the applicants will enable the Commission to review the features of the proposed project and make a determination on whether the proposed project meets the statutory criteria enumerated in the AWIA, as well as the early consultation requirements that the Commission has determined will help it seek to ensure that the proposed project's license application will be acted on no later than two years after the date of application filing.

131. *Internal Review:* The Commission has reviewed the revisions and has determined that they are necessary. These requirements conform to the Commission's need for efficient information collection, communication, and management within the energy industry. The Commission has assured itself, by means of internal review, that there is specific, objective support for the burden estimates associated with the information collection requirements.

132. Interested persons may obtain information on the reporting requirements by contacting the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426 [Attention: Ellen Brown, Office of the Executive Director], by email to *DataClearance@ferc.gov,* by phone (202) 502–8663, or by fax (202) 273–0873.

133. Comments concerning the collections of information and the associated burden estimates may also be sent to: Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 [Attention: Desk Officer for the Federal Energy Regulatory Commission]. Due to security concerns, comments should be sent electronically to the following email address: *oira_submission@omb.eop.gov.* Comments submitted to OMB should refer to FERC–500 (OMB Control No. 1902–0058) and FERC–505 (OMB Control No. 1902–0115).

B. Environmental Analysis

134. The Commission is required to prepare an EA or an EIS for any action that may have a significant adverse effect on the human environment.[177] The Commission has categorically excluded certain actions from this requirement as not having a significant effect on the human environment. Excluded from this requirement are rules that are clarifying, corrective, or procedural, or that do not substantially change the effect of legislation or the regulations being amended.[178] This final rule establishes an expedited licensing process for qualifying facilities at nonpowered dams and for closed-loop pumped storage projects, as directed by Congress in the AWIA. Because this final rule is procedural in nature and does not substantially change the effect of the underlying legislation, preparation of an EA or EIS is not required.

C. Regulatory Flexibility Act

135. The Regulatory Flexibility Act of 1980 (RFA) [179] generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities. The RFA mandates consideration of regulatory alternatives that accomplish the stated objectives of a final rule and minimize any significant economic impact on a substantial number of small entities.[180] In lieu of preparing a regulatory flexibility analysis, an agency may certify that a final rule will not have a

[176] The estimates for cost per response are derived using the following formula: Average Burden Hours per Response * $79 per Hour = Average Cost per Response. The hourly cost figure of $79 is the 2018 average FERC employee wage plus benefits. Commission staff assumes that respondents earn at a similar rate to FERC employees.

[177] *Regulations Implementing the National Environmental Policy Act,* Order No. 486, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs. ¶ 30,783 (1987) (cross-referenced at 41 FERC 61,284).

[178] 18 CFR 380.4(a)(2)(ii) (2018).

[179] 5 U.S.C. 601–612 (2012).

[180] *Id.* section 603(c).

significant economic impact on a substantial number of small entities.[181]

136. The Small Business Administration's (SBA) Office of Size Standards develops the numerical definition of a small business.[182] The SBA size standard for electric utilities is based on the number of employees, including affiliates.[183] Under SBA's current size standards, a hydroelectric power generator (NAICS code 221111)[184] is small if it, including its affiliates, employs 500 or fewer people.[185]

137. This final rule will directly affect only those entities that file an application for a qualifying facility at a nonpowered dam or for a closed-loop pumped storage project, and a request to use the expedited licensing process. While the information to be included in the licensing application and the required federal and state authorizations would remain the same, documentation regarding these authorizations will need to be submitted at an earlier point in the licensing process. Therefore, preparing a request to use the expedited licensing process would represent a slight increase (40 hours of reporting burden and corresponding wage costs of $3,160 per entity on an annual basis) in the information collection reporting requirements and burden for FERC–500 and FERC–505. However, we do not anticipate the impact of the final rule on affected entities, regardless of their status as a small entity or not, to be significant.

138. Accordingly, pursuant to section 605(b) of the RFA, the Commission certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

D. Document Availability

139. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE, Room 2A, Washington DC 20426.

140. From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number, excluding the last three digits of this document, in the docket number field.

141. User assistance is available for eLibrary and the Commission's website during normal business hours from the Commission's Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at ferconlinesupport@ferc.gov, or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

E. Effective Date and Congressional Notification

142. These regulations are effective July 23, 2019. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB, that this rule is not a major rule as defined in section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996.[186] This rule is being submitted to the Senate, House, Government Accountability Office, and Small Business Administration.

List of Subjects in 18 CFR Part 7

Administrative practice and procedure, Electric power, Reporting and recordkeeping requirements.

By direction of the Commission. Commissioner McNamee is not participating.

Issued: April 18, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

■ In consideration of the foregoing, the Commission adds part 7, chapter I, title 18, Code of Federal Regulations, as follows:

PART 7—EXPEDITED LICENSING PROCESS FOR QUALIFYING NON-FEDERAL HYDROPOWER PROJECTS AT EXISTING NONPOWERED DAMS AND FOR CLOSED-LOOP PUMPED STORAGE PROJECTS

Sec.

7.1 Applicability and definitions.
7.2 Use of expedited licensing process.
7.3 Adequacy review of application.
7.4 Additional information.
7.5 Decision on request to use expedited licensing process.
7.6 Notice of acceptance and ready for environmental analysis.
7.7 Amendment of application.
7.8 Other provisions.
7.9 Transition provision.

Authority: 16 U.S.C. 791a–825r; Pub. L. 115–270, 132 Stat. 3765.

§ 7.1 Applicability and definitions.

(a) *Applicability of the expedited licensing* process. This part applies to the processing of applications for original licenses for qualifying non-federal hydropower projects at existing nonpowered dams and for closed-loop pumped storage projects pursuant to sections 34 and 35 of the Federal Power Act.

(b) *Applicability of existing regulations.* Except where superseded by the expedited licensing process set forth in this part, the regulations governing license applications under parts 4 and 5 of this chapter, as applicable, also apply to license applications filed under this part.

(c) *Definitions.* The definitions in § 4.30(b) of this chapter apply to this part. In addition, for the purposes of this part—

(1) *Qualifying nonpowered dam* means any dam, dike, embankment, or other barrier—

(i) The construction of which was completed on or before October 23, 2018;

(ii) That is or was operated for the control, release, or distribution of water for agricultural, municipal, navigational, industrial, commercial, environmental, recreational, aesthetic, drinking water, or flood control purposes; and

(iii) That, as of October 23, 2018, was not generating electricity with hydropower generating works that were licensed under, or exempted from the license requirements contained in, Part I of the Federal Power Act.

(2) *Qualifying facility* means a facility that is determined under section 34 of the Federal Power Act to meet the qualifying criteria for non-federal hydropower projects at existing nonpowered dams.

(3) *Qualifying criteria for closed-loop pumped storage projects* means criteria that a pumped storage project must meet in order to qualify as a closed-loop pumped storage project eligible for the expedited process established under this part. These criteria require that the pumped storage project:

(i) Cause little to no change to existing surface and groundwater flows and uses;

(ii) Is unlikely to adversely affect species listed as a threatened species or endangered species, or designated critical habitat of such species, under the Endangered Species Act of 1973;

(iii) Utilize only reservoirs situated at locations other than natural waterways,

[181] *Id.* section 605(b).

[182] 13 CFR 121.101 (2018).

[183] *Id.* section 121.201.

[184] The North American Industry Classification System (NAICS) is an industry classification system that Federal statistical agencies use to categorize businesses for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. economy. United States Census Bureau, *North American Industry Classification System, https://www.census.gov/eos/www/naics/.*

[185] 13 CFR 121.201 (2018) (Sector 22—Utilities).

[186] 5 U.S.C. 804(2) (2012).

lakes, wetlands, and other natural surface water features; and

(iv) Rely only on temporary withdrawals from surface waters or groundwater for the sole purposes of initial fill and periodic recharge needed for project operation.

(d) *Who may file.* Any citizen, association of citizens, domestic corporation, municipality, or state that develops and files a license application under 18 CFR parts 4 and 5, as applicable, may request expedited processing under this part.

(e) *Use of expedited licensing process.* An applicant wishing to use this expedited licensing process must apply for and receive authorization from the Commission under this part. An applicant under this part may elect to use the licensing process provided for in 18 CFR part 5 (*i.e.,* integrated license application process), or as provided under 18 CFR 5.1:

(1) 18 CFR part 4, subparts D–H (*i.e.,* traditional process); or

(2) Section 4.34(i) of this chapter, *Alternative procedures.*

§ 7.2 Use of expedited licensing process.

(a) In order to pursue the expedited licensing process, an applicant must request authorization for the expedited process, as provided for in paragraph (b) of this section. The licensing procedures in this part do not apply to an application for a new or subsequent license.

(b) An application that accompanies a request for authorization to use the expedited licensing process must include the information specified below.

(1) *Section 34 of the Federal Power Act qualification—projects at nonpowered dams.* The application must demonstrate that the proposed facility meets the following qualifications pursuant to section 34(e) of the Federal Power Act:

(i) As of October 23, 2018, the proposed hydropower facility was not licensed under or exempted from the license requirements contained in Part I of the Federal Power Act;

(ii) The facility will be associated with a qualifying nonpowered dam;

(iii) The facility will be constructed, operated, and maintained for the generation of electric power;

(iv) The facility will use for such generation any withdrawals, diversions, releases, or flows from the associated qualifying nonpowered dam, including its associated impoundment or other infrastructure; and

(v) The operation of the facility will not result in any material change to the storage, release, or flow operations of the associated qualifying nonpowered dam.

(2) *Section 35 of the Federal Power Act qualification—closed-loop pumped storage projects.* The application must demonstrate that the proposed closed-loop pumped storage project meets the following qualifications pursuant to section 35(g)(2) of the Federal Power Act:

(i) The project will cause little to no change to existing surface and groundwater flows and uses; and

(ii) The project is unlikely to adversely affect species listed as a threatened species or endangered species, or designated critical habitat of such species, under the Endangered Species Act of 1973.

(3) *Section 401 of the Clean Water Act.* The application must include a copy of a request for certification under section 401(a)(1) of the Clean Water Act, including proof of the date on which the certifying agency received the request; or

(i) A copy of water quality certification; or

(ii) Evidence of waiver of water quality certification. A certifying agency is deemed to have waived the certification requirements of section 401(a)(1) of the Clean Water Act if the certifying agency has not denied or granted certification by one year after the date the certifying agency received a written request for certification. If a certifying agency denies certification, the applicant must file a copy of the denial within 30 days after the applicant received it.

(4) *Endangered Species Act (ESA).* The application must include:

(i) A no-effect determination that includes documentation that no listed species or critical habitat are present in the action area;

(ii) Documentation of concurrence from the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (Service(s)), as necessary, that the action is not likely to adversely affect ESA-listed species or critical habitat; or

(iii) A draft Biological Assessment that includes documentation of consultation with the Service(s).

(5) *Section 106 of the National Historic Preservation Act.* Documentation that section 106 consultation has been initiated with the state historic preservation officer(s) and any Indian Tribes identified as having an interest in the project.

(6) *Dam owner documentation.* For projects to be located at existing nonpowered dams:

(i) Documentation of consultation with any nonfederal owner of the nonpowered dam if the applicant is not the owner and confirmation that the owner is not opposed to a hydropower development at the location; or

(ii) Documentation from the federal entity that non-federal hydropower development is not precluded at the proposed location and confirmation that the federal entity is not opposed to a hydropower development at the location.

(7) *Public parks, recreation areas, and wildlife refuges.* If the project would use any public park, recreation area, or wildlife refuge established under state or local law, documentation from the managing entity indicating it is not opposed to the site's use for hydropower development.

§ 7.3 Adequacy review of application.

(a) *Adequacy review of license applications.* Review of the original license application for which expedited processing under this part is requested will be conducted pursuant to 18 CFR part 4 or 5, as applicable.

(b) *Deficient license applications.* If an original license application for which expedited processing is requested under this part is rejected under 18 CFR parts 4 and 5, as applicable, the request for authorization for the expedited licensing process under this part is deemed rejected.

§ 7.4 Additional information.

An applicant may be required to submit any additional information or documentation that the Commission considers relevant for an informed decision on the application for authorization under this part. The information or documents must take the form, and must be submitted within the time, that the Commission prescribes. An applicant may also be required to provide within a specified time additional copies of the application, or any of the additional information or documents that are filed, to the Commission or to any person, agency, Indian Tribe or other entity that the Commission specifies. If an applicant fails to provide timely additional information, documents, or copies of submitted materials as required, the Director of the Office of Energy Projects (Director) may dismiss the application, hold it in abeyance, or take other appropriate action under this chapter or the Federal Power Act.

§ 7.5 Decision on request to use expedited licensing process.

When the Commission has determined that the original license application is complete insofar as it meets the Commission's requirements as

specified in 18 CFR parts 4, 5, and this part; any deficiencies have been cured; and no other additional information is needed, the Director will make a decision on the request to use the expedited licensing process under this part no later than 180 days after receipt of a request for authorization to use the expedited process. If the Commission cannot deem the application complete within 180 days of application filing, the Director will deny the request to use the expedited licensing process. If the Director denies the request to use the expedited licensing process, the original license application will be processed pursuant to a standard processing schedule under 18 CFR parts 4 and 5, as applicable.

§ 7.6 Notice of acceptance and ready for environmental analysis.

If the Director deems the application complete and approves the request to use the expedited licensing process under § 7.5, the Commission will issue a public notice as required in the Federal Power Act, no later than 180 days after application filing, that:

(a) Accepts the application for filing and specifies the date upon which the application was accepted for filing;

(b) Finds the application ready for environmental analysis;

(c) Requests comments, protests, and interventions;

(d) Requests recommendations, preliminary terms and conditions, and preliminary fishway prescriptions, including all supporting documentation; and

(e) Establishes an expedited licensing process schedule, including estimated dates for:

(1) Filing of recommendations, preliminary terms and conditions, and fishway prescriptions;

(2) Issuance of a draft National Environmental Policy Act (NEPA) document, or an environmental assessment not preceded by a draft;

(3) Filing of a response, as applicable, to Commission staff's request for ESA concurrence or request for formal consultation under the ESA, or responding to other Commission staff requests to federal and state agencies, or Indian Tribes pursuant to Federal law, including the Magnuson-Stevens Fishery Conservation and Management Act and the National Historic Preservation Act;

(4) Filing of comments on the draft NEPA document, as applicable;

(5) Filing of modified recommendations, mandatory terms and conditions, and fishway prescriptions in response to a draft NEPA document or environmental assessment, if no draft NEPA document is issued; and

(6) Issuance of a final NEPA document, if any.

§ 7.7 Amendment of application.

(a) Any proposed amendments to the pending license application after issuance of the notice of acceptance and ready for environmental analysis under this section must include:

(1) An amended or new section 401 of the Clean Water Act water quality certification if the amendment would have a material adverse impact on the water quality in the discharge from the proposed project; and

(2) Updates to all other material submitted under § 7.2(b).

(b) If based on the information provided under paragraph (a) of this section, the proposed project under the amended license application no longer meets the requirements for expedited processing under § 7.2 of this part or if the proposed amendment significantly amends the license application, the Director will notify the applicant that the application will no longer be processed under the expedited licensing process under this part and that further processing of the application will proceed under parts 4 and 5 of this chapter, as applicable.

(c) If the Director approves the continued processing of the amended application under this part and the amendment to the application would materially change the project's proposed plans of development, as provided in § 4.35 of this chapter, an agency, Indian Tribe, or member of the public may modify the recommendations or terms and conditions or prescriptions it previously submitted to the Commission pursuant to § 7.6. Such modified recommendations, terms and conditions, or prescriptions must be filed no later than the due date specified by the Commission for comments on the amendment.

(d) *Date of acceptance.* The date of acceptance of an amendment of application for an original license filed under this part is governed by the provisions of § 4.35 of this chapter.

§ 7.8 Other provisions.

(a) Except for provisions required by statute, the Director may waive or modify any of the provisions of this part for good cause.

(b) Late-filed recommendations by fish and wildlife agencies pursuant to the Fish and Wildlife Coordination Act and section 10(j) of the Federal Power Act for the protection, mitigation of damages to, and enhancement of fish and wildlife affected by the development, operation, and management of the proposed project and late-filed terms and conditions or prescriptions filed pursuant to sections 4(e) and 18 of the Federal Power Act, respectively, may be considered by the Commission as cause to remove the application from the expedited licensing process. If the Director determines that late-filed recommendations, terms and conditions, or prescriptions are likely to prevent the Commission from issuing a final licensing decision within two years from application receipt, the Director will notify the applicant that the application will no longer be processed under the expedited licensing process under this part and that further processing of the application will proceed under 18 CFR parts 4 and 5, as applicable.

(c) *License conditions and required findings.* (1) All licenses shall be issued on the conditions specified in section 10 of the Federal Power Act and such other conditions as the Commission determines are lawful and in the public interest.

(2) Subject to paragraph (b) of this section, fish and wildlife conditions shall be based on recommendations timely received from the fish and wildlife agencies pursuant to the Fish and Wildlife Coordination Act.

(3) The Commission will consider the timely recommendations of resource agencies, other governmental units, and members of the public, and the timely recommendations (including fish and wildlife recommendations) of Indian Tribes affected by the project.

(4) Licenses for a project located within any Federal reservation shall be issued only after the findings required by, and subject to, any conditions that may be filed pursuant to section 4(e) of the Federal Power Act.

(5) The Commission will require the construction, maintenance, and operation of such fishways as may be prescribed by the Secretary of Commerce or the Secretary of the Interior, as appropriate, pursuant to section 18 of the Federal Power Act.

§ 7.9 Transition provision.

This part shall only apply to original license applications filed on or after July 23, 2019.

[FR Doc. 2019–08239 Filed 4–23–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 4

[Docket No. FDA–2008–N–0424]

Compliance Policy for Combination Product Postmarketing Safety Reporting; Immediately in Effect Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of an update to the immediately in effect guidance for industry entitled ''Compliance Policy for Combination Product Postmarketing Safety Reporting.'' This guidance describes FDA's compliance policy for combination product applicants and constituent part applicants and activities under FDA regulations that addresses combination product postmarketing safety reporting. FDA is updating this guidance by extending the period of time during which FDA does not intend to enforce certain combination product postmarketing safety reporting requirements.

DATES: The announcement of the updated guidance is published in the **Federal Register** on April 24, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2008–N–0424 for ''Compliance Policy for Combination Product Postmarketing Safety Reporting.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Melissa Burns, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–5616, *melissa.burns@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing an update to the immediately in effect guidance for industry entitled ''Compliance Policy for Combination Product Postmarketing Safety Reporting.'' This guidance was originally issued on March 21, 2018 (83 FR 12259). This guidance describes FDA's compliance policy for combination product applicants and constituent part applicants and activities under 21 CFR part 4, subpart B, which was published in the **Federal Register** of December 20, 2016 (81 FR 92603) and addresses postmarketing safety reporting for combination products. FDA is updating this guidance by extending the period of time during which FDA does not intend to enforce certain combination product postmarketing safety reporting requirements.

We are updating this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this updated guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)(i)) and § 10.115(g)(2)). We made this determination because FDA needs to communicate its compliance

policy in a timely manner given the compliance deadlines for certain provisions in 21 CFR part 4, subpart B, and the amount of time needed for firms to prepare for them. Although this guidance is immediately effective, it remains subject to comment in accordance with FDA's GGP regulation.

This guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 314.80(c) and (e), as well as for 21 CFR 314.81(b) are approved under OMB control numbers 0910–0001, 0910–0230, and 0910–0291. The information collection provisions for 21 CFR 600.80 and 600.81 are approved under OMB control number 0910–0308. Those for 21 CFR 606.170 are approved under OMB control number 0910–0116. Those for 21 CFR 606.171 are approved under OMB control number 0910–0458. The information collection provisions for 21 CFR 803.50, 803.53, and 803.56 are approved under OMB control numbers 0910–0291 and 0910–0437. The information collection provisions for 21 CFR 806.10 and 806.20 are approved under OMB control number 0910–0359. The information collection provisions for 21 CFR 4.102, 4.103, and 4.105 are approved under OMB control number 0910–0834.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: April 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–08284 Filed 4–23–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9851]

RIN 1545–BN55

Guidance Under Section 851 Relating to Investments in Stock and Securities; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to final regulations (TD 9851) that were published in the **Federal Register** on Tuesday, March 19, 2019. The final regulations provide guidance relating to the income test used to determine whether a corporation may qualify as a regulated investment company (RIC) for Federal income tax purposes.

DATES: This correction is effective on April 24, 2019 and is applicable to taxable years that begin after June 17, 2019.

FOR FURTHER INFORMATION CONTACT: Matthew Howard at (202) 317–7053 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9851) published on March 19, 2019 (84 FR 9959) that are the subject of this correction are issued under section 851 of the Internal Revenue Code.

Need for Correction

As published, the final regulations (TD 9851) contain errors that need to be corrected.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 1 is amended by making the following correcting amendments:

PART 1—INCOME TAXES

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

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

■ **Par. 2.** Section 1.851–2 is amended by revising paragraph (b)(1)(i)(F) and the first sentence of paragraph (b)(2)(iii) to read as follows:

§ 1.851–2 Limitations.

* * * * *

(b) * * *

(1) * * *

(i) * * *

(F) Other income (including but not limited to gains from options, futures, or forward contracts) derived with respect to the corporation's business of investing in such stock, securities, or currencies.

* * * * *

(2) * * *

(iii) If an amount is included in gross income of the corporation referred to in paragraph (b)(1) of this section under section 951(a)(1) or 1293(a) and is derived with respect to that corporation's business of investing in stock, securities, or currencies, then the amount is other income described in section 851(b)(2)(A) and paragraph (b)(1)(i)(F) of this section. * * *

* * * * *

Martin V. Franks,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2019–08285 Filed 4–23–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 726

[Docket ID: USN–2019–HQ–0004]

RIN 0703–AB16

Payments of Amounts Due Mentally Incompetent Members of the Naval Service

AGENCY: Department of the Navy, Department of Defense.

ACTION: Final rule.

SUMMARY: This final rule removes the Department of the Navy (DON) regulation concerning Payments of Amounts Due Mentally Incompetent Members of the Naval Service. Removal is appropriate because the regulation does not affect how the public engages the DON regarding these payments and does not place obligations on the public. The Department of Defense, the Secretary of the Navy, and the Bureau of Medicine and Surgery (BUMED) issue internal instructions that establish requirements for competency boards, the process for determining mental incompetence, and the process and requirements for making payments within the parameters established by many controlling statutes. These internal instructions do not require publication in the Code of Federal Regulations.

DATES: This rule is effective on April 24, 2019.

FOR FURTHER INFORMATION CONTACT: CDR Meredith Werner at 703–614–7408.

SUPPLEMENTARY INFORMATION: Section 603 of Title 37, United States Code, requires the Service Secretaries to prescribe regulations to carry out Chapter 11 of Title 37, United States Code: Payments to Mentally Incompetent Persons. The Department of Defense publishes the process and requirements for making payments in Chapter 33 of Volume 7A and Chapter 16 of Volume 7B of the Financial Management Regulation (DoD 7000.14–R, available at *https://comptroller.defense.gov/Portals/45/documents/fmr/Volume_07b.pdf*), of March 2018; BUMED publishes requirements for competency boards in Chapter 18 of the Manual of the Medical Department (MANMED) (NAVMED P–117, available at *https://www.med.navy.mil/directives/Documents/NAVMED%20P-117%20%28MANMED%29/MMDChapter18.pdf*), of January 10, 2005; and the Secretary of the Navy (SECNAV) publishes the process for determining mental competency (SECNAV Instruction 1850.4E, available at *https://www.secnav.navy.mil/mra/CORB/Documents/SECNAVINST-1850-4E.PDF*), of April 30, 2002.

32 CFR part 726 was last updated on October 29, 2008.

It has been determined that publication of this CFR part for public comment is impracticable, unnecessary, and contrary to the public interest since it is based upon removing internal content, and the ultimate statutory authority governing the payments of amounts due mentally incompetent members of the Naval service remains in effect in Chapter 11 of Title 37, United States Code.

This rule is not significant under Executive Order (E.O.) 12866, ''Regulatory Planning and Review.'' Therefore, E.O. 13771, ''Reducing Regulation and Controlling Regulatory Costs'' does not apply.

List of Subjects in 32 CFR Part 726

Administrative practice and procedure, Military personnel, Reporting and recordkeeping requirements, Trusts and trustees.

PART 726—[REMOVED]

■ Accordingly, by the authority of 5 U.S.C. 301, 32 CFR part 726 is removed.

Dated: April 19, 2019.

Meredith Steingold Werner,

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2019–08252 Filed 4–23–19; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2018–1084]

RIN 1625–AA00

Safety Zone; Cocos Lagoon, Merizo, GU

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters within Cocos Lagoon. This safety zone will encompass the designated swim course for the Cocos Crossing swim event in the waters of Cocos Lagoon, Merizo, Guam. This action is necessary to protect all persons and vessels participating in this marine event from potential safety hazards associated with vessel traffic in the area. Race participants, chase boats, and organizers of the event will be exempt from the safety zone. Entry of persons or vessels into the safety zone is prohibited unless authorized by the Captain of the Port Guam (COTP).

DATES: This rule is effective from 7 a.m. through 1 p.m. on May 26, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2018–1084 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Chief Petty Officer Todd Wheeler, Sector Guam, U.S. Coast Guard, by telephone at (671) 355–4866, or email at *WWMGuam@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 purpose of this rule is to ensure the safety of the participants and the navigable waters in the safety zone before, during, and after the scheduled swim event. In response, on March 8, 2019, the Coast Guard published an NPRM titled ''Safety Zone; Cocos Lagoon, Merizo, GU'' (84 FR 8489). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this safety zone. During the comment period that ended April 8, 2019, we received no comments.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The COTP has determined that potential hazards associated with the event will be a safety concern. The purpose of this rule is to protect all persons and vessels participating in this event from potential safety hazards associated with vessel traffic in the area.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published March 8, 2019. There is one change in the regulatory text of this rule from the proposed rule in the NPRM. Paragraph (b), regarding enforcement dates, has been updated to an enforcement date from 7 a.m. to 1 p.m. on May 26, 2019 whereas the enforcement date in the NPRM was from 6 a.m. to 1 p.m. on a specified day during either the last two weeks of May or the first two weeks of June. This change was made after we received notification of the exact date and time of the event. The date and time are within the time frame listed in the NPRM.

This rule establishes a safety zone from 7 a.m. until 1 p.m. on May 26, 2019. The safety zone will cover all navigable waters within 100-yards radius of race participants in Cocos Lagoon, Guam. This rulemaking would prohibit persons and vessels not involved in the event from being in the safety zone unless authorized by the COTP or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. 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), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, duration, and time-of-day of the safety zone. Vessel traffic will be able to safely transit around this safety zone, which will impact a small designated area of the Cocos Lagoon for 6 hours. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule allows vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no 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 contact 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. If you believe this 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 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 and Commandant Instruction M16475.1D, 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 lasting 6 hours that would prohibit entry within 100 yards of swim participants. 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. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

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.

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: 33 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T14–1084 to read as follows:

§ 165.T14–1084 Safety Zone; Cocos Lagoon, Merizo, GU.

(a) *Location.* The following area, within the Guam Captain of the Port (COTP) Zone (See 33 CFR 3.70–15), all navigable waters within a 100-yard radius of race participants in Cocos Lagoon, Merizo, Guam. Race participants, chase boats and organizers

of the event will be exempt from the safety zone.

(b) *Enforcement dates.* This section will be enforced from 7 a.m. to 1 p.m. on May 26, 2019.

(c) *Enforcement.* All persons are required to comply with the general regulations governing safety zones found in § 165.23. Entry into or remaining in this zone is prohibited unless authorized by the Coast Guard Captain of the Port, Guam. Persons desiring to transit the area of the safety zone must first request authorization from the Captain of the Port Guam or his designated representative. To seek permission to transit the area, the Captain of the Port Guam (COTP) and his designated representatives can be contacted at telephone number (671) 355–4821 or on Marine Band Radio, VHF–FM channel 16 (156.8 MHz). Any Coast Guard commissioned, warrant, or petty officer, and any other COTP representative permitted by law, may enforce this safety zone.

(d) *Waiver.* The COTP may waive any of the requirements of this section for any person, vessel, or class of vessel upon finding that application of the safety zone is unnecessary or impractical for the purpose of maritime security.

(e) *Penalties.* Vessels or persons violating this section are subject to the penalties set forth in 33 U.S.C. 1232.

Dated: April 19, 2019.

Christopher M. Chase,

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

[FR Doc. 2019–08224 Filed 4–23–19; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R04–OAR–2018–0523; FRL–9992–53–Region 4]

Air Plan Approval and Designation of Areas; FL; Redesignation of the Nassau County 2010 1-Hour Sulfur Dioxide Nonattainment Area to Attainment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In a letter dated June 7, 2018, the State of Florida, through the Florida Department of Environmental Protection (FDEP), submitted a request for the Environmental Protection Agency (EPA) to redesignate the Nassau County sulfur dioxide (SO_2) nonattainment area (hereinafter referred to as the ''Nassau County Area'' or ''Area'') to attainment for the 2010 1-hour SO_2 primary national ambient air quality standard (NAAQS) and to approve an accompanying state implementation plan (SIP) revision containing a maintenance plan for the Area. The submittal was received by EPA on June 12, 2018. EPA is taking final action to determine that the Nassau County Area attained the 2010 1-hour SO_2 NAAQS by its applicable attainment date of October 4, 2018; to approve the SIP revision containing the State's plan for maintaining attainment of the 2010 1-hour SO_2 standard and to incorporate the maintenance plan into the SIP; and to redesignate the Nassau County Area to attainment for the 2010 1-hour SO_2 NAAQS.

DATES: This rule will be effective May 24, 2019.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2018–0523. 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, Pesticides and Toxics Management 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: Madolyn Sanchez, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. Ms. Sanchez may be reached by phone at (404) 562–9644 or via electronic mail at *sanchez.madolyn@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What is the background for the actions?

On June 2, 2010, EPA revised the primary SO_2 NAAQS, establishing a new 1-hour SO_2 standard of 75 parts per billion (ppb). *See* 75 FR 35520 (June 22, 2010). Under EPA's regulations at 40 CFR part 50, the 2010 1-hour SO_2 NAAQS is met at a monitoring site when the 3-year average of the annual 99th percentile of daily maximum 1-hour average concentrations is less than or equal to 75 ppb (based on the rounding convention in 40 CFR part 50, appendix T). *See* 40 CFR 50.17. Ambient air quality monitoring data for the 3-year period must meet a data completeness requirement. A year meets data completeness requirements when all four quarters are complete, and a quarter is complete when at least 75 percent of the sampling days for each quarter have complete data. A sampling day has complete data if 75 percent of the hourly concentration values, including state-flagged data affected by exceptional events which have been approved for exclusion by the Administrator, are reported.[1]

Upon promulgation of a new or revised NAAQS, the CAA requires EPA to designate as nonattainment any area that does not meet (or that contributes to ambient air quality in a nearby area that does not meet) the NAAQS. EPA designated the Nassau County Area as nonattainment for the 2010 1-hour SO_2 NAAQS, effective on October 4, 2013, using 2009–2011 complete, quality assured, and certified ambient air quality data. *See* 78 FR 47191 (August 5, 2013). The Area is comprised of the portion of Nassau County encompassing the circular boundary with the center being Universal Transverse Mercator (UTM) Easting 455530 meters, UTM Northing 3391737 meters, UTM zone 17, using the NAD83 datum (the location of the ambient SO_2 monitor in the Area) and the radius being 2.4 kilometers (km). Under the CAA, nonattainment areas must attain the NAAQS as expeditiously as practicable but not later than five years after the October 4, 2013, effective date of the designation. *See* CAA section 192(a). Therefore, the Nassau County Area's applicable attainment date was no later than October 4, 2018.

EPA's 2010 SO_2 nonattainment designation for the Area triggered an obligation for Florida to develop a nonattainment SIP revision addressing certain requirements under title I, part D, subpart 1 (hereinafter ''Subpart 1''), and to submit that SIP revision to EPA

[1] *See* 40 CFR part 50, appendix T, section 3(b).

in accordance with the deadlines in title I, part D, subpart 5 (hereinafter ''Subpart 5''). Subpart 1 contains the general requirements for nonattainment areas for criteria pollutants, including requirements to develop a SIP that provides for the implementation of reasonably available control measures (RACM), requires reasonable further progress (RFP), includes base-year and attainment-year emissions inventories, a SIP-approved nonattainment new source review (NNSR) permitting program that accounts for growth in the area, enforceable emission limitations and other such control measures, and provides for the implementation of contingency measures. This SIP revision was due within 18 months following the October 4, 2013, effective date of designation (*i.e.,* April 4, 2015). *See* CAA section 191(a). Florida submitted a nonattainment SIP revision to EPA on April 3, 2015.

Florida's nonattainment SIP revision included permit conditions prescribing controls and emissions limits to reduce SO_2 emissions at the only point source of SO_2 emissions within the Nassau County Area—Rayonier Performance Fibers, LLC Fernandina Beach Sulfite Pulp Mill (Rayonier)—and at the largest source of SO_2 within 25 km outside of the nonattainment area—WestRock CP, LLC Fernandina Beach Mill (WestRock). These measures were fully implemented at Rayonier during the second quarter of 2014 and at WestRock in December 2017. Florida's nonattainment SIP revision also included a modeled attainment demonstration for the 2010 SO_2 NAAQS based on the permit conditions at Rayonier and WestRock provided therein, a base year emissions inventory, RACM/Reasonably Available Control Technology (RACT), an RFP plan, NNSR permitting program, and contingency measures for the Nassau County Area, thereby satisfying the required nonattainment planning requirements mentioned above for the Nassau County Area. On July 3, 2017 (82 FR 30749), EPA approved Florida's April 3, 2015, SO_2 nonattainment SIP revision, making the aforementioned permit conditions at Rayonier and WestRock permanent and enforceable.

On June 7, 2018, Florida submitted a request to EPA for redesignation of the Nassau County Area to attainment for the 2010 1-hour SO_2 NAAQS and a related SIP revision containing a maintenance plan for the Area. In a notice of proposed rulemaking (NPRM) published on February 15, 2019 (84 FR 4411), EPA proposed to determine that the Area attained the 2010 1-hour SO_2 NAAQS by its attainment date of October 4, 2018; to approve the maintenance plan for the Area as meeting the maintenance plan requirements of CAA section 175A and to incorporate it into the SIP; and to approve Florida's request for redesignation of the Area from nonattainment to attainment for the 2010 1-hour SO_2 NAAQS as meeting the redesignation requirements of CAA section 107(d)(3)(E). No adverse comments were received on the February 15, 2019, proposed rulemaking. The details of Florida's submittal and the rationale for EPA's actions are further explained in the NPRM, including the modeled attainment demonstration and quality-assured, complete, and certified 2015–2017 ambient air monitoring data used to determine attainment with the 2010 1-hour SO_2 NAAQS.

II. What are the effects of these actions?

Approval of the redesignation request changes the legal designation of the Nassau County Area, found at 40 CFR 81.310, from nonattainment to attainment for the 2010 1-hour SO_2 NAAQS. Approval of Florida's associated SIP revision also incorporates a plan into the SIP for maintaining the 2010 1-hour SO_2 NAAQS in the Nassau County Area as described in the NPRM. The maintenance plan also establishes contingency measures to remedy any future violations of the 2010 1-hour SO_2 NAAQS and procedures for evaluation of potential violations.

EPA is finalizing the redesignation of the Nassau County Area to attainment for the 2010 1-hour SO_2 NAAQS and finalizing the approval of the CAA section 175A maintenance plan for the 2010 1-hour SO_2 NAAQS. The Area is required to implement the CAA section 175A maintenance plan for the 2010 1-hour SO_2 NAAQS that is being approved in today's action and the prevention of significant deterioration program for the 2010 1-hour SO_2 NAAQS. The approved maintenance plan can only be revised if the revision meets the requirements of CAA section 110(l) and, if applicable, CAA section 193.

III. Final Action

EPA is taking final actions regarding Florida's request to redesignate the Nassau County Area to attainment for the 2010 1-hour SO_2 NAAQS and associated SIP revision. EPA is determining that the Nassau County Area attained the 2010 1-hour SO_2 NAAQS by its applicable attainment date of October 4, 2018. EPA is also approving the SIP revision containing the State's plan for maintaining attainment of the 2010 1-hour SO_2 standard and incorporating the maintenance plan into the SIP. Finally, EPA is approving Florida's redesignation request and redesignating the Nassau County Area to attainment for the 2010 1-hour SO_2 NAAQS. As mentioned above, approval of the redesignation request changes the official designation of the Nassau County Area from nonattainment to attainment, as found in 40 CFR part 81.

IV. Statutory and Executive Order Reviews

Under the CAA, redesignation of an area to attainment and the accompanying approval of a maintenance plan under section 107(d)(3)(E) are actions that affect the status of a geographical area and do not impose any additional regulatory requirements on sources beyond those imposed by state law. A redesignation to attainment does not in and of itself create any new requirements, but rather results in the applicability of requirements contained in the CAA for areas that have been redesignated to attainment. Moreover, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, these actions merely approve state law as meeting Federal requirements and do not impose additional requirements beyond those imposed by state law. For this reason, these actions:

- Are not significant regulatory actions subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Are not Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory actions because redesignations and SIP approvals are exempted under Executive Order 12866;
- Do not impose information collection burdens under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Are 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.*);
- Do 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);

• Do not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

• Are not economically significant regulatory actions based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• Are not significant regulatory actions subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Are 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; and

• Will not have disproportionate human health or environmental effects under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 24, 2019. 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

40 CFR Part 52

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

40 CFR Part 81

Environmental protection, Air pollution control.

Dated: April 11, 2019.

Mary S. Walker,

Acting Regional Administrator, Region 4.

40 CFR parts 52 and 81 are amended 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. Section 52.520(e) is amended by adding an entry for ''2010 1-hour SO_2 Maintenance Plan for the Nassau Area'' at the end of the table to read as follows:

§ 52.520 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED FLORIDA NON-REGULATORY PROVISIONS

Provision	State effective date	EPA approval date	**Federal Register**, notice	Explanation
* * *	*	*	*	*
2010 1-hour SO_2 Maintenance Plan for the Nassau Area	6/7/2018	4/24/2019	[Insert citation of publication].	

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 3. The authority citation for part 81 continues to read as follows:

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

■ 4. In § 81.310, the table entitled ''Florida-2010 Sulfur Dioxide NAAQS (Primary)'' is amended by revising the entry for ''Nassau County, FL'' to read as follows:

§ 81.310 Florida.

* * * * *

FLORIDA—2010 SULFUR DIOXIDE NAAQS

[Primary]

Designated area	Designation	
	Date [1]	Type
* * * * * * *		
Nassau County, FL [2]	4/24/2019	Attainment.
Nassau County (part):		
That portion of Nassau County encompassing the circular boundary with the center being UTM Easting 455530 meters, UTM Northing 3391737 meters, UTM zone 17, using the NAD83 datum (the location of the ambient SO_2 monitor) and the radius being 2.4 kilometers.		
* * * * * * *		

[1] This date is 4/9/2018, unless otherwise noted.
[2] Excludes Indian country located in each area, if any, unless otherwise specified.

* * * * *

[FR Doc. 2019–08162 Filed 4–23–19; 8:45 am]

BILLING CODE 6560–50–P

Proposed Rules

Federal Register
Vol. 84, No. 79
Wednesday, April 24, 2019

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 932

[Doc. No. AMS–SC–18–0105; SC19–932–1 PR]

Olives Grown in California; Increased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement a recommendation from the California Olive Committee (Committee) to increase the assessment rate established for the 2019 fiscal year and subsequent fiscal years. The assessment rate would remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Comments must be received by May 24, 2019.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposed rule. Comments must be sent to the Docket Clerk, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or internet: *http://www.regulations.gov.* Comments should reference the document number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *http://www.regulations.gov.* All comments submitted in response to this proposed rule will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Kathie Notoro, Marketing Specialist or Terry Vawter, Regional Director, California Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (559) 538–1672, Fax: (559) 487–5906, or Email: *Kathie.Notoro@usda.gov* or *Terry.Vawter@usda.gov.*

Small businesses may request information on complying with this regulation by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202)720–8938, or Email: *Richard.Lower@usda.gov.*

SUPPLEMENTARY INFORMATION: This action, pursuant to 5 U.S.C. 553, proposes an amendment to regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This proposed rule is issued under Marketing Agreement and Order No. 932, as amended (7 CFR part 932), regulating the handling of olives grown in California. Part 932 (referred to as the ''Order'') is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' The Committee locally administers the Order and is comprised of producers and handlers of olives operating within the area of production, and one public member.

The Department of Agriculture (USDA) is issuing this proposed rule in conformance with Executive Orders 13563 and 13175. This proposed rule falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review. Additionally, because this proposed rule does not meet the definition of a significant regulatory action, it does not trigger the requirements contained in Executive Order 13771. See OMB's Memorandum titled ''Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, titled 'Reducing Regulation and Controlling Regulatory Costs' '' (February 2, 2017).

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the Order now in effect, California olive handlers are subject to assessments. Funds to administer the Order are derived from such assessments. It is intended that the assessment rate would be applicable to all assessable olives beginning on January 1, 2019, and continue until amended, suspended, or terminated.

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

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

This proposed rule would increase the assessment rate from $24.00 per ton of assessed olives, the rate that was established for the 2017–18 and subsequent fiscal years, to $44.00 per ton of assessed olives for the 2019 and subsequent fiscal years. The proposed higher rate is a result of a significantly reduced crop size, a late season freeze, and the need to cover Committee expenses.

The Committee met on December 11, 2018, and unanimously recommended 2019 expenditures of $1,628,923, and an assessment rate of $44.00 per ton of assessed olives. In comparison, last year's budgeted expenditures were $1,749,477. The proposed assessment rate of $44.00 is $20.00 higher than the rate currently in effect. Producer receipts show a yield of 17,953 tons of

assessable olives from the 2018 crop year. This is substantially less than the 2017 crop year, which yielded 90,188 tons of assessable olives. The 2019 fiscal year assessment rate increase is necessary to ensure the Committee has sufficient revenue to fund the recommended 2019 budgeted expenditures while ensuring the funds in the financial reserve would be kept within the maximum permitted by § 932.40.

The Order has a fiscal year and a crop year that are independent of each other. The crop year is a 12-month period that begins on August 1 of each year and ends on July 31 of the following year. The fiscal year is the 12-month period that begins on January 1 and ends on December 31 of each year. Olives are an alternate-bearing crop, with a small crop followed by a large crop. For this assessment rate proposed rule, the actual 2018 crop year receipts are used to determine the assessment rate for the 2019 fiscal year.

The major expenditures recommended by the Committee for the 2019 fiscal year includes $713,900 for program administration, $513,500 for marketing activities, and $343,523 for research, and $58,000 for inspection equipment. Budgeted expenses for these items during the 2018 fiscal year were $401,200 for program administration, $973,500 for marketing activities, $297,777 for research, and $77,000 inspection equipment.

The assessment rate recommended by the Committee resulted from consideration of anticipated fiscal year expenses, actual olive tonnage received by handlers during the 2018 crop year, and the amount in the Committee's financial reserve. Income derived from handler assessments, along with interest income and funds from the Committee's authorized reserve will be adequate to cover budgeted expenses. Funds in the reserve will be kept within the maximum permitted by the Order of approximately one fiscal year's expenses.

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

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

Initial Regulatory Flexibility Analysis

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

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

There are approximately 1,100 producers of olives in the production area and two handlers subject to regulation under the Order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts less than $750,000, and small agricultural service firms are defined as those whose annual receipts are less than $7,500,000 (13 CFR 121.201).

Based upon National Agricultural Statistics Service (NASS) information as of June 2018, the average price to producers for the 2017 crop year was $974.00 per ton, and total assessable volume for the 2018 crop year was 17,953 tons. Based on production, price paid to producers, and the total number of California olive producers, the average annual producer revenue is less than $750,000 ($974.00 times 17,953 tons equals $17,486,222 divided by 1,100 producers equals an average annual producer revenue of $15,896.57). Thus, the majority of olive producers may be classified as small entities. Both of the handlers may be classified as large entities under the SBA's definitions because their annual receipts are greater than $7,500,000.

This proposal would increase the assessment rate collected from handlers for the 2019 and subsequent fiscal years from $24.00 to $44.00 per ton of assessable olives. The Committee unanimously recommended 2019 expenditures of $1,628,923 and an assessment rate of $44.00 per ton of assessable olives. The recommended assessment rate of $44.00 is $20.00 higher than the 2018 rate. The quantity of assessable olives for the 2019 Fiscal year is 17,953 tons. Thus, the $44.00 rate should provide $789,932 in assessment revenue. The higher assessment rate is needed because annual receipts for the 2018 crop year are 17,953 tons compared to 90,188 tons for the 2017 crop year. Olives are an alternate-bearing crop, with a small crop followed by a large crop. Income derived from the $44.00 per ton assessment rate, along with funds from the authorized reserve and interest income, should be adequate to meet this fiscal year's expenses.

The major expenditures recommended by the Committee for the 2019 fiscal year include $713,900 for program administration, $513,500 for marketing activities, $343,523 for research, and $58,000 for inspection equipment. Budgeted expenses for these items during the 2018 fiscal year were $401,200 for program administration, $973,500 for marketing activities, $297,777 for research, and $77,000 for inspection equipment. The Committee deliberated on many of the expenses, weighed the relative value of various programs or projects, and increased their expenses for marketing and research activities.

Prior to arriving at this budget and assessment rate, the Committee considered information from various sources including the Committee's Executive, Marketing, Inspection, and Research Subcommittees. Alternate expenditure levels were discussed by these groups, based upon the relative value of various projects to the olive industry and the increased olive production. The assessment rate of $44.00 per ton of assessable olives was derived by considering anticipated expenses, the low volume of assessable olives, a late season freeze, and additional pertinent factors.

A review of NASS information indicates that the average producer price for the 2017 crop year was $974.00 per ton. Therefore, utilizing the assessment rate of $44.00 per ton, the assessment revenue for the 2019 fiscal year as a percentage of total producer revenue would be approximately 4.52 percent.

This proposed action would increase the assessment obligation imposed on handlers. While assessments impose some additional costs on handlers, the costs are minimal and uniform on all handlers. Some of the additional costs

may be passed on to producers. However, these costs would be offset by the benefits derived by the operation of the Order. In addition, the Committee's meeting was widely publicized throughout the production area. The olive industry and all interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the December 11, 2018, meeting was a public meeting and all entities, both large and small, were able to express views on this issue. Interested persons are invited to submit comments on this proposed rule, including the regulatory and information collection impacts of this action on small businesses.

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

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

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

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

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

A 30-day comment period is provided to allow interested persons to respond to this proposed rule. All written comments timely received will be considered before a final determination is made on this rule.

List of Subjects in 7 CFR Part 932

Marketing agreements, Olives, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 932 is proposed to be amended as follows:

PART 932—OLIVES GROWN IN CALIFORNIA

■ 1. The authority citation for 7 CFR part 932 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 932.230 is revised to read as follows:

§ 932.230 Assessment rate.

On and after January 1, 2019, an assessment rate of $44.00 per ton is established for California olives.

Dated: April 18, 2019.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2019–08179 Filed 4–23–19; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 966

[Doc. No. AMS–SC–19–0011; SC19–966–2 PR]

Tomatoes Grown in Florida; Redistricting and Reapportionment of Producer Districts

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement a recommendation from the Florida Tomato Committee (Committee) to redistrict and reapportion producer representation on the Committee currently prescribed under the marketing order for tomatoes grown in Florida. This action would reduce the number of districts from four to two and reapportion producer membership on the Committee to provide equitable representation from both districts.

DATES: Comments must be received by May 24, 2019.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposal. Comments must be sent to the Docket Clerk, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or internet: *http://www.regulations.gov.* All comments should reference the document number and the date and page number of this issue of the **Federal Register** and will be made available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *http://www.regulations.gov.* All comments submitted in response to this proposal will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Steven W. Kauffman, Marketing Specialist, or Christian D. Nissen, Regional Director, Southeast Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (863) 324–3375, Fax: (863) 291–8614, or Email: *Steven.Kauffman@usda.gov* or *Christian.Nissen@usda.gov.*

Small businesses may request information on complying with this regulation by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Richard.Lower@usda.gov.*

SUPPLEMENTARY INFORMATION: This action, pursuant to 5 U.S.C. 553, proposes an amendment to regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This proposed rule is issued under Marketing Agreement No. 125 and Order No. 966, as amended (7 CFR part 966), regulating the handling of tomatoes grown in Florida. Part 966 (referred to as the ''Order'') is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' The Committee locally administers the Order and is comprised of producers operating within the production area.

The Department of Agriculture (USDA) is issuing this proposed rule in conformance with Executive Orders 13563 and 13175. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review. Additionally, because this proposed rule does not meet the definition of a significant regulatory action, it does not trigger the requirements contained in Executive Order 13771. See OMB's Memorandum titled ''Interim Guidance Implementing Section 2 of the Executive Order of

January 30, 2017, titled 'Reducing Regulation and Controlling Regulatory Costs' '' (February 2, 2017).

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. This proposed rule is not intended to have retroactive effect.

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

This proposed rule invites comments on redistricting and reapportionment of membership on the Committee prescribed under the Order for the 2020–21 and subsequent fiscal periods. This proposal would reduce the number of districts from four to two and reapportion producer membership on the Committee to provide equitable representation from both districts. Redistricting and reapportionment of membership would make it easier for committee staff to conduct producer nominations and ensure the appointment of a full Committee. When the Committee is fully appointed, it is easier to achieve a quorum for assembled meetings. The Committee unanimously recommended this change at its November 1, 2018, meeting.

Section 966.22 provides for the establishment of membership on the Committee. The twelve members and their alternates shall be producers, or officers or employees of a corporate producer, in the district for which selected and a resident of the production area. The Order provides districts from which producers serve as representatives on the Committee.

Section 966.25 provides the authority for the Committee to recommend, with the approval of the Secretary, reapportionment of members among districts, and the reestablishment of districts within the production area. This section also provides that, in making such recommendations, the Committee shall give consideration to: a. Shifts in tomato acreage within districts and within the production area during recent years; b. the importance of new production in its relation to existing districts; c. the equitable relationship of Committee membership and districts; d. economies to result for producers in promoting efficient administration due to redistricting or reapportionment of members within districts; and e. other relevant factors.

Section 966.24 defined the four districts within the production area by county. Districts 1 and 2 have previously been reestablished pursuant to § 996.160. Section 966.161 apportions Committee membership among the districts pursuant to § 966.25. Currently, Districts 1 and 2 are represented by two committee members and alternates each and Districts 3 and 4 are represented by four committee members and alternates each.

The Committee met on November 1, 2018, to discuss the changes in recent years to production and the shift in acreage location of Florida tomatoes. Over the past two decades, the Florida tomato industry has experienced significant changes in production volume and location. Decreasing production and shifts in acreage are due to increased production costs along with competition from imports and other growing regions. The increased costs and competition has contributed to a decrease in the number of producers and handlers. With fewer producers to represent the industry and the changes to production and acreage, the Committee discussed redistricting and reapportionment of membership on the Committee.

Tomato production has shifted from the eastern part of the production area in the state of Florida (Districts 1 and 2) to the western part of the production area (Districts 3 and 4). According to Committee data, production during the 2017–18 season in District 4 accounted for 56 percent of the production area's total production. The next largest district by production volume was District 3, accounting for 39 percent of total production. In comparison, District 1 accounted for 4 percent of total production and District 2 only 1 percent of the total volume for the production area.

According to Committee data, Districts 1 and 2 accounted for 28 percent of total production during the 1998–99 season but production had decreased to only 8 percent by the 2007–08 season. Industry production has slowly moved into Districts 3 and 4 over the last 20 years and now these two districts make-up 95 percent of total production.

The shift in tomato production between districts has created an imbalance in Committee representation. The members from Districts 1 and 2 combined represent one third of the membership on the Committee while these districts account for only 5 percent of the tomato production volume. Consequently, Districts 3 and 4 are underrepresented with only two thirds of the Committee membership. During the discussion, Committee members reviewed the data for acreage and production from all districts in the production area as required in the Order. The gradual shift in acreage and production from the eastern portion of the production area in the State of Florida to the western portion has made it difficult to find enough qualified producers to represent Districts 1 and 2 on the Committee. Committee members from these two districts represent four seats on the Committee. Committee members also noted that with fewer producers remaining in the Florida tomato industry, particularly in Districts 1 and 2, it is difficult to get enough members together to meet the Order's quorum requirements for a meeting.

As a result of the discussion and analysis, the Committee recommended combining the current Districts 1, 3, and a portion of District 2 into one district, and District 4 and the remaining portion of District 2 into another district. This would divide the production area into two districts with each district representing approximately half of the total volume of tomatoes produced in the production area. The Committee also recommended reapportioning the twelve Committee members and alternates so that six Committee members and alternates represent each district.

The two new districts would comprise the following Florida counties: District 1 would include the counties of Charlotte, Glades, Palm Beach, Lee, Hendry, Collier, Broward, Monroe, and Dade; and District 2 would include the counties of Pinellas, Hillsborough, Polk, Osceola, Brevard, Manatee, Hardee, Highlands, Okeechobee, Indian River, St. Lucie, Sarasota, De Soto, and Martin.

Accordingly, the Committee unanimously voted to reduce the number of districts from four to two and reapportion producer membership on the Committee so that each district would have six members and alternates. The Committee believes these proposed changes would adjust producer representation to reflect the composition of the industry, and create the opportunity for other producers to serve on the Committee.

Initial Regulatory Flexibility Analysis

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

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

There are approximately 75 producers of Florida tomatoes in the production area and 37 handlers subject to regulation under the Order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts less than $750,000, and small agricultural service firms are defined as those whose annual receipts are less than $7,500,000 (13 CFR 121.201).

According to industry and Committee data, the average annual price for fresh Florida tomatoes during the 2017–18 season was approximately $12.56 per 25-pound container, and total fresh shipments were 25.9 million containers. Using the average price and shipment information, the number of handlers, and assuming a normal distribution, the majority of handlers have average annual receipts of more than $7,500,000, ($12.56 times 25.9 million containers equals $325,304,000 divided by 37 handlers equals $8,792,000 per handler).

With an estimated producer price of $6.00 per 25-pound container, the number of Florida tomato producers, and assuming a normal distribution, the average annual producer revenue is above $750,000, ($6.00 times 25.9 million containers equals $155,400,000 divided by 75 producers equals $2,072,000 per producer). Thus, the majority of handlers and producers of Florida tomatoes may be classified as large entities.

The gradual shift in acreage and production from the eastern portion of the production area in the State of Florida to the western portion has made it difficult to find enough qualified producers to represent Districts 1 and 2 on the Committee. Committee members from these two districts represent one third of the seats on the Committee. Redistricting and reapportionment of membership would make it easier for Committee staff to conduct producer nominations, provide nominees for all seats, and readily achieve a quorum when meetings are assembled with a full committee.

This proposed rule would reduce the number of districts from four to two and reapportion producer membership on the Committee to provide six members and alternates from both districts. The Committee believes this change would adjust producer representation to reflect the composition of the industry, provide equitable representation from each district, and create the opportunity for other producers to serve on the Committee. This rulemaking would revise §§ 966.160 and 966.161. Authority for this action is provided in § 966.25 of the Order.

It is not anticipated that this action would impose any additional costs on the industry. This change would save time and operating resources by making it easier to find candidates to serve on the Committee. Additionally, a full committee would reduce the chance of a failed quorum. Thus, this action would help avoid the costs associated with travel and assembly of a meeting where a quorum is not achieved.

This action would have a beneficial impact as it more accurately aligns districts and reapportions Committee membership in accordance with the production of fresh Florida tomatoes. These changes should provide equitable representation to producers on the Committee and make the Committee more representative of the current industry. The effects of this proposed rule would not be disproportionately greater or less for small entities than for larger entities.

The Committee considered one alternative to this proposal. The Committee considered combining Districts 1 and 2 into one district. However, given the small volume of production currently produced in each of these districts, the Committee determined the best course of action was to divide the production area into two new districts with balanced production and representation. Therefore, this alternative was rejected.

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

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

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

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

The Committee's meetings were widely publicized throughout the Florida tomato industry, and all interested persons were invited to attend the meetings and participate in Committee deliberations on all issues. Like all Committee meetings, the November 1, 2018, meeting was a public meeting, and all entities, both large and small, were able to express their views on this issue. Finally, interested persons are invited to submit comments on this proposed rule, including the regulatory and information collection impacts of this action on small businesses.

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

A 30-day comment period is provided to allow interested persons to respond to this proposal. All written comments timely received will be considered before a final determination is made on this matter.

List of Subjects in 7 CFR Part 966

Marketing agreements, Reporting and recordkeeping requirements, Tomatoes.

For the reasons set forth in the preamble, 7 CFR part 966 is proposed to be amended as follows:

PART 966—TOMATOES GROWN IN FLORIDA

■ 1. The authority citation for 7 CFR part 966 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Amend § 966.160 by revising paragraphs (a) and (b) to read as follows:

§ 966.160 Reestablishment of districts.

(a) District No. 1: The counties of Charlotte, Glades, Palm Beach, Lee, Hendry, Collier, Broward, Monroe, and Dade in the State of Florida.

(b) District No. 2: The counties of Pinellas, Hillsborough, Polk, Osceola, Brevard, Manatee, Hardee, Highlands, Okeechobee, Indian River, St. Lucie, Sarasota, De Soto, and Martin in the State of Florida.

* * * * *

■ 3. Revise § 966.161 to read as follows:

§ 966.161 Reapportionment of Committee Membership.

Pursuant to § 966.25, industry membership on the Florida Tomato Committee shall be reapportioned as follows:

(a) District 1—six members and their alternates.

(b) District 2—six members and their alternates.

Dated: April 18, 2019.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2019–08173 Filed 4–23–19; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TREASURY

Office of the Comptroller of the Currency

12 CFR Parts 3, 6, 34, 46, 160, 161, 163, and 167

[Docket ID OCC–2019–0004]

RIN 1557–AE50

Other Real Estate Owned and Technical Amendments

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice of proposed rulemaking with request for public comment.

SUMMARY: The OCC is inviting comment on a proposed rule that would clarify and streamline its regulation on other real estate owned (OREO) for national banks and update the regulatory framework for OREO activities at Federal savings associations. The OCC is also proposing to remove outdated capital rules for national banks and Federal savings associations, which include provisions related to OREO, and make conforming edits to other rules that reference those capital rules.

DATES: Comments must be received by June 24, 2019.

ADDRESSES: You may submit comments to the OCC by any of the methods set forth below. Commenters are encouraged to submit comments through the Federal eRulemaking Portal or email, if possible. Please use the title ''Other Real Estate Owned and Technical Amendments'' to facilitate the organization and distribution of the comments. You may submit comments by any of the following methods:

- *Federal eRulemaking Portal—''Regulations.gov'':* Go to *www.regulations.gov.* Enter ''Docket ID OCC–2019–0004'' in the Search Box and click ''Search.'' Click on ''Comment Now'' to submit public comments.
- Click on the ''Help'' tab on the *Regulations.gov* home page to get information on using *Regulations.gov*, including instructions for submitting public comments.
- *Email: regs.comments@occ.treas.gov.*
- *Mail:* Chief Counsel's Office, Attention: Comment Processing, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.

Instructions: You must include ''OCC'' as the agency name and ''Docket ID OCC–2019–0004'' in your comment.

In general, the OCC will enter all comments received into the docket and publish the comments on the *Regulations.gov* website without change, including any business or personal information that you provide such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this rulemaking action by any of the following methods:

- *Viewing Comments Electronically:* Go to *www.regulations.gov.* Enter ''Docket ID OCC–2019–0004'' in the Search box and click ''Search.'' Click on ''Open Docket Folder'' on the right side of the screen. Comments and supporting materials can be viewed and filtered by clicking on ''View all documents and comments in this docket'' and then using the filtering tools on the left side of the screen.
- Click on the ''Help'' tab on the *Regulations.gov* home page to get information on using *Regulations.gov.* The docket may be viewed after the close of the comment period in the same manner as during the comment period.
- *Viewing Comments Personally:* You may personally inspect comments at the OCC, 400 7th Street SW, Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hearing impaired, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect comments.

FOR FURTHER INFORMATION CONTACT:

For revisions to Part 34, Subpart E (OREO): Charlotte Bahin, Senior Advisor for Thrift Supervision, (202) 649–6281; or, J. William Binkley, Attorney, Chief Counsel's Office, (202) 649–5500.

For all revisions: Kevin Korzeniewski, Counsel, Chief Counsel's Office, (202) 649–5490; or for persons who are deaf or hearing impaired, TTY, (202) 649–5597.

SUPPLEMENTARY INFORMATION:

I. Background

The OCC is proposing to update its regulatory framework for other real estate owned (OREO) by revising its rules to clarify and streamline the regulation for national banks and to apply the regulatory framework to OREO activities Federal savings associations for the reasons discussed below. The OCC's last significant revision to the national bank OREO rules occurred over twenty years ago.[1] Since that time, the OCC has gained additional supervisory experience related to OREO, which it can apply to improve the OREO rules. In addition, the OCC now supervises Federal savings associations pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act).[2] Federal savings associations, unlike national banks, are not subject to statutory provisions governing OREO. However, capital regulations and handbooks issued by the Office of Thrift Supervision (OTS) generally established requirements and supervisory expectations for OREO activities. Following OCC and OTS integration, the OCC rescinded or superseded many of those documents, creating ambiguity with respect to OREO standards for Federal savings associations. The OCC is proposing a framework for Federal savings associations that generally is consistent with the OTS framework

[1] *See* 61 FR 11294 (March 20, 1996).

[2] *See* 12 U.S.C. 5412.

described above. This framework is still followed by many savings associations and would offer flexibility consistent with provisions in the Home Owners' Loan Act (HOLA).

The OCC also is proposing to remove Appendices A and B to 12 CFR part 3 (risk-based capital guidelines for national banks) and 12 CFR part 167 (capital requirements for FSAs) and make conforming technical edits to other parts that reference those provisions. When the OCC revised Part 3 it superseded Appendices A and B to part 3 and part 167. However, because there was a transition period for part 3, the OCC retained those appendices at that time.[3] Part 167 includes provisions relating to treatment of OREO held by Federal savings associations that is no longer in effect. The OCC is proposing to remove part 167 and related references to avoid any confusion with the OREO treatment proposed in this notice. Since Appendices A and B to part 3 include the corresponding capital provisions for national banks and are similarly outdated, the OCC proposes to rescind those appendices in this proposal as well.

II. Statutory Authority for OREO

Twelve U.S.C. 29 establishes a framework for when a national bank may hold real property. A national bank may hold real property for use in its business as premises, as mortgaged to it as security for a debt, in satisfaction of debts previously contracted (DPC),[4] or as purchased at foreclosure to secure a related debt. The statute limits a national bank to a five-year holding period for real property, other than real property used as premises. However, the statute allows a national bank to seek approval from the Comptroller of the Currency to hold real property for up to five additional years. The OCC may approve this additional time if the bank has made a good faith attempt to dispose of the property within the initial five-year period or if disposal within the five-year period would be detrimental to the bank.

Twelve U.S.C. 1464 establishes requirements for the chartering and operation of Federal savings associations, including the power to make loans and investments. The authority for a Federal savings association to obtain real property in connection with satisfaction of a loan previously made, including at foreclosure, is an inherent power associated with making a loan secured by a mortgage on real property, which is permitted by 12 U.S.C. 1464(c)(1)(B) and (2)(B). In addition, 12 U.S.C. 1464(c)(4)(B) authorizes Federal savings associations to invest in service corporations,[5] which, by regulation, are permitted to engage in additional activities in connection with real property.[6] Federal savings associations are not subject to a five-year statutory limit on the holding period for real property.

III. Proposed Regulation for OREO

A. Definitions (§ 34.81)

This section would contain definitions used in the OREO regulation. This section would continue to use the existing definitions for *other real estate owned (OREO); market value;* and *recorded investment amount* in the revised regulation. The term *OREO* would continue to mean DPC real estate and former banking premises. The term *market value* would continue to mean the value of the property, as determined under the appraisal rule in 12 CFR part 34, subpart C. *Recorded investment amount* would continue to mean the recorded loan balance (for loans) or the net book value (for former banking premises).

In addition, the proposal would continue to use the current definition of *DPC real estate,* but with minor revisions related to lease accounting described below. The definition of *DPC real estate* would continue to mean real estate acquired through any means in satisfaction of a debt previously contracted, consistent with the authorities described earlier in this preamble for national banks and Federal savings associations to obtain property in this manner. The existing definition of the term includes capitalized and operating leases, which are the two types of leases recognized under current accounting standards from the lessee's perspective. However, revised accounting standards requiring operating leases to be capitalized, among other provisions, are scheduled to be implemented in the near future.[7] Therefore, the OCC proposes to revise the terminology in the current definition of DPC real estate to refer to leased real estate, rather than to refer specifically to capitalized and operating leases. The proposed definition would continue to cover all leases, but the revision will ensure the regulation will not become outdated after implementation of the new accounting standards.

In addition, the proposal would revise the definition of *former banking premises* to include a reference to 12 CFR 7.1000(a)(2), which establishes categories of real estate that national banks and Federal savings associations are permitted to own for use in their banking activities. The revised definition would define former banking premises as real estate permitted under section 7.1000(a)(2) that is no longer used or contemplated to be used for the purposes permitted by that rule. The proposed revision should improve regulatory consistency by clarifying that both rules cover the same types of real estate for banking activities and eliminate confusion about whether the rules refer to different types of properties.

B. Holding Period (§ 34.82)

This section would specify how long a national bank or a Federal saving association may hold OREO, provide the starting date for that holding period, and address additional related provisions affecting the holding period.

The holding period for national banks under the current rule is the period required by 12 U.S.C. 29. The statute and the current rule provide for an initial five-year holding period, with up to an additional five years if approved by the OCC. The proposal would not change this holding period.

The proposal also would establish an initial holding period for Federal savings associations of five years after commencement of the holding period to ensure the safe and sound management of OREO holdings. If the Federal savings association has not disposed of the OREO within the initial five-year holding period, the savings association may request OCC approval to continue to hold the real property as OREO for up to five additional years. These provisions are consistent with the rules that apply to national banks. The OCC's supervisory experience is that both types of institutions generally have or

[3] *See* 78 FR 62018 (October 11, 2013).

[4] Generally, DPC property is property not mortgaged in connection with obtaining a loan, but instead used to satisfy a pre-existing loan.

[5] Under 12 U.S.C. 1464(c)(4)(B), a Federal savings association may invest in a service corporation if (i) the service corporation is organized in the state where the Federal savings association's home office is located; (ii) the corporation's stock is available for purchase only by other Federal and state savings associations having home offices in such state; and (iii) the Federal savings association's aggregate investments in service corporations do not exceed three percent (3%) of its assets, with amounts in excess of two percent (2%) of assets serving primarily community, inner city, and community development purposes. *See also* 12 CFR 5.59. If the service corporation is controlled by a Federal savings association, then the service corporation is a subsidiary of the association. *See* 12 CFR 5.59(d)(5).

[6] These activities include acquiring real estate for development, leasing, or resale, and maintaining and managing real estate. *See* 12 CFR 5.59(f)(5).

[7] *See* FASB ASU 2016–02, ''Leases (Topic 842)'' (February 2016).

obtain similar types of OREO. As with national banks, in deciding whether to grant the approval to hold OREO beyond the initial five-year holding period, the OCC would expect to consider, among other factors, the Federal savings association's current and prior efforts to dispose of the property and safety and soundness concerns related to an immediate disposition of the property. During the initial five-year holding period and any subsequent approved period, the Federal savings association would need to make reasonable efforts to dispose of the OREO. This provision is consistent with prior OTS expectations. This proposed framework also is consistent with the requirement previously applicable to Federal savings associations under 12 CFR part 167, which required savings associations to deduct from regulatory capital the value of OREO held for more than five years, or a longer period with OCC approval, as an equity investment. This provision created incentives for Federal savings associations to dispose of OREO within five years, or a longer period approved by the OCC, as the regulatory capital treatment for failure to dispose of the property generally would be more onerous than disposing of the property. The OCC believes that an initial five-year holding period is a sufficient amount of time to dispose of most OREO and the option to extend the holding period for an additional five years should be sufficient to address atypical properties or unusual real estate market conditions.

Question 1: Should the OCC require national banks and Federal savings associations to make specific efforts to dispose of OREO within the specified timeframes? If so, what efforts should the OCC require?

The proposal also would adopt for Federal savings associations the existing national bank provision describing the date the holding period for OREO begins. Generally, the holding period for DPC real estate would begin on the date the property is transferred to the national bank or Federal savings association (for example, after a judicial foreclosure or deed-in-lieu of foreclosure), which may be different than the date the institution must recognize the property as OREO for accounting and financial reporting purposes. The title transfer law of the state or other jurisdiction where the property is located would govern when the property is considered transferred to the national bank or Federal savings association. The holding period for former bank premises would begin when the national bank or Federal savings association ceases using a property as bank premises (whether outright or after relocating) or abandons a plan to use property held for future bank premises.

The OCC is proposing a modification for OREO obtained by a Federal savings association prior to the effective date of this proposed rule. For this OREO, the holding period would begin on the rule's effective date to provide for a full initial five-year holding period. The OCC still would consider the entire time the OREO has been held by the Federal savings association in evaluating any request for an additional holding period beyond that initial five years. The OCC believes this accommodation would provide Federal savings associations with a reasonable timeframe to dispose of OREO held prior to the effective date of the rule, rather than calculating the holding period back to the initial transfer date.

Question 2: Does the proposed adjustment to the calculation of the holding period for OREO obtained by a Federal savings association prior to the effective date of the rule provide an appropriate amount of time to dispose of the OREO consistent with the proposed rule?

The OCC also proposes to clarify that when a national bank or Federal savings association obtains OREO from a merged or acquired institution, the relevant holding period would commence on the effective date of the merger or acquisition and would not include any time the OREO had been held by the acquired institution prior to the merger or acquisition. Similarly, when an institution converts to a national bank or Federal savings association, the relevant holding period would begin on the date of conversion. However, if the institution was already a national bank or Federal savings association immediately prior to the conversion, the holding period would not reset on the conversion date.[8] The OCC believes this is appropriate because different OREO standards might apply to an institution before it becomes a national bank or Federal savings association, unless the institution is already covered by the OCC's OREO rule. The proposed revision also would apply to Federal savings associations the existing national bank regulation that the holding period for DPC real estate that is subject to a redemption period imposed under state law begins after the expiration of the redemption period.

The proposed revised section also would address an interpretive issue that arises when a national bank or Federal savings association enters into a transaction to dispose of OREO, but the real estate is conveyed back to the institution for a reason other than a subsequent purchase by the institution (for example, if there is a failure to complete the disposition or the disposition is validly rescinded or unwound). In those cases, the holding period would be tolled during the period of time the OREO property was not under the bank's or savings association's control. For example, if a third party purchases OREO from a national bank or Federal savings association but later legally rescinds the sale, the bank or savings association cannot start a new five-year holding period for the property. Instead, any previous holding period (including approved extensions) would be tolled between the time the bank or savings association sold and reacquired the real property. Similarly, in certain U.S. government mortgage loan programs a national bank or Federal savings association may be required to transfer a foreclosed property to a U.S. government entity, and that entity may later validly reject receipt of the property and return title to the bank or savings association. In that case, the national bank or Federal savings association could not start a new five-year holding period for the property but could toll any previous holding period (including approved extensions) during the time the government entity had possession of the property. However, if the national bank or Federal savings association re-acquires property that was previously OREO and had been disposed of consistent with this part, then the five-year holding period would reset on that property. For example, if a bank originates a mortgage loan in connection with the sale of an OREO property that met the requirements for a valid disposition under part 34, but later foreclose on that property due to missed mortgage payments, then the bank will obtain a new five-year holding period.

Question 3: Are there ways the calculations for the start of the holding period and any subsequent tolling could be improved? Should the OCC establish a bright line for when a property is acquired, rather than rely on state transfer laws and redemption periods? For real property, should the OCC refer to accounting standards to determine when a property is transferred to OREO?

[8] For example, if a Federal savings association that had OREO with a holding period that began in January 2016, converted to a national bank in June 2019, the OCC would still consider the holding period for the OREO to have begun in January 2016, not June 2019.

Question 4: Should the OCC allow a national bank or Federal savings association to restart the holding period on OREO, even if the institution converts to a different charter also subject to part 34?

C. Disposition of OREO (§ 34.83)

This section would specify methods for national banks and Federal savings associations to dispose of OREO. Generally, the proposal would retain the existing disposal methods for national banks and allow Federal savings associations to dispose of OREO using those same methods. These methods include: (i) Selling the property outright or over a period of time; (ii) using DPC real estate as bank premises or affiliate premises; or (iii) entering into subleases of OREO leases. Writing OREO (whether owned or leased) down to zero for accounting purposes is not a valid disposition under the existing rules and would not be a valid disposition under the proposed revisions.

To provide for additional flexibility to dispose of OREO, the OCC also proposes to add a new paragraph (a)(5) that would allow the disposition of OREO in other ways approved by the OCC consistent with safe and sound banking practices. For example, the OCC previously has approved national banks and Federal savings associations to dispose of OREO in certain circumstances by donating or escheating OREO or by negotiating early terminations of OREO leases.

The proposal would recognize that, unlike a national bank, a Federal savings association also may transfer OREO to a service corporation. Under HOLA and 12 CFR 5.59, a Federal savings association may invest in a service corporation, which may engage in the same activities as its parent Federal savings association under the same terms and conditions. A service corporation also may engage in additional activities not permitted at a Federal savings association, including certain real estate related services such as holding property as an investment in real estate.[9] In addition, 12 CFR 5.59(i) permits a Federal savings association to make a contribution to a service corporation in the exercise of the association's salvage powers.[10] Consistent with HOLA and 12 CFR 5.59, the proposal would allow a Federal savings association, through a service corporation, to hold OREO property as an investment or for longer than 10 years. However, under current statutory and regulatory capital requirements, a Federal savings association must deconsolidate, and deduct any investments in, a subsidiary engaged in activities not permissible for a national bank, including holding property as an investment in real estate.[11]

Finally, the proposed revised section would retain the requirement that a national bank must make a diligent and ongoing effort to dispose of OREO and maintain documentation of those efforts. The proposal also would apply these provisions to Federal savings associations. Compliance with the requirement to document the national bank's or Federal savings association's diligence when attempting to dispose of OREO is an important consideration if the national bank or Federal savings association requests an extension to hold OREO beyond the initial five-year holding period. The proposed requirement that a Federal savings association make diligent efforts to dispose of OREO and maintain relevant documentation is consistent with both prior OTS expectations that savings associations develop salvage plans that included provisions for disposition of OREO and the existing requirement that Federal savings associations maintain documentation of appraisals of OREO.[12]

Question 5: Should the proposed rule include additional disposition methods for OREO held by national banks and Federal savings associations? Are there ways the proposed methods could be improved or clarified? For owned, rather than leased, real estate, should the OCC defer to accounting standards to determine when a property is sold (that is, based on whether the transfer qualifies for sales treatment under accounting standards)?

D. Appraisal Requirements (§ 34.85)

This section would specify the appraisal requirements applicable to OREO. The proposal would carry over the existing requirements for appraisals of OREO for national banks and apply those same requirements to Federal savings associations. Generally, this section requires an appraisal consistent with 12 CFR part 34, subpart C when property is obtained as OREO followed by periodic monitoring thereafter. In addition, the proposed section would continue to include existing exceptions from the appraisal requirements. For example, an appraisal would not be required if there is still a valid appraisal that was created in a transaction involving the property, as described in § 34.85(b). Because the requirements for appraisals of OREO held by Federal savings associations would be set out in the proposed rule, the OCC also is proposing to repeal 12 CFR 160.172, which currently includes comparable appraisal standards for OREO held by Federal savings associations.

E. OREO Expenditures and Notification (§ 34.86)

This section would contain provisions related to permissible expenditures on OREO. The proposal would codify various interpretations regarding other permissible expenses related to OREO for national banks and Federal savings associations in new paragraphs (a) and (b). Paragraph (a) would allow national banks and Federal savings associations to pay any normal operating expenses relating to the OREO property, such as taxes, insurance, utilities, and maintenance, and condominium association fees, to the extent those fees are reasonable and consistent with safe and sound banking practices. This proposed addition is consistent with a provision in existing paragraph (b)(1), prior interpretations issued by the OCC for national banks, and prior OTS expectations concerning payment of taxes, insurance, and similar expenses on OREO by Federal savings associations.[13]

Paragraph (b) would allow national banks and Federal savings associations to pay expenses for the operation of a business associated with the OREO property, if: (i) Payment of the expenses reduces the shortfall between the current value of the property and the national bank or Federal savings association's investment in the property; and (ii) the expenses are consistent with safe and sound banking practices. For example, if a national bank or Federal savings association obtains an OREO property that includes a functioning hotel and resort, the national bank or Federal savings association may be able to minimize its loss on the defaulted loan by continuing to pay business

[9] *See* 12 U.S.C. 1464(c)(4)(B) and 12 CFR 5.59.

[10] 12 CFR 5.59(i) provides that a Federal savings association may exercise its salvage power to make a contribution or a loan . . . to a service corporation (''salvage investment'') that exceeds the maximum amount otherwise permitted under law or regulation.'' The Federal savings association must demonstrate that: (i) The salvage investment protects the association's interest in the service corporation; (ii) the salvage investment is consistent with safety and soundness; and (iii) the association considered alternatives to the salvage investment but determined the alternatives would not satisfy (i) and (ii).

[11] 12 U.S.C. 1464(t)(5) and 12 CFR 3.22(a)(8). Holding property as an investment in real estate is not authorized for a national bank under 12 U.S.C. 29.

[12] 12 CFR 160.172.

[13] *See* Comptroller's Handbook on ''Other Real Estate Owned'' (August 2018). For Federal savings associations, this provision was included in the OTS Examination Handbook, Section 251, ''Real Estate Owned and Repossessed Assets'' (December 2010), which has since been rescinded by the OCC.

expenses to operate the hotel and resort, such as staff wages, inventory, management fees, and licensing fees, while the OREO is being prepared for sale. The OCC has previously addressed these types of expenses for national banks consistent with safe and sound banking practices, and this provision would extend the permission to Federal savings associations.[14]

Under the current rule, a national bank is permitted to make advances to complete an OREO development or improvement project (referred to as ''additional expenditures''). Paragraph (c) would continue the existing requirements for additional expenditures on OREO for a national bank and apply the same requirements to a Federal savings association. A national bank or Federal savings association could make additional expenditures only if: (i) The expenditures are reasonably calculated to reduce the shortfall between the current value of the property and the bank's investment in the property; (ii) the expenditures are not made for purposes of speculation in real estate; and (iii) the expenditures are consistent with safe and sound banking practices. These proposed requirements are consistent with prior OTS expectations, which addressed a Federal savings association's reasonable capital expenditures to reduce the loss on OREO obtained by the savings association.[15]

In addition, paragraph (d) would update the requirements for prior notification for significant additional expenditures on OREO for national banks and extend the provision to Federal savings associations. Currently, under 12 CFR 34.86(b), a national bank must notify the OCC at least 30 days before making additional expenditures if the amount of the expenditures and recorded investment in the OREO exceeds ten percent of the national bank's capital and surplus, which generally is based on regulatory capital calculated under 12 CFR part 3. Federal savings associations, in turn, were subject to supervisory review of any expenditures on OREO in excess of their lending limits, which are calculated based on a formula that incorporates a percentage of capital and surplus.[16] While based on different calculations, the supervisory review for Federal savings associations had a similar purpose as the required OCC notification for national banks, namely, to ensure that institutions did not expend an excessive amount of funds to complete or renovate OREO. The OCC proposes to update and streamline the notification provision by requiring prior notification only when the proposed additional expenditures and recorded investment in an individual OREO property exceeds 10 percent of the institution's total equity capital based on the institution's most recent Consolidated Reports of Condition and Income (Call Report). The OCC believes using a measure based on total equity capital for this purpose, rather than a measure tied to 12 CFR part 3 regulatory capital or lending limits, allows for a less burdensome and more transparent calculation, while not impairing the OCC's supervisory review of institutions that propose making significant additional expenditures on OREO.

A comparison of capital and surplus and total equity capital for national banks supports this approach.[17] Based on information from the June 30, 2018 Call Report, the measures of regulatory capital and total equity capital are numerically comparable, and identical in some cases, for many national banks that hold OREO. Under the proposed measure, national banks with significant loan loss reserves or excessive losses recorded in accumulated other comprehensive income would generally have a lower limit for notification compared with the existing measure. The OCC believes this result is appropriate, as those losses may indicate national banks with a higher risk profile for which notification of significant OREO expenditures is most relevant. National banks holding assets that are deducted under the regulatory capital rule, such as mortgage servicing assets or investments in other financial institutions, would generally have a higher limit for notification under the proposed measure.

Question 6: Is the proposed allowance for payment of operating and business expenses related to OREO, subject to the proposed safety and soundness standards, reasonable? Are there other common OREO expenses the OCC should consider specifically including in the regulation?

Question 7: Should the proposed threshold for notification be based on a measure other than total equity capital? Should the proposed threshold be higher or lower?

F. Additional Provisions

The OCC proposes to rescind existing 12 CFR 34.87, which requires national banks to account for OREO consistent with the instructions for the Call Report, because it is now redundant to statutory requirements. Historically, there have been differences between regulatory accounting principles and generally accepted accounting principles (GAAP). However, currently, national banks and Federal savings associations must follow GAAP when accounting for transactions involving OREO.[18] Therefore, codifying this requirement in the OREO rule is unnecessary. Guidance on the application of GAAP for OREO transactions can be found in the instructions for the Call Report and the OCC's Bank Accounting Advisory Series.[19] However, the OCC notes that, although the accounting standard generally establishes a bright line for when a bank must report a property as OREO for financial reporting purposes (*i.e.,* when a judge completes a judicial foreclosure), section 34.82(b) does not establish a bright line for when property is originally transferred to a bank. As a result, the date on which reporting requirements begin for OREO under the accounting standard may be different than the date that the holding period commences under 34.82(b), as described above in Section III.B. We also note that writing off a property or lease classified as OREO for accounting purposes does not eliminate the need to comply with the requirements of this subpart, including the requirement for appraisals and disposition of the property or lease under one of the allowed methods.

IV. Proposed Technical Amendments

As described above, the OCC also is proposing to remove Appendices A and B to 12 CFR part 3 (risk-based capital guidelines for national banks) and 12 CFR part 167 (capital requirements for FSAs) and make conforming technical edits to other parts, as part 167 is outdated and includes OREO provisions that conflict with the provisions described in this proposal. The OCC did not immediately rescind those rules due to an extended transition period to the new capital rule for certain provisions. The proposed rule also makes

[14] *See* Comptroller's Handbook on ''Other Real Estate Owned'' (August 2018).

[15] *Id.* For Federal savings associations, this provision was included in the OTS Examination Handbook, Section 251, ''Real Estate Owned and Repossessed Assets'' (December 2010), which has since been rescinded by the OCC.

[16] This provision was reflected in the OTS lending limits at 12 CFR 560.93 and included in the OTS Examination Handbook, Section 211, ''Loans to One Borrower'' (December 2007)., The OCC has superseded the rule and rescinded the guidance.

[17] The OCC did not review these measures for Federal savings associations because Federal savings associations currently are not subject to either the existing limit or proposed notification provision for improvements to OREO.

[18] *See* 12 U.S.C. 1831n(a)(2).

[19] Bank Accounting Advisory Series (August 2018), *available at: https://www.occ.gov/publications/publications-by-type/other-publications-reports/baas.pdf.*

conforming technical changes to portions of the OCC's rules that refer to Appendices A and B to 12 CFR part 3 or to 12 CFR part 167. Specifically, the OCC would make conforming edits to 12 CFR 3.1, 6.1, 6.2, Appendix A to Subpart D of part 34, 46.6, 160.100, Appendix A to 160.101, 161.55, 163.74, and 163.80. This proposed rule does not impact the legal status of any reference to the superseded capital rules in outstanding compliance and enforcement orders, agreements, and memoranda of understanding entered into by the OCC and a national bank or Federal savings association, as those references became references to 12 CFR part 3 when the revised capital rule became effective.

V. Regulatory Analyses

A. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995,[20] the OCC may not conduct or sponsor, and a person is not required to respond to, an information collection unless the information collection displays a valid OMB control number. The OCC has submitted the information collection requirements imposed by this proposal to OMB for review. However, the proposal will not result in a change in burden. While the respondent count will increase with the addition of Federal savings associations, we estimate fewer notices from national banks due to a decrease in charters since the last review, resulting in no change in burden.

Section 34.86(d) updates the requirements for prior notification for significant additional expenditures on OREO for national banks and extends the provision to Federal savings associations. Currently, a national bank must notify the OCC at least 30 days before making additional expenditures if the amount of the expenditures and recorded investment in the OREO exceeds ten percent of its capital and surplus, based on regulatory capital calculated under 12 CFR part 3. Federal savings associations are subject to supervisory review of any expenditures on OREO in excess of their lending limits, which are calculated based on a formula that incorporates a percentage of capital and surplus.

The proposal updates and streamlines the notification provision by requiring prior notification only when the proposed additional expenditures and recorded investment in an individual OREO property exceeds 10 percent of the institution's total equity capital based on its most recent Call Report. National banks with significant loan loss reserves or excessive losses recorded in accumulated other comprehensive income will generally have a reduced limit for notification. National banks holding assets that are deducted under the regulatory capital rule, will generally have an increase limit for notification under the proposal.

Title: Real Estate Lending and Appraisals.

OMB Control No.: 1557–0190.

Frequency of Response: On occasion.

Affected Public: Businesses or other for-profit organizations.

Estimated Number of Respondents: 6.

Estimated Burden per Respondent: 5 hours.

Estimated Total Annual Burden: 30 hours.

Comments are invited on:

(a) Whether the collections of information are necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimates of the burden of the collections of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collections on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

B. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act[21] requires an agency, in connection with a proposed rule, to prepare an Initial Regulatory Flexibility Analysis describing the impact of the rule on small entities (defined by the SBA for purposes of the RFA to include commercial banks and savings institutions with total assets of $550 million or less and trust companies with total revenue of $38.5 million or less) or to certify that the proposed rule would not have a significant economic impact on a substantial number of small entities. As of December 31, 2017, the OCC supervised 886 small entities. The proposed rule would apply to all entities supervised by the OCC, and therefore would affect a substantial number of small entities. The economic impact on each small Federal savings association is estimated to be approximately $1,872, which is not significant based on 5% of total annual salaries or 2.5% of other noninterest income. The economic impact on each small national bank is estimated to be *de minimis.* Therefore, the OCC certifies the proposed rule would not have a significant economic impact on a substantial number of small entities.

C. OCC Unfunded Mandates Reform Act of 1995

The OCC analyzed the proposed rule under the factors set forth in the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1532). Under this analysis, the OCC considered whether the proposed rule includes a Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year (adjusted for inflation). The OCC estimates that the total cost of the proposed rule is $583,000. Therefore, the OCC has determined that this proposed rule would not result in expenditures by State, local, and Tribal governments, or the private sector, of $100 million or more in any one year. Accordingly, the OCC has not prepared a written statement to accompany this proposal.

D. Riegle Community Development and Regulatory Improvement Act of 1994

This rulemaking would not impose additional reporting, disclosure, or other requirements on an insured depository institution. Therefore, section 302(a) of the Riegle Community Development and Regulatory Improvement Act of 1994 does not apply to this rulemaking.

List of Subjects

12 CFR Part 3

Administrative practice and procedure, Capital, National banks, Reporting and recordkeeping requirements, Risk.

12 CFR Part 6

National banks.

12 CFR Part 34

Appraisal, Appraiser, Banks, Banking, Consumer protection, Credit, Mortgages, National banks, Reporting and recordkeeping requirements, Savings associations, Truth in lending.

12 CFR Part 46

Banks, Banking, Capital, Disclosures, National banks, Reporting and recordkeeping requirements, Risk, Stress test.

12 CFR Part 160

Consumer protection, Investments, Manufactured homes, Mortgages, Reporting and recordkeeping

[20] 44 U.S.C. 3501 *et seq.*

[21] 5 U.S.C. 601 *et seq.*

requirements, Savings associations, Securities.

12 CFR Part 161

Administrative practice and procedure, Savings associations.

12 CFR Part 163

Accounting, Administrative practice and procedure, Advertising, Conflicts of interest, Crime, Currency, Investments, Mortgages, Reporting and recordkeeping requirements, Savings associations, Surety bonds.

12 CFR Part 167

Capital, Reporting and recordkeeping requirements, Risk, Savings associations.

For the reasons set out in the preamble, the OCC proposes to revise the following parts as follows:

PART 3—CAPITAL ADEQUACY STANDARDS

■ 1. The authority citation for part 3 continues to read as follows:

Authority: 12 U.S.C. 93a, 161, 1462, 1462a, 1463, 1464, 1818, 1828(n), 1828 note, 1831n note, 1835, 3907, 3909, and 5412(b)(2)(B).

§ 3.1 [Amended]

■ 2. Section 3.1 is amended by removing and reserving paragraph (f)(1)(ii) and removing paragraphs (f)(1)(ii)(A), (f)(1)(ii)(B), (f)(1)(ii)(C), and footnotes 1 and 2.

Appendix A to Part 3 [Removed]

■ 3. Remove Appendix A to part 3.

Appendix B to Part 3 [Removed]

■ 4. Remove Appendix B to part 3.

PART 6—PROMPT CORRECTIVE ACTION

■ 5. The authority citation for part 6 continues to read as follows:

Authority: 12 U.S.C. 93a, 1831o, 5412(b)(2)(B).

§ 6.1 [Amended]

■ 6. Section 6.1 is amended by removing and reserving paragraph (f)(1), and removing paragraphs (f)(1)(i) and (f)(1)(ii).

§ 6.2 [Amended]

■ 7. Section 6.2 is amended by removing footnotes 30, 31, 32, 33, 34, and 35.

PART 34—REAL ESTATE LENDING AND APPRAISALS

■ 8. The authority citation for part 34 continues to read as follows:

Authority: 12 U.S.C. 1 *et seq.,* 25b, 29, 93a, 371, 1462a, 1463, 1464, 1465, 1701j–3, 1828(o), 3331 *et seq.,* 5101 *et seq.,* and 5412(b)(2)(B) and 15 U.S.C. 1639h.

Subpart D—Real Estate Lending Standards

Appendix A to Subpart D of Part 34 [Amended]

■ 9. Footnote 2 of Appendix A to Subpart D of part 34 is amended to read as follows:

* * * * *

[2] For the state member banks, the term ''total capital'' means ''total risk-based capital'' as defined in Appendix A to 12 CFR part 208. For insured state non-member banks, ''total capital'' refers to that term described in table I of Appendix A to 12 CFR part 325. For national banks and Federal savings associations, the term ''total capital'' is defined at 12 CFR 3.2.

* * * * *

Subpart E—Other Real Estate Owned

■ 10. Section 34.81 is amended by:
■ a. Removing the paragraph designations for paragraphs (a) through (f);
■ b. Removing the definition of *capital and surplus;* and
■ c. Revising the definitions of *debts previously contracted (DPC) real estate* and *former banking premises.*

The revisions read as set forth below.

§ 34.81 Definitions.

* * * * *

Debts previously contracted (DPC) real estate means real estate (including leases) acquired by a national bank or Federal savings association through any means in full or partial satisfaction of a debt previously contracted.

* * * * *

Former banking premises means real estate permissible under § 7.1000(a)(2) of this chapter that is no longer used or contemplated to be used for the purposes permitted in that section.

* * * * *

■ 11. Section 34.82 is amended by:
■ a. Revising paragraphs (a) and (b); and
■ b. Adding paragraphs (d) and (e).

The revisions and additions read as set forth below.

§ 34.82 Holding Period.

(a) *Holding period for OREO.* (1) *National bank.* A national bank shall dispose of OREO at the earliest time that prudent judgment dictates, but not later than the end of the holding period (or an extension thereof) permitted by 12 U.S.C. 29.

(2) *Federal savings association.* A Federal savings association may hold OREO for not more than five years after commencement of the holding period. On the request of a Federal savings association, the OCC may extend the holding period for not more than an additional five years.

(b) *Commencement of holding period.* The holding period begins on the date that:

(1) Ownership of the property is originally transferred to a national bank or Federal savings association, including as a result of a merger with or acquisition of another organization holding OREO;

(2) A national bank or Federal savings association completes relocation from former banking premises to new banking premises or ceases to use the former banking premises without relocating; or

(3) A national bank or Federal savings association decides not to use real estate acquired for future banking expansion; or

(4) An institution converts to a national bank or Federal savings association, unless the institution was a national bank or Federal savings association immediately prior to the conversion.

(5) Is the effective date of the final rule, for OREO obtained by a Federal savings association prior to that date.

* * * * *

(d) *Effect of failed disposition.* If a national bank or Federal savings association disposes of OREO, but the real estate subsequently is conveyed back to the institution within five years as a result of a valid rescission or invalidation of the original disposition, then the holding period will be tolled for the period during which the real estate was not in possession of the national bank or Federal savings association.

(e) *Re-acquisition of former OREO.* If a national bank or Federal savings association reacquires a property that had been OREO and was disposed of consistent with § 34.83, the holding period will reset.

■ 12. Section 34.83 is amended by:
■ a. Revising the section heading;
■ b. Revising paragraphs (a) introductory text, (a)(3) introductory text, (a)(3)(i)(B), (a)(3)(ii);
■ c. Revising paragraph (a)(4) by removing ''.'' at the end of the paragraph and adding ''; or'' in its place;
■ d. Adding paragraph (a)(5);
■ e. Redesignating paragraph (b) as paragraph (c);
■ f. Adding new paragraph (b); and
■ g. Adding in paragraph (c) the words ''or Federal savings association'' after ''national bank'' in the first sentence.

The revisions and additions read as set forth below.

§ 34.83 Disposition of OREO.

(a) *Disposition.* A national bank or Federal savings association may dispose of OREO in the following ways:

* * * * *

(3) With respect to a lease:

(i) By obtaining an assignment or a coterminous sublease. If a national bank or Federal savings association enters into a sublease that is not coterminous, the period during which the master lease must be divested will be suspended for the duration of the sublease, and will begin running again upon termination of the sublease. A national bank or Federal savings association holding a lease as OREO may enter into an extension of the lease that would exceed the holding period referred to in § 34.82 if the extension meets the following criteria:

(A) * * *

(B) The national bank or Federal savings association, prior to entering into the extension, has a firm commitment from a prospective subtenant to sublease the property; and

* * * * *

(ii) Should the OCC determine that a national bank or Federal savings association has entered into a lease, extension of a lease, or a sublease for the purpose of real estate speculation, the OCC will take appropriate measures to address the violation, which may include requiring the bank or savings association to take immediate steps to divest the lease or sublease; and

* * * * *

(5) By any other method approved by the OCC.

(b) *Additional method for Federal savings associations.* A Federal savings association also may transfer OREO to a service corporation. A service corporation may hold real property transferred to it:

(1) As OREO, subject to the requirements otherwise applicable to the Federal savings association under this Subpart E; or

(2) As an investment in real estate under § 5.59.

* * * * *

§ 34.85 [Amended]

■ 13. Section 34.85 is amended by:

■ a. Adding the words ''or Federal savings association'' after ''national bank'', wherever it appears; and

■ b. Adding the words ''or savings association'' after ''the bank'', wherever it appears.

■ 14. Revise § 34.86 including the section heading to read as follows:

§ 34.86 OREO expenditures and notification.

(a) *Operating expenditures.* A national bank or Federal savings association may pay operating expenses on OREO, including taxes, insurance, utilities, and maintenance, that are reasonable and consistent with safe and sound banking practices.

(b) *Business expenditures.* A national bank or Federal savings association may pay expenses for OREO that includes the operation of a business, provided the expenses are:

(1) Reasonably calculated to reduce any shortfall between the property's market value and the recorded investment amount; and

(2) Consistent with safe and sound banking practices.

(c) *Additional expenditures.* For OREO that is a development or improvement project, a national bank or Federal savings association may make advances to complete the project if the advances are:

(1) Reasonably calculated to reduce any shortfall between the property's market value and the recorded investment amount;

(2) Not made for the purpose of speculation in real estate; and

(3) Consistent with safe and sound banking practices.

(d) *Notification procedures for additional expenditures.*

(1) A national bank or Federal savings association shall notify the appropriate supervisory office at least 30 days before implementing a development or improvement plan for OREO when the sum of the plan's estimated cost and the bank's or savings association's current recorded investment amount (including any unpaid prior liens on the property) exceeds 10 percent of the bank's or savings association's total equity capital on its most recent report of condition. A national bank or Federal savings association need notify the OCC under this paragraph (d)(1) only once.

(2) The required notification must demonstrate that the additional expenditure is consistent with the conditions and limitations in paragraph (c) of this section.

(3) Unless informed otherwise, the national bank or Federal savings association may implement the proposed plan on the thirty-first day (or sooner, if notified by the OCC) following receipt by the OCC of the notification, subject to any conditions imposed by the OCC.

§ 34.87 [Removed]

■ 15. Remove § 34.87.

PART 46—ANNUAL STRESS TEST

■ 16. The authority citation for part 46 continues to read as follows:

Authority: 12 U.S.C. 93a; 1463(a)(2); 5365(i)(2); and 5412(b)(2)(B).

§ 46.6 [Amended]

■ 17. Section 46.6 paragraph (a)(2) is amended by removing the words ''or part 167, as applicable,'' after ''12 CFR part 3'' in the first sentence.

PART 160—LENDING AND INVESTMENT

■ 18. The authority for part 160 continues to read as follows:

Authority: 12 U.S.C. 1462a, 1463, 1464, 1467a, 1701j–3, 1828, 3803, 3806, 5412(b)(2)(B); 42 U.S.C. 4106.

§ 160.100 [Amended]

■ 19. Section 160.100 is amended by removing ''or 167.1, as applicable,''.

Appendix A to § 160.101 [Amended]

■ 20. Footnote 2 of the Appendix to Section 160.101 is amended to read as follows:

* * * * *

[2] For the state member banks, the term ''total capital'' means ''total risk-based capital'' as defined in Appendix A to 12 CFR part 208. For insured state non-member banks, ''total capital'' refers to that term described in table I of Appendix A to 12 CFR part 325. For national banks and Federal savings associations, the term ''total capital'' is defined at 12 CFR 3.2.

* * * * *

§ 160.172 [Removed]

■ 21. Remove § 160.172.

PART 161—DEFINITIONS FOR REGULATIONS AFFECTING ALL SAVINGS ASSOCIATIONS

■ 22. The authority for part 161 continues to read as follows:

Authority: 12 U.S.C. 1462a, 1463, 1464, 1467a, 5412(b)(2)(B).

§ 161.55 [Amended]

■ 23. Section 161.55 paragraph (c) is amended by removing the words ''or part 167, as applicable'' after ''12 CFR part 3''.

PART 163—SAVINGS ASSOCIATIONS—OPERATIONS

■ 24. The authority for part 163 continues to read as follows:

Authority: 12 U.S.C. 1462a, 1463, 1464, 1467a, 1817, 1820, 1828, 1831o, 3806, 5101 *et seq.,* 5412(b)(2)(B); 31 U.S.C. 5318; 42 U.S.C. 4106.

§ 163.74 [Amended]

■ 25. Section 163.74 is amended:

■ a. Removing in paragraph (i)(2)(iv), the wording ''or part 167, as applicable,'' after ''12 CFR part 3''; and;
■ b. Removing in the first sentence of paragraph (i)(2)(v) the wording ''or part 167, as applicable,'' after ''12 CFR part 3''.

§ 163.80 [Amended]

■ 26. In § 163.80 amend the first sentence of paragraph (e)(1) by removing the wording ''or part 167, as applicable''.

PART 167 [Removed]

■ 27. Remove part 167.

Dated: April 17, 2019.

Joseph M. Otting,

Comptroller of the Currency.

[FR Doc. 2019–08128 Filed 4–23–19; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0250; Product Identifier 2018–NM–157–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede Airworthiness Directive (AD) 2015–17–14, which applies to all Airbus SAS Model A319 series airplanes; Model A320–211, –212, –214, –231, –232, and –233 airplanes, and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. AD 2015–17–14 requires repetitive rototest inspections of the open tack holes and rivet holes at the cargo floor support fittings of the fuselage, including doing all applicable related investigative actions, and repair if necessary. Since we issued AD 2015–17–14, further analysis and widespread fatigue damage (WFD) evaluations identified the need to reduce the initial compliance times and repetitive intervals for the inspections for certain airplanes, and to add work for certain airplanes. This proposed AD would continue to require the actions of AD 2015–17–14, would add actions for certain airplanes, and would reduce the compliance times for certain airplanes, as specified in an European Aviation Safety Agency (EASA) AD, which will be incorporated by reference. This proposed AD would also reduce the applicability. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by June 10, 2019.

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

For the incorporation by reference (IBR) material described in the ''Related IBR material under 1 CFR part 51'' section in **SUPPLEMENTARY INFORMATION**, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 1000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view this IBR material at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket on the internet at *http://www.regulations.gov.*

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0250; 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 regulatory evaluation, any comments received, and other information. The street address for Docket Operations (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2019–0250; Product Identifier 2018–NM–157–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this NPRM.

Discussion

Fatigue damage can occur locally, in small areas or structural design details, or globally, in widespread areas. Multiple-site damage is widespread damage that occurs in a large structural element such as a single rivet line of a lap splice joining two large skin panels. Widespread damage can also occur in multiple elements such as adjacent frames or stringers. Multiple-site damage and multiple-element damage cracks are typically too small initially to be reliably detected with normal inspection methods. Without intervention, these cracks will grow, and eventually compromise the structural integrity of the airplane. This condition is known as WFD. It is associated with general degradation of large areas of structure with similar structural details and stress levels. As an airplane ages, WFD will likely occur, and will certainly occur if the airplane is operated long enough without any intervention.

The FAA's WFD final rule (75 FR 69746, November 15, 2010) became effective on January 14, 2011. The WFD rule requires certain actions to prevent structural failure due to WFD throughout the operational life of certain existing transport category airplanes and all of these airplanes that will be certificated in the future. For existing and future airplanes subject to the WFD rule, the rule requires that design approval holders (DAHs) establish a limit of validity (LOV) of the engineering data that support the structural maintenance program. Operators affected by the WFD rule may not fly an airplane beyond its LOV, unless an extended LOV is approved.

The WFD rule (75 FR 69746, November 15, 2010) does not require identifying and developing maintenance actions if the DAHs can show that such actions are not necessary to prevent WFD before the airplane reaches the LOV. Many LOVs, however, do depend on accomplishment of future maintenance actions. As stated in the WFD rule, any maintenance actions necessary to reach the LOV will be mandated by airworthiness directives through separate rulemaking actions.

In the context of WFD, this action is necessary to enable DAHs to propose LOVs that allow operators the longest operational lives for their airplanes, and still ensure that WFD will not occur. This approach allows for an implementation strategy that provides flexibility to DAHs in determining the timing of service information development (with FAA approval), while providing operators with certainty regarding the LOV applicable to their airplanes.

We issued AD 2015–17–14, Amendment 39–18247 (80 FR 52182, August 28, 2015) (''AD 2015–17–14''), for all Airbus SAS Model A319 series airplanes; Model A320–211, –212, –214, –231, –232, and –233 airplanes, and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. AD 2015–17–14 requires repetitive rototest inspections of the open tack holes and rivet holes at the cargo floor support fittings of the fuselage, including doing all applicable related investigative actions, and repair if necessary. AD 2015–17–14 resulted from reports that during a full-scale fatigue test, several broken frames in certain areas of the cargo compartment were found, especially on the cargo floor support fittings and open tack holes on the left-hand side. We issued AD 2015–17–14 to address cracking in the open tack holes and rivet holes at the cargo floor support fittings of the fuselage, which could affect the structural integrity of the airplane.

Actions Since AD 2015–17–14 Was Issued

Since we issued AD 2015–17–14, further analysis and WFD evaluations identified the need to reduce the compliance time for the repetitive inspections for certain airplanes, and to add work for certain airplanes, and remove certain airplanes from the applicability.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2018–0233R1, dated November 28, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Airbus SAS 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. The MCAI states:

> During a full scale fatigue test, several broken frames in the cargo compartment area between Frame (FR) 50 and FR63 have been found, especially on the cargo floor support fittings and open tack holes on left hand (LH) side.
>
> This condition, if not detected and corrected, could affect the structural integrity of the aeroplane.
>
> To address this unsafe condition, Airbus issued SB [service bulletin] A320–53–1257, providing inspection instructions, and SB A320–53–1261, providing modification instructions.
>
> Consequently, EASA published AD 2013–0310 [which corresponds to FAA AD 2015–17–14], requiring repetitive inspections of the frames in the cargo compartment area and of the cargo floor support fittings and open tack holes on the LH side and, depending on findings, accomplishment of corrective action(s). That [EASA] AD also required a modification, which constituted terminating action for the required repetitive inspections.
>
> After that [EASA] AD was issued, further analyses and widespread fatigue damage evaluations identified the need to reduce the threshold and intervals for the repetitive inspections for certain configurations, and Airbus issued the inspection SB accordingly. Airbus issued SB A320–53–1360, SB A320–53–1364 and SB A320–53–1365 to supplement SB A320–53–1261, and SB Information Transmission (SBIT) 16–0070 providing additional information. Consequently, EASA issued AD 2018–0233, retaining the requirements of EASA AD 2013–0310, which was superseded, but requiring accomplishment of the repetitive inspections within reduced compliance times for certain configurations. That [EASA] AD also required additional work for aeroplanes that had already been modified in accordance with the instructions of Airbus SB A320–53–1261, Rev. 02.
>
> Since that [EASA] AD was issued, it has been determined that certain A319 aeroplanes may be excluded from the Applicability of the [EASA] AD, since the calculated compliance time for the initial inspection is beyond the applicable limit of validity.
>
> For the reason described above, this [EASA] AD is revised to reduce the Applicability.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0250.

Explanation of Retained Requirements

Although this proposed AD does not explicitly restate the requirements of AD 2015–17–14, this proposed AD would retain certain requirements of AD 2015–17–14. Those requirements are referenced in EASA AD 2018–0233R1, which, in turn, is referenced in paragraph (g) of this proposed AD.

Related IBR Material Under 1 CFR Part 51

EASA AD 2018–0233R1 describes procedures for repetitive inspections of the open tack holes and rivet holes of the fuselage frames below the cargo floor support fittings for cracking. 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, and it is publicly available through the EASA website.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Proposed Requirements of This NPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2018–0233R1 described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA worked with Airbus and EASA to develop a process to use certain EASA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. As a result, EASA AD 2018–0233R1 will be incorporated by reference in the FAA final rule. This proposed AD would, therefore, require compliance with the provisions specified in EASA AD 2018–0233R1, through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Service information specified in EASA AD 2018–0233R1 that is required for compliance with EASA AD 2018–0233R1 will be available on the internet *http://www.regulations.gov* by searching

for and locating Docket No. FAA–2019–0250 after the FAA final rule is published.

Costs of Compliance

We estimate that this proposed AD affects 1,009 airplanes of U.S. registry. We estimate 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 2015–17–14.	Up to 471 work-hours × $85 per hour = $40,035.	$0	Up to $40,035	Up to $40,395,315.
New proposed actions	Up to 474 work-hours × 85 per hour = $40,290.	13,000	Up to $53,290	Up to $53,769,610.

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions 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.

We are 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.

This proposed AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

We 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. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

4. 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 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 removing Airworthiness Directive (AD) 2015–17–14, Amendment 39–18247 (80 FR 52182, August 28, 2015), and adding the following new AD:

Airbus SAS: Docket No. FAA–2019–0250; Product Identifier 2018–NM–157–AD.

(a) Comments Due Date

We must receive comments by June 10, 2019.

(b) Affected ADs

This AD replaces AD 2015–17–14, Amendment 39–18247 (80 FR 52182, August 28, 2015) (''AD 2015–17–14'').

(c) Applicability

This AD applies to Airbus SAS 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, as identified in European Aviation Safety Agency (EASA) AD 2018–0233R1, dated November 28, 2018 (''EASA AD 2018–0233R1'').

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Reason

This AD was prompted by further analysis and widespread fatigue damage (WFD) evaluations and full-scale fatigue testing that indicated that several broken frames in certain areas of the cargo compartment were found, especially on the cargo floor support fittings and open tack holes on the left-hand side, which identified the need to reduce the initial compliance times and repetitive intervals for the inspections for certain airplanes, and to add work for certain airplanes. We are issuing this AD to address cracking in the open tack holes and rivet holes at the cargo floor support fittings of the fuselage, which could affect the structural integrity of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2018–0233R1.

(h) Exceptions to EASA AD 2018–0233R1

(1) For purposes of determining compliance with the requirements of this AD: Where EASA AD 2018–0233R1 refers to ''the effective date of the original issue of this AD,'' this AD requires using the effective date of this AD, and where EASA AD 2018–0233R1 refers to ''the effective date of EASA AD 2013–0310,'' this AD requires using October 2, 2015 (the effective date of AD 2015–17–14).

(2) The ''Remarks'' section of EASA AD 2018–0233R1 does not apply to this AD.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International

Section, Transport Standards 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 International Section, send it to the attention of the person identified in paragraph (j)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.*

(i) 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.

(ii) AMOCs approved previously for AD 2015–17–14 are approved as AMOCs for the corresponding provisions of EASA AD 2018–0233R1 that are required by paragraph (g) of this AD.

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

(3) *Required for Compliance (RC*): For any service information referenced in EASA AD 2018–0233R1 that contains RC procedures and tests: Except as required by paragraph (i)(2) of this AD, RC procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(j) Related Information

(1) For information about EASA AD 2018–0233R1, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 6017; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.* You may view this EASA AD at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. EASA AD 2018–0233R1 may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0250.

(2) For more information about this AD, contact Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223.

Issued in Des Moines, Washington, on April 10, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–08172 Filed 4–23–19; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 40

[Docket No. RM18–20–000]

Critical Infrastructure Protection Reliability Standard CIP–012–1—Cyber Security—Communications Between Control Centers

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Energy Regulatory Commission (Commission) proposes to approve Reliability Standard CIP–012–1 (Cyber Security—Communications between Control Centers). The North American Electric Reliability Corporation (NERC), the Commission-certified Electric Reliability Organization, submitted the proposed Reliability Standard for Commission approval in response to a Commission directive. In addition, the Commission proposes to direct that NERC develop certain modifications to Reliability Standard CIP–012–1 to require protections regarding the availability of communication links and data communicated between bulk electric system control centers and, further, to clarify the types of data that must be protected.

DATES: Comments are due June 24, 2019.

ADDRESSES: Comments, identified by docket number, may be filed in the following ways:

- *Electronic Filing through http://www.ferc.gov.* Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format.
- *Mail/Hand Delivery:* Those unable to file electronically may mail or hand-deliver comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

Instructions: For detailed instructions on submitting comments and additional information on the rulemaking process, see the Comment Procedures Section of this document.

FOR FURTHER INFORMATION CONTACT:

Vincent Le (Technical Information), Office of Electric Reliability, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–6204, *vincent.le@ferc.gov.*

Kevin Ryan (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–6840, *kevin.ryan@ferc.gov.*

SUPPLEMENTARY INFORMATION:

1. Pursuant to section 215(d)(2) of the Federal Power Act (FPA),[1] the Commission proposes to approve Reliability Standard CIP–012–1 (Cyber Security—Communications between Control Centers). The North American Electric Reliability Corporation (NERC), the Commission-certified Electric Reliability Organization (ERO), submitted the proposed Reliability Standard for Commission approval in response to a Commission directive in Order No. 822.[2] Specifically, pursuant to section 215(d)(5) of the FPA, the Commission directed that NERC develop modifications to require responsible entities to implement controls to protect, at a minimum, communications links and sensitive bulk electric system data communicated between bulk electric system Control Centers ''in a manner that is appropriately tailored to address the risks posed to the bulk electric system by the assets being protected (*i.e.,* high, medium, or low impact).'' [3]

2. Proposed Reliability Standard CIP–012–1 is intended to augment the currently-effective Critical Infrastructure Protection (CIP) Reliability Standards to mitigate cybersecurity risks associated with communications between bulk electric system Control Centers.[4] Specifically, proposed Reliability Standard CIP–012–1 supports situational awareness and reliable bulk electric system operations by requiring responsible entities to protect the confidentiality and integrity of Real-time Assessment and Real-time monitoring data transmitted between

[1] 16 U.S.C. 824o(d)(2) (2012).

[2] *Revised Critical Infrastructure Protection Reliability Standards,* Order No. 822, 154 FERC ¶ 61,037, at P 53, *order denying reh'g,* Order No. 822–A, 156 FERC ¶ 61,052 (2016).

[3] 16 U.S.C. 824o(d)(5); Order No. 822, 154 FERC ¶ 61,037 at P 53.

[4] BES Cyber System is defined as ''[o]ne or more BES Cyber Assets logically grouped by a responsible entity to perform one or more reliability tasks for a functional entity.'' Glossary of Terms Used in NERC Reliability Standards (NERC Glossary), *http://www.nerc.com/files/glossary_of_terms.pdf.* The acronym BES refers to the bulk electric system.

bulk electric system Control Centers.[5] Accordingly, the Commission proposes to approve proposed Reliability Standard CIP–012–1 based on a determination that the standard is largely responsive to the Commission's directive in Order No. 822 and improves the cybersecurity posture of applicable entities.

3. However, we are concerned that there still may be certain cyber security risks associated with the protection of communications links and sensitive bulk electric system data communicated between bulk electric system Control Centers that are not adequately addressed in NERC's proposal. First, proposed Reliability Standard CIP–012–1 does not require protections regarding the availability of communication links and data communicated between bulk electric system Control Centers as directed in Order No. 822.[6] As discussed below, at this time, we are not persuaded by NERC's explanation that certain currently-effective CIP Reliability Standards address the issue of availability. Second, proposed Reliability Standard CIP–012–1 does not adequately identify the types of data covered by its requirements, due to, among other things, the fact that the term ''Real-time monitoring'' is not defined in the proposed Reliability Standard or the NERC Glossary. Clarification of the types of covered data is warranted.

4. To address these issues, pursuant to section 215(d)(5) of the FPA, the Commission proposes to direct that NERC develop modifications to the CIP Reliability Standards to: (1) Require protections regarding the availability of communication links and data communicated between bulk electric system Control Centers; and (2) clearly identify the types of data that must be protected.

I. Background

A. Section 215 and Mandatory Reliability Standards

5. Section 215 of the FPA requires a Commission-certified ERO to develop mandatory and enforceable Reliability Standards, subject to Commission review and approval. Reliability Standards may be enforced by the ERO, subject to Commission oversight, or by the Commission independently.[7] Pursuant to section 215 of the FPA, the Commission established a process to select and certify an ERO,[8] and subsequently certified NERC.[9]

B. Order No. 822

6. In Order No. 822, the Commission approved seven modified CIP Reliability Standards and directed NERC to develop additional modifications to the CIP Reliability Standards.[10] Specifically, the Commission directed NERC to, among other things, develop modifications to the CIP Reliability Standards to require responsible entities to implement controls to protect, at a minimum, communications links and sensitive bulk electric system data communicated between bulk electric system Control Centers ''in a manner that is appropriately tailored to address the risks posed to the bulk electric system by the assets being protected (*i.e.,* high, medium, or low impact).'' [11] The Commission observed that NERC, as well as other commenters in that proceeding, ''recognize that inter-Control Center communications play a critical role in maintaining bulk electric system reliability by . . . helping to maintain situational awareness and support reliable operations through timely and accurate communication between Control Centers.'' [12]

7. The Commission explained that Control Centers associated with responsible entities, including reliability coordinators, balancing authorities, and transmission operators, must be capable of receiving and storing a variety of bulk electric system data from their interconnected entities in order to adequately perform their reliability functions. The Commission, therefore, determined that ''additional measures to protect both the integrity and availability of sensitive bulk electric system data are warranted.'' [13] The Commission also recognized that the data managed by responsible entities has different attributes that may require different information protection controls, and the Commission stated that NERC should consider the different attributes of bulk electric system data as it assesses appropriate information protection controls. The Commission concluded that NERC ''should have flexibility in the manner in which it addresses the Commission's directive.'' [14]

8. In Order No. 822, the Commission found to be reasonable the following principles outlined in NERC's comments in that Commission proceeding regarding protections for communication links and sensitive bulk electric system data communicated between bulk electric system Control Centers:

> (1) should not have an adverse effect on reliability, including the recognition of instances where the introduction of latency could have negative results; (2) should account for the risk levels of assets and information being protected, and require protections that are commensurate with the risks presented; and (3) should be results-based in order to provide flexibility to account for the range of technologies and entities involved in bulk electric system communications.[15]

In addition, the Commission cautioned that ''not all communication network components and data pose the same risk to bulk electric system reliability and may not require the same level of protection.'' [16] Therefore, the Commission determined that NERC should develop controls that reflect the risk being addressed in a reasonable manner.

C. NERC Petition and Proposed Reliability Standard CIP–012–1

9. On September 18, 2018, NERC submitted for Commission approval proposed Reliability Standard CIP–012–1 and the associated violation risk factors and violation severity levels, implementation plan, and effective date.[17] NERC states that the purpose of the proposed Reliability Standard is to help maintain situational awareness and reliable bulk electric system operations by protecting the confidentiality and integrity of Real-time Assessment and Real-time monitoring data transmitted between Control Centers.

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[5] The NERC Glossary defines Real-time Assessment as ''An evaluation of system conditions using Real-time data to assess existing (pre-Contingency) and potential (post-Contingency) operating conditions. The assessment shall reflect applicable inputs including, but not limited to: Load, generation output levels, known Protection System and Special Protection System status or degradation, Transmission outages, generator outages, Interchange, Facility Ratings, and identified phase angle and equipment limitations. (Real-time Assessment may be provided through internal systems or through third-party services.)'' NERC Glossary of Terms Used in NERC Reliability Standards (July 3, 2018).

[6] Order No. 822, 154 FERC ¶ 61,037 at P 54.

[7] 16 U.S.C. 824o(e).

[8] *Rules Concerning Certification of the Electric Reliability Organization; and Procedures for the Establishment, Approval, and Enforcement of Electric Reliability Standards,* Order No. 672, 114 FERC ¶ 61,104, *order on reh'g,* Order No. 672–A, 114 FERC ¶ 61,328 (2006).

[9] *North American Electric Reliability Corp.,* 116 FERC ¶ 61,062, *order on reh'g and compliance,* 117 FERC ¶ 61,126 (2006), *aff'd sub nom. Alcoa, Inc.* v. *FERC,* 564 F.3d 1342 (D.C. Cir. 2009).

[10] Order No. 822, 154 FERC ¶ 61,037 at PP 1, 3.

[11] *Id.* P 53.

[12] *Id.* P 54 (citing NERC Comments at 20).

[13] *Id.* P 54.

[14] *Id.* P 55.

[15] *Id.*

[16] *Id.* P 56.

[17] Proposed Reliability Standard CIP–012–1 is not attached to this notice of proposed rulemaking (NOPR). The proposed Reliability Standards are available on the Commission's eLibrary document retrieval system in Docket No. RM18–20–000 and on the NERC website, *www.nerc.com.*

10. NERC explains that, although the Commission directed modifications to Reliability Standard CIP–006–6, the standard drafting team determined to address the Commission's communications directive by developing a new Reliability Standard. According to NERC, the differences in the scope and applicability between the existing requirements of Reliability Standard CIP–006–1 and the Commission's directive necessitated the development of a new Reliability Standard. Specifically, NERC notes that while Reliability Standard CIP–006–6, Requirement R1, Part 1.10 mandates protections for nonprogrammable communication components outside a Physical Security Perimeter (PSP) but inside the same Electronic Security Perimeter (ESP) for certain Cyber Assets, proposed Reliability Standard CIP–012–1 ''requires protections for communications between Control Centers that transmit certain data regardless of the location of Cyber Assets inside or outside a PSP or ESP.'' [18] In addition, NERC explains that unlike Reliability Standard CIP–006–6, which applies to high and medium impact BES Cyber Assets at Control Centers, proposed Reliability Standard CIP–012–1 applies to assets associated with communications between certain Control Centers.

11. NERC states that proposed Reliability Standard CIP–012–1 ''requires Responsible Entities to develop and implement a plan to address the risks posed by unauthorized disclosure (confidentiality) and unauthorized modification (integrity) of Real-time Assessment and Real-time monitoring data while being transmitted between applicable Control Centers.'' [19] According to NERC, the required plan must include the following: (1) Identification of security protections; (2) identification of where the protections are applied; and (3) identification of the responsibilities of each entity in case a Control Center is owned or operated by different responsible entities.[20]

12. NERC posits that, consistent with the Commission's directive in Order No. 822, the risks posed by different types of BES Control Centers and the associated data communicated between the Control Centers were considered by the standard drafting team to determine its appropriate scope and applicability.[21] With regard to functional entities and facilities, NERC states that proposed Reliability Standard CIP–012–1 applies to balancing authorities, generator operators, reliability coordinators, transmission operators and transmission owners that own or operate a Control Center. NERC explains that proposed Reliability Standard CIP–012–1 applies to all Control Centers, with one exemption discussed below, ''regardless of the impact level of BES Cyber Systems located at or associated with those control centers.'' [22] In that regard, NERC explains that the standard drafting team determined that the sensitivity of data communicated between Control Centers ''is not necessarily dependent on the impact level of the BES Cyber Systems located at or associated with the Control Centers.'' [23] NERC states that the standard drafting team, instead, focused on the types of Real-time data a Control Center will communicate and whether the compromise of that data would pose a high risk to bulk electric system reliability.

13. As noted above, the types of data within the scope of proposed Reliability Standard CIP–012–1 consists of Real-time Assessment and Real-time monitoring data exchanged between Control Centers. NERC states that it is critical that this information is accurate since responsible entities operate and monitor the bulk electric system based on this Real-time information. However, NERC points out that proposed Reliability Standard CIP–012–1 exempts Control Centers ''that transmit[ ] to another Control Center Real-time Assessment or Real-time monitoring data pertaining only to the generation resource of transmission station or substation co-located with the transmitting Control Center.'' [24] NERC explains that proposed Reliability Standard CIP–012–1 ''excludes other data typically transferred between Control Centers, such as Operational Planning Analysis data, that is not used by the Reliability Coordinator, Balancing Authority, and Transmission Operator in Real-time.'' [25] According to NERC, while Operational Planning Analysis data provides information for next-day operations, ''entities adjust their operating actions during the current day based on the data from Real-time Assessments and Real-time monitoring.'' [26] NERC contends that if there is a risk that Operational Planning Analysis data has been compromised, the responsible entity has the opportunity to verify the data prior to any impact on Real-time operations. Therefore, NERC concludes that while ''an Operational Planning Analysis factors into how an entity operates, there is less of a risk that an entity would act on compromised data from an Operational Planning Analysis given it will base its operating actions on Real-time inputs.'' [27]

14. NERC also indicates that data at rest and oral communications fall outside the scope of proposed Reliability Standard CIP–012–1. Regarding data at rest, NERC states that the standard drafting team determined that since data at rest resides within BES Cyber Systems, it is already protected by the controls mandated by Reliability Standards CIP–003–6 through CIP–011–2. According to NERC, oral communications are out of scope of proposed Reliability Standard CIP–012–1 ''because operators have the ability to terminate the call and initiate a new one via trusted means if they suspect a problem with, or compromise of, the communication channel.'' [28] NERC notes that Reliability Standard COM–001–3 requires reliability coordinators, balancing authorities, and transmission operators to have alternative interpersonal communication capability, which could be used if there is a suspected compromise of oral communication on one channel.

II. Discussion

15. Pursuant to section 215(d)(2) of the FPA, the Commission proposes to approve proposed Reliability Standard CIP–012–1 as just, reasonable, not unduly discriminatory or preferential, and in the public interest. The proposed Reliability Standard will enhance existing protections for bulk electric system reliability by augmenting the currently-effective CIP Reliability Standards to mitigate cybersecurity risks associated with communications between bulk electric system Control Centers. Specifically, consistent with the Commission's directive in Order No. 822, proposed Reliability Standard CIP–012–1 supports situational awareness and reliable bulk electric system operations by requiring responsible entities to protect the confidentiality and integrity of Real-time Assessment and Real-time monitoring data transmitted between bulk electric system Control Centers.

16. While the Commission proposes to approve Reliability Standard CIP–012–1, certain cyber security risks associated with communications between bulk electric system Control

[18] NERC Petition at 9.

[19] *Id.* at 10.

[20] *Id.* at 3.

[21] *Id.*

[22] *Id.* at 10.

[23] *Id.*

[24] *Id.* at 11.

[25] *Id.* at 12.

[26] *Id.*

[27] *Id.* at 13.

[28] *Id.* at 14.

Centers may not be fully addressed even with the implementation of the proposed Reliability Standard. As discussed below, the Commission is concerned that a significant cyber security risk associated with the protection of communications links and sensitive bulk electric system data communicated between bulk electric system Control Centers may persist because: (1) The CIP Reliability Standards do not address the availability of communication links and data communicated between bulk electric system Control Centers; and (2) proposed Reliability Standard CIP–012–1 does not adequately identify the types of data covered by its Requirements, due to, among other things, the fact that the term ''Real-time monitoring'' is not defined.

17. To address these gaps, the Commission seeks comment on proposals to direct NERC, pursuant to section 215(d)(5) of the FPA, to develop modifications to the CIP Reliability Standards to: (1) Require protections regarding the availability of communication links and data communicated between bulk electric system Control Centers; and (2) clearly identify the types of data that must be protected.

18. Below, we discuss the following issues: (A) Availability of bulk electric system communication links and data; and (B) scope of bulk electric system data that must be protected.

A. Availability of Bulk Electric System Communication Links and Data Order No. 822

19. In Order No. 822, the Commission directed that NERC ''should identify the scope of sensitive bulk electric system data that must be protected and specify how the confidentiality, integrity, and availability of each type of bulk electric system data should be protected while it is being transmitted or at rest.'' [29] In addition, the Commission clarified that ''the directed modification should encompass communication links and data for intra-Control Center and inter-Control Center communications.'' [30]

20. Specifically, the Commission explained that bulk electric system Control Centers must be capable of exchanging and storing sensitive bulk electric system data from interconnected entities in order for responsible entities to adequately perform their reliability functions. The Commission determined ''that additional measures to protect both the integrity and *availability* of sensitive bulk electric system data are warranted.'' [31] The Commission explained that protecting the availability of sensitive bulk electric system data involves ensuring that the data required for bulk electric system operations is available when needed. The Commission responded to concerns that the risks posed by bulk electric system communication networks do not justify the cost of implementing controls by explaining that communications between Control Centers are fundamental to reliable bulk electric system operations. The Commission, however, also recognized that ''not all communication network components and data pose the same risk to bulk electric system reliability and may not require the same level of protection.'' [32] The Commission therefore determined that it expected NERC to develop controls that reflect the associated risk and that can be implemented in a reasonable manner.

NERC Petition

21. NERC states that proposed Reliability Standard CIP–012–1, Requirement R1 mandates that:

> each Responsible Entity develop a plan to mitigate the risks posed by unauthorized disclosure and unauthorized modification of Real-time Assessment and Real-time monitoring data while being transmitted between and applicable Control Centers.[33]

NERC acknowledges that Order No. 822 directed that ''NERC should develop measures to protect the confidentiality, integrity, and availability of sensitive [bulk electric system] data.'' [34] NERC states, however, that while proposed Reliability Standard CIP–012–1 requires protections for the confidentiality (*i.e.,* unauthorized disclosure) and integrity (*i.e.,* unauthorized modification) of Real-time Assessment and Real-time monitoring data, the availability of that data is addressed in currently-effective Reliability Standards.

22. Specifically, NERC maintains that Reliability Standard IRO–002–5 ''requires redundant and diversely routed data exchange infrastructure within the Reliability Coordinator's primary Control Center in order to exchange Real-time data used in Real-time monitoring and Real-time Assessments with Balancing Authorities, Transmission Operators, and other entities the Reliability Coordinator deems necessary.'' [35] Similarly, NERC states that Reliability Standard TOP–001–4 ''requires Balancing Authorities and Transmission Operators to have redundant and diversely routed data exchange infrastructure to exchange Real-time data.'' [36] According to NERC, the ''redundancy of data exchange infrastructure helps to ensure the availability of critical Real-time data for Control Centers.'' [37] Further, NERC notes that Reliability Standards IRO–010–2 and TOP–003–3 require reliability coordinators, transmission operators, and balancing authorities to use a mutually agreeable security protocol for exchange of Real-time data. NERC contends that, by agreeing on security protocols, entities communicate directly with the appropriate entities rather than having to translate different protocols, which helps to ensure the availability of Real-time data.

Discussion

23. We are not persuaded by the explanation in NERC's petition that currently-effective CIP Reliability Standard requirements address the availability directive in Order No. 822. Sensitive bulk electric system data generally includes monitoring, operational, and system planning data. Ensuring timely and reliable access to and use of this information is essential to the reliable operation of the bulk electric system. As the Commission noted in Order No. 822, bulk electric system Control Centers ''must be capable of receiving and storing a variety of sensitive bulk electric system data from interconnected entities.'' [38] In particular, the Commission stated that additional protections to address the availability of sensitive bulk electric system data are warranted.[39]

24. We are not persuaded that the currently-effective Reliability Standards cited in NERC's petition require responsible entities to protect the availability of sensitive bulk electric system data in a manner consistent with the directives in Order No. 822. For instance, Reliability Standards IRO–002–5 and TOP–001–4 require responsible entities to have redundant and diversely routed data exchange infrastructure *within* the Control Center environment, but do not pertain to communications *between* individual Control Centers, which was the subject of the Commission's directive in Order No. 822. Similarly, Reliability Standards IRO–010–2 and TOP–003–3 require responsible entities to have mutually agreeable security protocols for

[29] Order No. 822, 154 FERC ¶ 61,037 at P 56.

[30] *Id.* P 58.

[31] *Id.* P 54 (emphasis added).

[32] *Id.* P 56.

[33] Petition at 15–16.

[34] *Id.* at 17.

[35] *Id.* at 18.

[36] *Id.*

[37] *Id.*

[38] Order No. 822, 154 FERC ¶ 61,037 at P 54.

[39] *Id.*

exchange of Real-time data, which may have the effect of contributing to greater availability; however, these requirements do not create an obligation, as directed in Order No. 822, to protect the availability of those communication capabilities and associated data by applying appropriate security controls. Creating an *obligation* to protect availability, while affording flexibility in terms of what data is protected and how, is distinct from relying on currently-effective Reliability Standards whose *effect* may be to improve availability.

25. Bonneville Power Administration (BPA) and CenterPoint Energy Houston Electric addressed this distinction during the standards development process when they responded to the standard drafting team's assertion that the availability directive is adequately addressed by currently-effective CIP Reliability Standards. BPA explained that ''[w]hile the requirements of TOP–001–4 and IRO–002–5 (redundant and diverse routing of data) can be used to achieve increased Availability, it can also be achieved through other equally effective methods . . . [and] [t]herefore, 'availability' is not adequately addressed by TOP–001–4 and IRO–002–5 and limits entities' options to address availability by other methods more appropriate to their systems.'' [40] CenterPoint stated that, ''TOP–001–4 and IRO–002–5 do not ensure availability or communication of data between inter-entity and intra-entity Control Centers, but only the redundancy of infrastructure internal to the requesting entity's primary Control Center.'' [41]

26. Not addressing the availability of covered communication links and data could lead to unreliable operations resulting from the inability to communicate data between Control Centers. While NERC contends that currently-effective CIP Reliability Standards adequately protect the availability of sensitive bulk electric system data, there is no obligation on responsible entities to affirmatively protect the availability of such data. Moreover, while the Commission in Order No. 822 allowed NERC flexibility in what data is protected and how, NERC has not addressed the directive to protect the availability of sensitive bulk electric system data.

27. Accordingly, pursuant to section 215(d)(5) of the FPA, the Commission proposes to direct that NERC develop modifications to the CIP Reliability Standards to require protections regarding the availability of communication links and data communicated between bulk electric system Control Centers. We seek comment on this proposal.

B. Scope of Bulk Electric System Data That Must Be Protected Order No. 822

28. In Order No. 822, the Commission stated that NERC ''should identify the scope of sensitive bulk electric system data that must be protected and specify how the confidentiality, integrity, and availability of each type of bulk electric system data should be protected while it is being transmitted or at rest.'' [42] In addition, the Commission clarified that ''the directed modification should encompass communication links and data for intra-Control Center and inter-Control Center communications.'' [43]

NERC Petition

29. NERC states that proposed Reliability Standard CIP–012–1 applies to Real-time Assessment and Real-time monitoring data due to the critical nature of the information. NERC explains that:

> Reliability Coordinators and Transmission Operators must perform Real-time Assessments every 30 minutes to assess the conditions on the system and determine whether there are any actual or potential exceedances of System Operating Limits or Interconnection Reliability Operating Limits.[44]

In addition, NERC states that reliability coordinators, balancing authorities, and transmission operators must perform Real-time monitoring. NERC contends that since responsible entities ''operate and monitor the [bulk electric system] according to this Real-time information, it is of critical importance that it is accurate.'' [45]

Discussion

30. Proposed Reliability Standard CIP–012–1 requires the protection of Real-time Assessment and Real-time monitoring data. While Real-time Assessment is broadly defined by NERC, Real-time monitoring data is not defined. Moreover, the proposed Reliability Standard does not specifically indicate the types of data to be protected. We are concerned that without further clarity, Reliability Standard CIP–012–1 may be implemented and enforced in an inconsistent manner.

31. In the Technical Rationale document appended to NERC's petition, NERC explained in more detail (relative to the language of the proposed Reliability Standard's requirements) what data should be protected under proposed Reliability Standard CIP–012–1:

> The SDT recognized the FERC reference to additional Reliability Standards and the responsibilities to protect the applicable data in accordance with NERC Reliability Standards TOP–003 and IRO–010. The SDT used these references to drive the identification of sensitive BES data and chose to base the CIP–012–1 requirements on the Real-time data specification elements in these standards. This approach provides consistent scoping of identified data, and does not require each entity to devise its own list or inventory of this data. Many entities are required to provide this data under agreements executed with their [reliability coordinator (RC)], [balancing authority (BA)] or [transmission operator (TOP)]. Data requiring protection in CIP–012–1 consists of a subset of data that is identified by the RC, BA, and TOP in the TOP–003 and IRO–010 data specification standards, limited to Real-time Assessment data and Real-time monitoring data.[46]

The references to Reliability Standards TOP–003 and IRO–010 in the Technical Rationale document are not found in proposed Reliability Standard CIP–012–1. Instead Requirement R1 of proposed Reliability Standard CIP–012–1 only uses the terms ''Real-time Assessment and Real-time monitoring data.'' In addition, as the Technical Rational indicates at the outset: ''This Technical Rationale and Justification for CIP–012–1 is not a Reliability Standard and should not be considered mandatory and enforceable.'' [47]

32. Not clearly defining the types of data that must be protected under the proposed Reliability Standard could result in uneven compliance and enforcement. The term ''Real-time Assessment'' is broadly defined in the NERC Glossary of Terms, and the term ''Real-time monitoring'' is not defined at all. These terms, alone, may not be understood or enforced in a consistent manner. This concern arose during the standard drafting process in comments regarding an earlier version of the proposed Reliability Standard, which was later modified.[48] Still relevant,

[40] NERC Petition at page 273 of pdf.

[41] *Id.* at page 274 of pdf.

[42] Order No. 822, 154 FERC ¶ 61,037 at P 56.

[43] *Id.* P 58.

[44] NERC Petition at 12.

[45] *Id.*

[46] NERC Petition, Exhibit F (Technical Rationale) at 1–2; *see also* Exhibit E (Draft Implementation Guidance) at 5 (providing similar context as to what data should be protected).

[47] NERC Petition, Exhibit F at iv; *see also* Exhibit E at 3 (indicating that the draft Implementation Guidance document only provides examples in achieving compliance).

[48] An early version of Requirement R1 of proposed Reliability Standard CIP–012–1 identified the scope of the data to be protected as ''data used for Operational Planning Analysis, Real-time Assessments, and Real-time monitoring.''

however, are concerns raised regarding the potential ambiguities associated with enforcement of the scope of data that must be protected. In particular, while NERC identifies Reliability Standards IRO–002–5, Requirements R5 and R6, and TOP–001–4, Requirements R10 and R11 in discussing the parameters of Real-time monitoring data, the information outlined in the identified requirements is not included in the language of proposed Reliability Standard CIP–012–1 itself and, therefore, implementation and compliance concerns may arise.[49]

33. The compliance obligations imposed under proposed Reliability Standard CIP–012–1 should be clear in order for responsible entities to effectively and reasonably implement the required protections. The lack of clarity regarding the scope of Real-time monitoring data is inconsistent with principles outlined by the Commission in Order No. 672.[50] In particular, the lack of clarity may result in: (1) A failure to establish a clear and unambiguous requirement regarding the protection of Real-time monitoring data; [51] and (2) a failure to identify clear and objective criterion to facilitate consistent and non-preferential enforcement since responsible entities will not have a clear understanding of the Real-time monitoring data to be protected.[52] Since the controls required under Reliability Standard CIP–012–1 are plan-based, the scope of data to be protected should be clear and unambiguous so that responsible entities will accurately identify vulnerabilities or risks requiring mitigation.

34. Therefore, pursuant to section 215(d)(5) of the FPA, the Commission proposes to direct that NERC develop modifications to the CIP Reliability Standards to clearly identify the types of data that must be protected. We seek comment on this proposal. In particular, we seek comment on the specific information covered by the term ''Real-time monitoring'' and whether a NERC Glossary definition would assist with implementation and compliance.

III. Information Collection Statement

35. The FERC–725B information collection requirements contained in this notice of proposed rulemaking are subject to review by the Office of Management and Budget (OMB) under section 3507(d) of the Paperwork Reduction Act of 1995.[53] OMB's regulations require approval of certain information collection requirements imposed by agency rules.[54] Upon approval of a collection of information, OMB will assign an OMB control number and expiration date. Respondents subject to the filing requirements of this rule will not be penalized for failing to respond to these collections of information unless the collections of information display a valid OMB control number. The Commission solicits comments on the Commission's need for this information, whether the information will have practical utility, the accuracy of the burden estimates, ways to enhance the quality, utility, and clarity of the information to be collected or retained, and any suggested methods for minimizing respondents' burden, including the use of automated information techniques.

36. The Commission bases its paperwork burden estimates on the changes in paperwork burden presented by the newly proposed Reliability Standard CIP–012–1.

37. The NERC Compliance Registry, as of December 2017, identifies approximately 1,250 unique U.S. entities that are subject to mandatory compliance with Reliability Standards. Of this total, we estimate that 714 entities will face an increased paperwork burden under proposed Reliability Standard CIP–012–1. Based on these assumptions, we estimate the following reporting burden:

ANNUAL CHANGES PROPOSED BY THE NOPR IN DOCKET NO. RM18–20–000

	Number of respondents	Number of responses [55] per respondent	Total number of responses	Average burden hrs. & cost per response [56]	Total annual burden hours & total annual cost
	(1)	(2)	(1) × (2) = (3)	(4)	(3) × (4) = 5
Implementation of Documented Plan(s) (Requirement R1) [57].	714	1	714	128 hrs.; $10,496	91,392 hrs.;$7,494,144.
Document Identification of Security Protection (Requirement R1.1) [57].	714	1	714	40 hrs.; $3,280	28,560 hrs.; $2,341,920.
Identification of Security Protection Application (if owned by same Responsible Entity) (Requirement R1.2) [57].	714	1	714	20 hrs.; $1,640	14,280 hrs.; $1,170,960.
Identification of Security Protection Application (if *not* owned by same Responsible Entity) (Requirement R1.3) [57].	714	1	714	160 hrs.; $13,120	14,240 hrs.; $9,367,680.
Maintaining Compliance (ongoing)	714	1	714	83 hrs.; $6,806	59,262 hrs.; $4,859,484.
Total (one-time)			2,856		148,472 hrs.; $12,174,704.
Total (ongoing)			714		59,262 hrs.; $4,859,484.
TOTAL			3,570		207,734 hrs.; $17,034,188.

[49] *See* NERC Petition at page 505 of pdf.

[50] Order No. 672, 114 FERC ¶ 61,104, *order on reh'g,* Order No. 672–A, 114 FERC ¶ 61,328.

[51] *Id.* PP 322, 325.

[52] *Id.* P 327.

[53] 44 U.S.C. 3507(d) (2012).

[54] 5 CFR 1320.11.

[55] We consider the filing of an application to be a ''response.''

[56] The loaded hourly wage figure (includes benefits) is based on the average of the occupational categories for 2017 found on the Bureau of Labor Statistics website (*http://www.bls.gov/oes/current/naics2_22.htm*):

Information Security Analysts (Occupation Code: 15–1122): $42.84.

Computer and Mathematical (Occupation Code: 15–0000): $44.02.

Legal (Occupation Code: 23–0000): $143.68.

Computer and Information Systems Managers (Occupation Code: 11–3021): $96.51.

These various occupational categories' wage figures are averaged and weighted equally as follows: ($42.84/hour + $44.02/hour + $143.68/hour + $96.51/hour) ÷ 4 = $81.76/hour. The resulting wage figure is rounded to $82.00/hour for use in calculating wage figures in the NOPR in Docket No. RM18–20–000.

[57] This is a one-time reporting requirement.

38. The one-time burden for the FERC–725B information collection will be averaged over three years:

- 148,472 hours ÷ 3 = 49,491 hours/year over three years
- The number of one-time responses for the FERC–725B information collection is also averaged over three years: 2,856 responses ÷ 3 = 952 responses/year

39. The responses and burden for one-time and ongoing burden for Years 1–3 will total respectively as follows:

- Year 1: 1,666 responses [952 responses (one-time) + 714 responses (ongoing)]; 108,753 hours [49,491 hours (one-time) + 59,262 hours (ongoing)]
- Year 2: 1,666 responses [952 responses (one-time) + 714 responses (ongoing)]; 108,753 hours [49,491 hours (one-time) + 59,262 hours (ongoing)]
- Year 3: 1,666 responses [952 responses (one-time) + 714 responses (ongoing)]; 108,753 hours [49,491 hours (one-time) + 59,262 hours (ongoing)]

40. *Title:* Mandatory Reliability Standards for Critical Infrastructure Protection [CIP] Reliability Standards.

Action: Proposed revision to FERC–725B information collection.

OMB Control No.: 1902–0248.

Respondents: Businesses or other for-profit institutions; not-for-profit institutions.

Frequency of Responses: On occasion.

Necessity of the Information: This notice of proposed rulemaking proposes to approve the requested modifications to Reliability Standards pertaining to critical infrastructure protection. As discussed above, the Commission proposes to approve NERC's proposed Reliability Standard CIP–012–1 pursuant to section 215(d)(2) of the FPA because they improve upon the currently-effective suite of cyber security Reliability Standards.

Internal Review: The Commission has reviewed the proposed Reliability Standard and made a determination that its action is necessary to implement section 215 of the FPA.

41. Interested persons may obtain information on the reporting requirements by contacting the following: Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426 [Attention: Ellen Brown, Office of the Executive Director, email: *DataClearance@ferc.gov,* phone: (202) 502–8663, fax: (202) 273–0873].

42. For submitting comments concerning the collection(s) of information and the associated burden estimate(s), please send your comments to the Commission, and to the Office of Management and Budget, Office of Information and Regulatory Affairs, 725 17th Street NW, Washington, DC 20503, [Attention: Desk Officer for the Federal Energy Regulatory Commission, phone: (202) 395–4638, fax: (202) 395–7285]. For security reasons, comments to OMB should be submitted by email to: *oira_submission@omb.eop.gov.* Comments submitted to OMB should include Docket Number RM18–20–000 and FERC–725B (OMB Control No. 1902–0248).

IV. Environmental Analysis

43. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[58] The Commission has categorically excluded certain actions from this requirement as not having a significant effect on the human environment. Included in the exclusion are rules that are clarifying, corrective, or procedural or that do not substantially change the effect of the regulations being amended.[59] The actions proposed herein fall within this categorical exclusion in the Commission's regulations.

V. Regulatory Flexibility Act Analysis

44. The Regulatory Flexibility Act of 1980 (RFA) generally requires a description and analysis of proposed rules that will have significant economic impact on a substantial number of small entities.[60] The Small Business Administration's (SBA) Office of Size Standards develops the numerical definition of a small business.[61] The SBA revised its size standard for electric utilities (effective January 22, 2014) to a standard based on the number of employees, including affiliates (from the prior standard based on megawatt hour sales).[62]

45. Proposed Reliability Standard CIP–012–1 is expected to impose an additional burden on 714 entities[63] (reliability coordinators, generator operators, generator owners, interchange coordinators or authorities, transmission operators, balancing authorities, and transmission owners).

46. Of the 714 affected entities discussed above, we estimate that approximately 82% percent of the affected entities are small entities. We estimate that each of the 585 small entities to whom the proposed modifications to Reliability Standard CIP–012–1 apply will incur one-time costs of approximately $17,051 per entity to implement the proposed Reliability Standards, as well as the ongoing paperwork burden reflected in the Information Collection Statement (approximately $6,806 per year per entity). We do not consider the estimated costs for these 585 small entities to be a significant economic impact. Accordingly, we propose to certify that proposed Reliability Standard CIP–012–1 will not have a significant economic impact on a substantial number of small entities.

VI. Comment Procedures

47. The Commission invites interested persons to submit comments on the matters and issues proposed in this notice to be adopted, including any related matters or alternative proposals that commenters may wish to discuss. Comments are due June 24, 2019. Comments must refer to Docket No. RM18–20–000, and must include the commenter's name, the organization they represent, if applicable, and address.

48. The Commission encourages comments to be filed electronically via the eFiling link on the Commission's website at *http://www.ferc.gov.* The Commission accepts most standard word processing formats. Documents created electronically using word processing software should be filed in

[58] *Regulations Implementing the National Environmental Policy Act of 1969,* Order No. 486, FERC Stats. & Regs. ¶ 30,783 (1987) (cross-referenced at 41 FERC ¶ 61,284).

[59] 18 CFR 380.4(a)(2)(ii).

[60] 5 U.S.C. 601–12 (2012).

[61] 13 CFR 121.101.

[62] 13 CFR 121.201, Subsection 221.

[63] Public utilities may fall under one of several different categories, each with a size threshold based on the company's number of employees, including affiliates, the parent company, and subsidiaries. For the analysis in this NOPR, we are using a 500 employee threshold due to each affected entity falling within the role of Electric Bulk Power Transmission and Control (NAISC Code: 221121).

native applications or print-to-PDF format and not in a scanned format. Commenters filing electronically do not need to make a paper filing.

49. Commenters that are not able to file comments electronically must send an original of their comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

50. All comments will be placed in the Commission's public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commenters on this proposal are not required to serve copies of their comments on other commenters.

VII. Document Availability

51. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE, Room 2A, Washington, DC 20426.

52. From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number of this document, excluding the last three digits, in the docket number field.

53. User assistance is available for eLibrary and the Commission's website during normal business hours from the Commission's Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov*.

By direction of the Commission.

Issued: April 18, 2019

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–08236 Filed 4–23–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 7

[Docket No. FDA–2018–D–2074]

Initiation of Voluntary Recalls Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry and FDA staff entitled ''Initiation of Voluntary Recalls Under 21 CFR part 7, subpart C.'' The draft guidance, if finalized, would establish guidance for industry and FDA staff regarding timely initiation of voluntary recalls of FDA-regulated products. The draft guidance discusses what preparations firms in a distribution chain, including manufacturers and distributors, should consider making to establish recall initiation procedures; to ensure timely identification of, and response to, product problems that might lead to a recall; and to promptly issue recall communications and press releases or other public notices. It also discusses preparations that firms in a distribution chain should consider making to ensure timely responses to a recall communication. In addition, it discusses how FDA assists firms with carrying out their recall responsibilities to protect the public health from distributed products in violation of the Federal Food, Drug, and Cosmetic Act and other laws administered by FDA.

DATES: Submit either electronic or written comments on the draft guidance by June 24, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–2074 for ''Initiation of Voluntary Recalls Under 21 CFR part 7, subpart C; Draft Guidance for Industry and FDA Staff.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff office between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management

Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Building, Rm. 4141, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Peter Fox, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Building, Rm. 4146, Rockville, MD 20857, 240–402–1857.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled ''Initiation of Voluntary Recalls Under 21 CFR part 7, subpart C.'' The draft guidance, if finalized, would establish guidance for industry and FDA staff regarding timely initiation of voluntary recalls of FDA-regulated products under 21 CFR part 7, subpart C. The draft guidance is part of a larger effort FDA is undertaking to give additional guidance to industry and FDA staff regarding the execution and oversight of voluntary recalls under part 7, subpart C.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, if finalized, would represent the current thinking of FDA on ''Initiation of Voluntary Recalls Under 21 CFR part 7, subpart C.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 7.45(c), 7.46(a), and 7.59 have been approved under OMB control number 0910–0249.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/FoodGuidances* or *https://www.regulations.gov.*

Dated: April 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–08198 Filed 4–23–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 170, 177, and 189

[Docket No. FDA–2015–F–0537]

Natural Resources Defense Council et al.: Response to the Objections and Denial of the Requests for a Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; response to objections and denial of public hearing requests.

SUMMARY: The Food and Drug Administration (FDA or we) is overruling the objections and is denying the requests for a public hearing, submitted by the Environmental Defense Fund, Natural Resources Defense Council, Center for Food Safety, Clean Water Action, Center for Science in the Public Interest, Breast Cancer Prevention Partners, Center for Environmental Health, Environmental Working Group, and Improving Kids' Environment.

DATES: April 24, 2019.

FOR FURTHER INFORMATION CONTACT: Hui-Chen (Anita) Chang, Center for Food Safety and Applied Nutrition (HFS–275), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740–3835, 240–402–1161.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 16, 2015 (80 FR 13508), we announced the filing of a food additive petition (FAP 4B4808) (''petition'') submitted by the Natural Resources Defense Council, 1152 15th St. NW, Suite 300, Washington, DC 20005; the Center for Food Safety, 303 Sacramento St., Second Floor, San Francisco, CA 94111; Clean Water Action, 1444 I St. NW, Suite 400, Washington, DC 20005; the Center for Science in the Public Interest, 1220 L St. NW, Suite 300, Washington, DC 20005; Children's Environmental Health Network, 110 Maryland Ave. NE, Suite 402, Washington, DC 20002; the Breast Cancer Fund (now known as Breast Cancer Prevention Partners), 1388 Sutter St., Suite 400, San Francisco, CA 94109–5400; the Center for Environmental Health, 2201 Broadway, Suite 302, Oakland, CA 94612; Environmental Working Group, 1436 U St. NW, Suite 100, Washington, DC 20009; and Improving Kids' Environment, 1915 West 18th St., Indianapolis, IN 46202 (collectively, ''petitioners''). The petition asked FDA to take three separate regulatory actions: (1) Revoke our 2005 approval of Threshold of Regulation (TOR) exemption No. 2005–006 allowing as much as 1.2 percent sodium perchlorate monohydrate in dry food packaging; (2) issue a new regulation under part 189 (21 CFR part 189) prohibiting the use of perchlorate as a conductivity enhancer in the manufacture of antistatic agents to be used in food contact articles; and (3) remove potassium perchlorate as an allowed additive in sealing gaskets for food containers in existing § 177.1210 (21 CFR 177.1210).

In the **Federal Register** of June 30, 2016 (81 FR 42585), we announced that we filed a food additive petition (FAP 6B4816) (''abandonment petition'') submitted on behalf of Society of the Plastics Industry, Inc. (SPI) by Keller and Heckman LLP, 1001 G Street NW, Suite 500 West, Washington, DC 20001. The abandonment petition proposed to amend § 177.1210 to no longer provide for the use of potassium perchlorate as an additive in closure sealing gaskets for food containers because the use has

been intentionally and permanently abandoned.

In response to the abandonment petition, we issued a final rule in the **Federal Register** on May 4, 2017 (82 FR 20829), to no longer provide for the use of potassium perchlorate as an additive in closure-sealing gaskets for food containers because this use has been abandoned. The final rule removed the entry for ''Potassium perchlorate'' from § 177.1210(b)(5), table 1.

Additionally, in the **Federal Register** of May 4, 2017 (82 FR 20847), we announced that we were denying the petition (''2017 denial''). The 2017 denial advised that objections and requests for a hearing were due by June 4, 2017. The 2017 denial explained that the requests to revoke TOR exemption No. 2005–006 and issue a regulation under part 189 prohibiting the use of perchlorate in the manufacture of antistatic agents to be used in food-contact articles are not directed at regulations issued under the food additive petition process and are not subject to the statutory processes for food additive petitions (82 FR 20847 at 20858). Because the requests to revoke TOR exemption No. 2005–006 and issue a regulation under part 189 are not within the scope of a food additive petition, the provision for objections and a hearing under section 409(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(f)) does not apply to these two requests (Id.). The 2017 denial also explained that the petitioners' request to remove potassium perchlorate as an allowed additive in closure-sealing gaskets for food containers in § 177.1210 was moot when we amended § 177.1210 to no longer authorize this use of potassium perchlorate because it had been abandoned (see 82 FR 20847 at 20849).

II. Objections and Requests for Hearing

Section 409(f) of the FD&C Act provides that, within 30 days after publication of an order relating to a food additive regulation, any person adversely affected by such order may file objections, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. FDA may deny a hearing request if the objections to the regulation do not raise genuine and substantial issues of fact that can be resolved at a hearing (*Community Nutrition Inst.* v. *Young,* 773 F.2d 1356, 1364 (D.C. Cir. 1985)).

Under the food additive regulations at 21 CFR 171.110, objections and requests for a hearing are governed by part 12 (21 CFR part 12) of FDA's regulations. Under § 12.22(a), each objection must: (1) Be submitted on or before the 30th day after the date of publication of the final rule; (2) be separately numbered; (3) specify with particularity the provision of the regulation or proposed order objected to; (4) specifically state each objection on which a hearing is requested; failure to request a hearing on an objection constitutes a waiver of the right to a hearing on that objection; and (5) include a detailed description and analysis of the factual information to be presented in support of the objection if a hearing is requested; failure to include a description and analysis for an objection constitutes a waiver of the right to a hearing on that objection.

Within the 30-day objection period following publication of the 2017 denial, we received one submission raising objections. The submission, dated June 4, 2017, from most of the petitioners and the Environmental Defense Fund, raised specific objections to the 2017 denial and requested a hearing on the issues raised by each objection. However, as explained in this document, the provision for objections and a hearing under section 409(f) of the FD&C Act does not apply to all objections in the submission. As further explained in this document, for the objections to which this provision does not apply, we do not address the submission's arguments and we do not consider the related requests for a hearing. For purposes of this document, our use of the term ''objections'' does not mean that the provision for objections and hearing under section 409(f) of the FD&C Act necessarily applies.

III. Standards for Granting a Hearing

Specific criteria for deciding whether to grant or deny a request for a hearing are set out in § 12.24(b). Under that regulation, a hearing will be granted if the material submitted by the requester shows, among other things, the following: (1) There is a genuine and substantial factual issue for resolution at a hearing; a hearing will not be granted on issues of policy or law; (2) the factual issue can be resolved by available and specifically identified reliable evidence; a hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions; (3) the data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the requester; a hearing will be denied if the data and information submitted are insufficient to justify the factual determination urged, even if accurate; (4) resolution of the factual issue in the way sought by the person is adequate to justify the action requested; a hearing will not be granted on factual issues that are not determinative with respect to the action requested (*e.g.,* if the action would be the same even if the factual issue were resolved in the way sought); (5) the action requested is not inconsistent with any provision in the FD&C Act or any FDA regulation; and (6) the requirements in other applicable regulations, *e.g.,* 21 CFR 10.20 and §§ 12.21 and 12.22, and in the document issuing the final regulation or the notice of opportunity for hearing are met.

A party seeking a hearing is required to meet a ''threshold burden of tendering evidence suggesting the need for a hearing'' (*Costle* v. *Pac. Legal Found.,* 445 U.S. 198, 214 (1980), citing *Weinberger* v. *Hynson, Westcott & Dunning, Inc.,* 412 U.S. 609, 620–21 (1973)). An allegation that a hearing is necessary to '''sharpen the issues' and 'fully develop the facts' does not meet this test'' (*Georgia-Pacific Corp.* v. *U.S. EPA,* 671 F.2d 1235, 1241 (9th Cir. 1982)). If a hearing request fails to identify any factual evidence that would be the subject of a hearing, there is no point in holding one. In judicial proceedings, a court is authorized to issue summary judgment without an evidentiary hearing whenever it finds that there are no genuine issues of material fact in dispute and a party is entitled to judgment as a matter of law (see Fed. R. Civ. P. 56). The same principle applies in administrative proceedings (see § 12.24).

A hearing request must not only contain evidence, but that evidence should raise a material issue of fact ''concerning which a meaningful hearing might be held'' (*Pineapple Growers Ass'n* v. *FDA,* 673 F.2d 1083, 1085 (9th Cir. 1982)). Where the issues raised in the objection are, even if true, legally insufficient to alter the decision, an agency need not grant a hearing (see *Dyestuffs and Chem., Inc.* v. *Flemming,* 271 F.2d 281, 286 (8th Cir. 1959)). A hearing is justified only if the objections are made in good faith and if they ''draw in question in a material way the underpinnings of the regulation at issue'' (*Pactra Indus.* v. *CPSC,* 555 F.2d 677, 684 (9th Cir. 1977)). A hearing need not be held to resolve questions of law or policy (see *Citizens for Allegan Cnty., Inc.* v. *FPC,* 414 F.2d 1125, 1128 (D.C. Cir. 1969); *Sun Oil Co.* v. *FPC,* 256 F.2d 233, 240 (5th Cir. 1958)).

Even if the objections raise material issues of fact, FDA need not grant a hearing if those same issues were

adequately raised and considered in an earlier proceeding. Once an issue has been so raised and considered, a party is estopped from raising that same issue in a later proceeding without new evidence. The various judicial doctrines dealing with finality, such as collateral estoppel, can be validly applied to the administrative process (see *Pac. Seafarers, Inc.* v. *Pac. Far East Line, Inc.,* 404 F.2d 804, 809 (D.C. Cir. 1968)). In explaining why these principles ought to apply to an agency proceeding, the U.S. Court of Appeals for the District of Columbia Circuit wrote: ''The underlying concept is as simple as this: justice requires that a party have a fair chance to present his position. But overall interests of administration do not require or generally contemplate that he will be given more than a fair opportunity'' (*Retail Clerks Union, Local 1401* v. *NLRB,* 463 F.2d 316, 322 (D.C. Cir. 1972); see also *Costle* v. *Pac. Legal Found.,* 445 U.S. at 215–17).

IV. Analysis of Objections and Response to Hearing Requests

As explained in the 2017 denial (82 FR 20847 at 20849), a food additive petition must either propose the issuance of a regulation prescribing the conditions under which a food additive may be safely used or propose the amendment or repeal of an existing food additive regulation (see section 409(b)(1) and (i) of the FD&C Act). The petitioners' requests to revoke TOR exemption No. 2005–006 and issue a regulation under part 189 prohibiting the use of perchlorate in the manufacture of antistatic agents to be used in food-contact articles do not propose the issuance of a new food additive regulation or the amendment or repeal of an existing food additive regulation (82 FR 20847 at 20849). As the 2017denial states, the petitioners' TOR exemption revocation request and part 189 regulation request are not within the scope of a food additive petition and FDA's denial of these requests is not an order under section 409(c)(1)(B) of the FD&C Act (82 FR 20847 at 20858). Therefore, the provision for objections and public hearing under section 409(f) of the FD&C Act does not apply to the requests to revoke TOR exemption No. 2005–006 and issue a regulation under part 189.

A. Objections 1 and 2

The submission's first two ''objections'' are not subject to the objections and hearing procedure in section 409(f) of the FD&C Act. Therefore, we will not address the arguments detailed in those objections and we do not consider the related requests for a hearing.

The submission's first ''objection'' asserts that we improperly dismissed its request to revoke TOR exemption No. 2005–006 because, it claims, we relied on a flawed interpretation of the definition of a food additive in the TOR regulation. The submission additionally asserts that the use of sodium perchlorate monohydrate allowed under TOR exemption No. 2005–006 is not eligible for a TOR exemption and that we made ''myriad errors'' in determining that it was eligible for a TOR exemption. Because TOR exemption No. 2005–006 is not subject to the objections and hearing procedure in section 409(f) of the FD&C Act, we will not address the arguments detailed in ''objection'' 1.

To the extent that any of the arguments made in ''objection'' 1 may be construed as also pertaining to the petitioners' request to amend § 177.1210 to remove potassium perchlorate as an allowed additive in closure-sealing gaskets for food containers, a request that is subject to section 409(f) of the FD&C Act, this request became moot when we amended § 177.1210 to no longer authorize this use of potassium perchlorate because it had been abandoned (see 82 FR 20847 at 20849). A hearing will not be granted on factual issues that are not determinative with respect to the action requested (see § 12.24(b)(4)). Therefore, to the extent that ''objection'' 1 pertains to the petitioners' request to amend § 177.1210, we are overruling the submission's objection and denying the submission's request for a hearing on this point.

The submission's second ''objection'' challenges as ''contrary to law'' FDA's determination that the petition's requests to revoke TOR exemption No. 2005–006 and issue a regulation under part 189 are not within the scope of a food additive petition. Section 409(f)(1) of the FD&C Act permits objections and requests for a hearing only to orders made under section 409(c) and (d) of the FD&C Act. Because FDA's denial of the petitioners' TOR revocation request and part 189 request was not an order under section 409(c)(1)(B) of the FD&C Act (see 82 FR 20847 at 20850), the submission's second ''objection'' is not an objection to an order under section 409(c)(1)(B) of the FD&C Act and is not subject to the objections and hearing procedure in section 409(f) of the FD&C Act. Therefore, we will not address the arguments presented in ''objection'' 2.

B. Objection 3

Objection 3 challenges FDA's determination that the petitioners' request to amend § 177.1210 was moot when we issued a final rule in response to the abandonment petition that removed potassium perchlorate as an allowed additive in closure-sealing gaskets for food containers. Specifically, the submission alleges that FDA's mootness determination was ''poor public policy'' because it discourages industry to file abandonment petitions except in the face of a petition that may find the use no longer safe, and unfair to the petitioners, whose petition was filed before the abandonment petition.

In presenting objection 3, the submission fails to identify any specific factual dispute that could be resolved by a hearing. Accordingly, we are denying the submission's hearing request on objection 3 because a hearing will not be granted on issues of policy (§ 12.24(b)(1)). We also note that, in granting the abandonment petition and removing potassium perchlorate as an allowed additive in closure-sealing gaskets for food containers, we took the third action requested in the petition. As stated in response to a similar comment from the petitioners to the filing notice for the abandonment petition, FDA has numerous responsibilities related to food additives, and we receive and respond to hundreds of submissions annually under the various petition and notification programs that we administer. Accordingly, if a use of a food additive is no longer authorized in response to an abandonment petition, we may determine that it is neither necessary nor an efficient use of our limited resources to address safety arguments related to an abandoned use (see 82 FR 20829 at 20831).

V. Summary and Conclusion

After evaluating the objections from the submitters, we have concluded that ''objections'' 1 and 2 are not within the scope of the objections and hearing provision under section 409(f) of the FD&C Act. Therefore, we do not address the arguments related to these ''objections'' and we do not address the related requests for a hearing. To the extent that ''objection'' 1 pertains to the petitioners' request to amend § 177.1210, this request became moot when we amended § 177.1210 to no longer authorize this use of potassium perchlorate, and therefore we are overruling the submission's objection and denying the request for a hearing on this point. Objection 3 does not provide any basis to reconsider our decision to

deny the petition. We also have determined that objection 3 does not raise any genuine and substantial issue of fact that would justify an evidentiary hearing. Therefore, we are overruling this objection and are denying the related request for a hearing.

Dated: April 17, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–08262 Filed 4–23–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2019–N–1250]

General and Plastic Surgery Devices; Reclassification of Certain Surgical Staplers

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is proposing to reclassify surgical staplers for internal use (currently regulated under the classification for ''manual surgical instrument for general use'' and assigned the product code GAG) from class I (general controls) into class II (special controls) and subject to premarket review. FDA is identifying the proposed special controls for surgical staplers for internal use that the Agency believes are necessary to provide a reasonable assurance of the safety and effectiveness of the device. FDA is proposing this reclassification on its own initiative based on new information. As part of this reclassification, FDA is also proposing to amend the existing classification for ''manual surgical instrument for general use'' to remove staplers and to create a separate classification regulation for surgical staplers that distinguishes between surgical staplers for internal use and external use.

DATES: Submit either electronic or written comments on the proposed order by June 24, 2019. Please see section XI of this document for the proposed effective date of any final order that may publish based on this proposed order.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 24, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 24, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal Rulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–1250 for ''General and Plastic Surgery Devices; Reclassification of Certain Surgical Staplers.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: R. Dale Rimmer, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G425, Silver Spring, MD 20993, 240–402–4828, *ralph.rimmer@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to

provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Section 513(a)(1) of the FD&C Act defines the three classes of devices. Class I devices are those devices for which the general controls of the FD&C Act (controls authorized by or under section 501, 502, 510, 516, 518, 519, or 520 (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, or 360j) or any combination of such sections) are sufficient to provide reasonable assurance of safety and effectiveness; or those devices for which insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness or to establish special controls to provide such assurance, but because the devices are not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and do not present a potential unreasonable risk of illness or injury, are to be regulated by general controls (section 513(a)(1)(A) of the FD&C Act). Class II devices are those devices for which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions the Agency deems necessary to provide such assurance (section 513(a)(1)(B) of the FD&C Act). Class III devices are those devices for which insufficient information exists to determine that general controls and special controls would provide a reasonable assurance of safety and effectiveness, and which are purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or which present a potential unreasonable risk of illness or injury (section 513(a)(1)(C) of the FD&C Act).

Under section 513(d)(1) of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments (Medical Device Amendments of 1976, Pub. L. 94–295), May 28, 1976 (generally referred to as ''preamendments devices''), are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution before May 28, 1976 (generally referred to as ''postamendments devices''), are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless, and until: (1) FDA reclassifies the device into class I or II or (2) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the FD&C Act and part 807, subpart E of the regulations (21 CFR part 807).

On July 9, 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144). Section 608(a) of FDASIA amended section 513(e) of the FD&C Act, changing the process for reclassifying a device from rulemaking to an administrative order. Section 513(e)(1)(A)(i) of the FD&C Act sets forth the process for issuing a final order. Specifically, prior to the issuance of an administrative order reclassifying a device, the following must occur: (1) Publication of a proposed reclassification order in the **Federal Register**, (2) a meeting of a device classification panel described in section 513(b) of the FD&C Act, and (3) consideration of comments to a public docket. The proposed reclassification order must set forth the proposed reclassification and a substantive summary of the valid scientific evidence concerning the proposed reclassification, including the public health benefits of the use of the device, and the nature and incidence (if known) of the risks of the device.

Section 513(e)(1)(A)(i) provides that FDA may, by administrative order, reclassify a device based on ''new information.'' FDA can initiate a reclassification under section 513(e) or an interested person may petition FDA. The term ''new information,'' as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, *e.g., Holland-Rantos* v. *United States Dep't of Health, Educ. & Welfare,* 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn Co.* v. *Finch,* 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard,* 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell* v. *Goddard,* 366 F.2d 177, 181 (7th Cir. 1966)) or in light of changes in ''medical science'' (see *Upjohn Co.* v. *Finch,* 422 F.2d 944, 951 (6th Cir. 1970)). Whether data before the Agency are old or new, the ''new information'' to support reclassification under section 513(e) of the FD&C Act must be ''valid scientific evidence'', as defined in section 513(a)(3) of the FD&C Act and 21 CFR 860.7(c)(2). (See, *e.g., General Medical Co.* v. *FDA,* 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Mfrs. Assoc.* v. *FDA,* 766 F.2d 592 (D.C. Cir.1985), cert. denied, 474 U.S. 1062 (1986)).

FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the ''valid scientific evidence'' upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, *e.g.,* the contents of a pending premarket approval application (see section 520(c) of the FD&C Act).

Section 510(m) of the FD&C Act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the FD&C Act if the Agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device. FDA has determined that premarket notification is necessary to reasonably assure the safety and effectiveness of surgical staplers for internal use. Therefore, the Agency does not intend to exempt this proposed class II device from premarket notification (510(k)) submission as provided under section 510(m) of the FD&C Act.

II. Regulatory History of the Devices

Surgical staplers were classified in part 878 (21 CFR part 878) in a final rule published in the **Federal Register** on June 24, 1988 (53 FR 23856), that classified 51 general and plastic surgery devices. This 1988 rule classified staplers into class I (general controls).

These devices were grouped with other devices under ''Manual surgical instrument for general use'' in § 878.4800 (21 CFR 878.4800). At the time, surgical staplers had been in common use in medical practice for many years, and FDA believed that general controls were sufficient to provide reasonable assurance of the safety and effectiveness of those devices. This rule was amended on April 5, 1989 (54 FR 13826), to clarify that manual surgical instruments for general use, § 878.4800, made of the same materials as used in the preamendments devices were exempt from premarket notification (510(k)) review.

On December 7, 1994, FDA further amended the classification when it published a final rule in the **Federal Register** (59 FR 63005) that exempted 148 class I devices from premarket notification, with limitations. Surgical staplers were one of those exempted devices. FDA determined that manufacturers' submissions of premarket notifications were unnecessary for the protection of the public health and that FDA's review of such submissions would not advance its public health mission.

On March 8, 2019, FDA issued a letter to healthcare providers to inform them of the risks associated with misuse of surgical staplers and to provide recommendations for reducing the risk of adverse events associated with these devices (Ref. 1). This letter recommends that users carefully follow the stapler manufacturer's instructions for use and provides additional recommendations for selecting the appropriate staple sizes and tissue types appropriate for use with the stapler.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability for a draft guidance entitled ''Surgical Staplers and Staples for Internal Use—Labeling Recommendations; Draft Guidance for Industry and Food and Drug Administration Staff.'' As identified in this draft guidance, FDA has become aware of a large number of adverse events associated with surgical staplers and staples for internal use. This draft guidance communicates FDA's recommendations for contraindications, warnings, directions for use, and technical characteristics and performance parameters to be included in the product labeling to help promote the safe and effective use of surgical staplers and staples for internal use. This draft guidance also provides recommendations for content to be included in the package labels, so that users may easily look at the label and obtain critical information necessary for proper device selection.

Surgical staples are currently regulated as class II devices under 21 CFR 878.4750 (Implantable staple) and are subject to premarket notification (510(k)) review. FDA does not intend to change the classification of surgical staples at this time and they are outside the scope of this reclassification action.

III. Device Description

A surgical stapler is a specialized prescription device used to deliver compatible staples during surgery. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met.

To delineate between surgical staplers and their intended uses, FDA has identified two subsets of surgical staplers: (1) Surgical staplers for internal use and (2) surgical staplers for external use.

A surgical stapler for internal use is a specialized prescription device used to deliver compatible staples to internal tissues during surgery for removing part of an organ (*i.e.,* resection), cutting through organs and tissues (*i.e.,* transection), and creating connections between structures (*i.e.,* anastomoses). It may be used in open, minimally invasive, and endoscopic surgery. Surgical staplers for internal use may be indicated for use in a wide range of surgical applications, including, but not limited to, gastrointestinal, gynecologic, and thoracic surgery.

Many types of surgical staplers for internal use exist, including, but not limited to, linear non-cutting staplers, transverse approximating staplers, transverse anastomoses staplers, gastrointestinal anastomoses linear cutting (articulating and non-articulating) staplers, and circular (*i.e.,* end-to-end anastomoses) staplers. Surgical staplers for internal use include both manual and powered staplers.

A surgical stapler for external use is a specialized prescription device used to deliver compatible staples to skin during surgery. FDA is proposing to reclassify internal staplers only; external staplers will remain class I, exempt from premarket review.

IV. Proposed Reclassification

FDA is proposing to reclassify surgical staplers for internal use from class I (general controls), exempt from premarket review, to class II (special controls), subject to premarket review. FDA believes that general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness for these devices, and that there is sufficient information to establish special controls to provide such assurance. In accordance with section 513(e)(1)(A)(i) of the FD&C Act, FDA, on its own initiative, is proposing to reclassify these devices based on new information. The process for issuing a final order for reclassification of a device from class I to class II pursuant to section 513(e) of the FD&C Act is provided in 21 CFR 860.130 of the regulations. Specifically, prior to the issuance of a final order reclassifying a device, the following must occur: (1) Publication of a proposed reclassification order in the **Federal Register**; (2) a meeting of a device classification panel described in section 513(b) of the FD&C Act; and (3) consideration of comments to a public docket. The Commissioner of Food and Drugs is required to consult with a classification panel and may secure a recommendation with respect to the reclassification of the device. FDA will consult with the panel regarding the reclassification of the device in accordance with the procedures set forth in 21 CFR 860.125 and intends to secure the panel's recommendation. If FDA issues a final order, the Agency will publish the panel's recommendation in the **Federal Register** when the Agency publishes the final order.

FDA is also proposing to revise § 878.4800 (Manual surgical instrument for general use) to remove staplers and to create a separate classification regulation in part 878 for surgical staplers that distinguishes between surgical staplers for internal use and external use.

V. Public Health Benefits and Risks to Health

As required by section 513(e)(1)(A)(i) of the FD&C Act, FDA is providing a substantive summary of the valid scientific evidence concerning the proposed reclassification including the public health benefit of the use of surgical staplers for internal use, and the nature, and if known, the incidence of the risk of the devices, as discussed in section VI of this proposed order.

Surgical staplers for internal use provide benefit to the public health by facilitating surgical procedures and allowing for shorter surgical procedure times compared to manual suturing.

FDA has evaluated the risks to health associated with the use of surgical staplers for internal use and has identified the following risks for this device:

• *Complications associated with device failure/malfunction.* Device failures or malfunctions may result in prolonged surgical procedures, unplanned surgical interventions, and other complications such as bleeding, sepsis, fistula formation, tearing of internal tissues and organs, increased risk of cancer recurrence, and death.

• *Complications associated with use error/improper device selection and use.* Use error may result from a device design that is difficult to operate and/or labeling that is difficult to comprehend. For example, user difficulty in firing the stapler may result in staples not being fully deployed, and misfiring may result in staples being inadvertently applied to the wrong tissue. Inadequate instructions for use may result in selection of incorrectly sized staples for the target tissue. When staples are applied to the wrong tissue or when incorrectly sized staples are applied, staples are unable to properly approximate the underlying tissue, resulting in tissue damage, anastomotic leakage, and bleeding. This in turn, may lead to more severe complications, such as abscess, sepsis, peritonitis, hemorrhage, or death.

• *Adverse tissue reaction.* If the patient-contacting materials of the device are not biocompatible, local tissue irritation and sensitization, cytotoxicity, or systemic toxicity may occur when the device contacts sterile tissue.

• *Infection.* If the device is not adequately reprocessed or sterilized, the device may introduce pathogenic organisms into sterile tissue and may cause an infection in a patient.

As discussed further in this document, these findings regarding the public health benefits and risks to health associated with surgical staplers for internal use are based on publicly available information, including Medical Device Reporting (MDR) analyses, recalls, and the published literature.

VI. Summary of Data Upon Which the Reclassification Is Based

Surgical staplers for internal use have been shown to provide several benefits over manual suturing, including reduction in surgical time, reduced tissue trauma/manipulation, reduction in surgical contamination by intestinal contents, and simple closure of vessels and/or tissues (Ref. 2); however, they have also been associated with numerous adverse events.

As discussed below, based on a review of the MDR database, recalls database, and the published scientific literature, there have been many malfunctions and other problems associated with surgical staplers for internal use, and some of these malfunctions or other problems have been associated with serious complications, including death.

Because surgical staplers are used together with staples as a system, a search of the MDR database was conducted for both surgical staplers for internal use under product code GAG (Stapler, Surgical) and surgical staples for internal use under product code GDW (Staple, Implantable) to obtain a comprehensive picture of the safety profile for surgical staplers for internal use. From January 1, 2011, to March 31, 2018, FDA received over 41,000 individual MDRs for surgical staplers and staples for internal use, including 366 deaths, over 9,000 serious injuries, and over 32,000 malfunctions. Some of the most commonly reported problems in these adverse event reports include an opening of the staple line or malformation of staples, misfiring, difficulty in firing, failure of the stapler to fire the staple, and misapplied staples (*e.g.,* user applying staples to the wrong tissue or applying staples of the wrong size to tissue). Although the majority of the adverse events were reported under product code GDW, FDA believes that many of the problems identified in these reports can be primarily attributed to surgical staplers for internal use, since proper staple formation is largely contingent on proper function and use of the stapler.

Of the 366 deaths, the cause of death was associated with an opening of the staple line or malformation of staples in 159 reports, bleeding during surgery in 53 reports, sepsis in 47 reports, peritonitis in 5 reports, necrosis in 5 reports, and air embolism in 4 reports. Additionally, of the 366 deaths, 195 reports included misfiring, difficulty in firing, and/or misapplied staples. Common reasons cited for these problems included mechanical issues with the device (*e.g.,* mechanical jams), broken device components, and the device operating differently than the user expected (*e.g.,* different force needed to deploy the device than expected). In 11 of the 366 deaths, use error was determined to be a contributing factor to the death. Many of the same complications that resulted in death (*e.g.,* bleeding during surgery, peritonitis, and sepsis) were also reported in the serious injury reports; additional complications commonly reported in the serious injury reports included tissue damage, organ perforation or dehiscence, fistula formation, infection, hernia, and pain.

The majority of staplers reported in these adverse events were linear staplers, including articulating and curved tip linear staplers, followed by circular staplers. Of the 366 deaths, 262 deaths were reported for linear staplers while 63 were reported for circular staplers; of the remaining 41 deaths, a type of stapler was not identified in the MDR. The staplers involved in these adverse events spanned a variety of different manufacturers; there were no distinct differences between manufacturers and the reported causes of death.

Of the 41,000 individual MDRs, over 32,000 MDRs were received for malfunctions, under either the product code GAG (Stapler, Surgical) or product code GDW (Staple, Implantable). The most common device-related malfunctions included failure of the stapler to fire the staple, failure to form staples, difficulty of opening/closing the stapler, stapler misfiring, and stapler breakage. The most commonly reported patient consequences from malfunctions with surgical staplers for internal use included a delay in surgical procedure, hemorrhage, and tissue damage. It should be noted that some patient consequences may not be limited to a single reporting category of death, serious injury, or malfunction. For example, a malfunction could result in sepsis, which could lead to other serious injury and later death.

The types and incidence of malfunctions and clinical consequences to patients seen in the adverse event reports are also corroborated by the published literature. In a systematic review of 30 clinical studies (Refs. 3 to 32), including randomized controlled trials and observational studies, the occurrence of stapler malfunctions in these studies ranged from incidents in 0 to 19.2 percent (median = 1.8 percent) of patients and 0.1 to 5.2 percent of deployments.

Consistent with the malfunctions seen in the adverse event reports received by FDA, the most common malfunctions reported in these clinical studies were related to opening of the staple line or malformation of staples. In these studies, malformed staples and/or staple lines comprised 31.8 percent of the malfunctions, while missing staples and/or staple lines not forming comprised 19.5 percent of the malfunctions. Problems with stapler firing and/or stapler function were also commonly reported. Device sticking, locking, and/or jamming comprised 15.9 percent of the malfunctions, while stapler misfiring comprised 10.3 percent of the malfunctions. Inability of the stapler to cut through tissue comprised

3.1 percent of the malfunctions, while stapler breakage comprised 2.6 percent of all malfunctions. Finally, problems with the stapler cartridge not loading properly comprised 2.1 percent of the malfunctions. Although the majority of studies in the systematic literature review did not report on the incidence of stapler problems associated with use error, a prospective, single-arm study evaluating use of a surgical stapler in gastrointestinal stapling applications found that 3.5 percent of stapler deployments in the study (15 of 423 deployments) were attributed to use error (Ref. 10). Additionally, as discussed further below, common causes for surgical complications reported in the literature include use error.

While 75.8 percent of the stapler malfunctions in these studies did not result in any major consequences to the patient, 10.5 percent of the malfunctions resulted in the need to convert to open surgery, while 9.7 percent of the malfunctions resulted in hemorrhage; 4.0 percent of the malfunctions resulted in both hemorrhage and the need to convert to open surgery. In addition, multiple studies suggest that surgical stapler malfunctions are associated with a higher risk of complications. In a retrospective study of 349 colorectal resections using a circular stapler, surgeries with surgical stapler malfunctions were found to have higher incidences of unplanned proximal diversions, ileus, gastrointestinal bleeding, and blood transfusions (Ref. 27). In a retrospective study of 1,174 patients undergoing liver transections using a stapler device, surgeries with surgical stapler malfunctions were found to have a higher likelihood of transfusion, higher median blood loss, and higher odds of morbidity and mortality compared to surgeries without stapler malfunctions (Ref. 28). Anastomotic leaks from surgical stapler malfunctions have also been associated with an increased risk of cancer recurrence (Refs. 33 to 35). Altogether, the adverse event reports and published literature indicate that surgical stapler malfunctions are not uncommon and may produce adverse outcomes such as conversion to open surgery, bleeding, morbidity, and death.

Common causes for surgical complications reported in the literature also include the use of incorrectly sized staples for the tissue, incorrect use of the device by the user, and improper use of the device for the condition of the patient's tissues, which may result in reoperation or prolonged hospitalization (Ref. 36). For example, early postoperative anastomotic leak due to such device issues may result in a septic patient with peritonitis, requiring immediate surgery with diversion of stool into a stoma. Minor or delayed anastomotic leaks due to such device issues may result in an intra-abdominal abscess requiring surgical or other invasive drainage procedures, temporary diversion of stool, and prolonged intravenous nutrition. These complications commonly result in prolonged hospital stays (Ref. 37). Altogether, the adverse event reports and published literature indicate that surgical stapler for internal use use error may cause or contribute to surgical complications, *e.g.,* anastomotic leaks, abscess, sepsis, peritonitis, and death.

From November 1, 2002, to December 30, 2018, FDA received a total of 168 recalls for surgical staplers and staples for internal use under product codes GAG and GDW, including one class I recall and 167 class II recalls. The class I recall was for a hemorrhoidal circular stapler that may result in incomplete staple formation due to difficulty in firing. Of the 167 class II recalls, the most common reasons for recall included non-conforming device components or device design-related issues that may result in incomplete staple formation, failure to form a staple line, malformed staples, or difficulty in firing. Several devices were also recalled due to a potential breach in sterility.

FDA acknowledges that the available valid scientific evidence, including the review of the MDR database, recalls database, and the published literature, primarily discuss surgical staplers for internal use, and not surgical staplers for external use. At this time, FDA does not believe that available information suggests that reclassification of surgical staplers for external use is necessary to maintain a reasonable assurance of safety and effectiveness of these devices.

Based on its review of the MDR database, recalls database, and the published literature, FDA has tentatively determined that special controls, in addition to general controls, are necessary to provide a reasonable assurance of safety and effectiveness for surgical staplers for internal use. FDA believes the establishment of special controls is necessary to ensure that the risks to health are adequately mitigated by an assessment of these devices through completion of performance testing, usability and labeling comprehension testing, biocompatibility evaluation, sterility and shelf-life testing, and adequate labeling. In addition, FDA believes that design controls under 21 CFR 820.30 are necessary to ensure that specified design requirements are met and to ensure compatibility of surgical staplers for internal use with staples. Therefore, FDA, on its own initiative, is proposing to reclassify these devices from class I into class II (special controls) subject to premarket review.

VII. Summary of Reasons for Reclassification

Based on the information reviewed by FDA, including the valid scientific evidence regarding the public health benefit and nature and incidence of the risk of the devices discussed in section VI, FDA tentatively concludes that special controls, in addition to general controls, are necessary to provide a reasonable assurance of safety and effectiveness for surgical staplers for internal use. Therefore, FDA proposes to reclassify surgical staplers for internal use from class I into class II (special controls).

VIII. Proposed Special Controls

FDA believes that the following special controls, together with general controls, are necessary and sufficient to mitigate the risks to health described in section V (complications associated with device failure/malfunction, complications associated with use error/improper device selection and use, adverse tissue reaction, and infection) and provide a reasonable assurance of safety and effectiveness for surgical staplers for internal use.

Both device misuse and device malfunctions are root causes of the adverse events associated with use of surgical staplers for internal use (Ref. 38). Device misuse may be exacerbated by inadequate instructions for use and insufficient warnings or precautions in the device labeling (Ref. 39). To mitigate the risks of tissue damage, anastomotic leakage, and bleeding arising from use error or improper device use, FDA believes that the labeling must include specific instructions for device use, including procedures associated with proper device use and measures for preventing device malfunction, evaluating the appropriateness of the target tissue for stapling, and evaluating the resultant staple line. To further mitigate these risks, the labeling must also include appropriate warnings, contraindications, and limitations needed for safe use of the device. To prevent stapler malfunction (*e.g.,* from stapler jamming, locking, sticking, or misfiring), information on the staples with which the stapler is compatible must be provided in the labeling, such as models of compatible staples, cartridge colors/staple heights, staple rows per cartridge, staple patterns, and

maximum and minimum tissue thicknesses for each staple type. To prevent improper application of staples to target tissue, the recommended tissues (*e.g.,* tissue thicknesses and tissue types) on which the stapler is intended to be used must be identified in the labeling. Unless data demonstrates the safety of doing so, contraindications must be identified regarding use of the device on tissues for which the risk of stapling outweighs any reasonably foreseeable benefit due to known complications, including the stapling of necrotic or ischemic tissues and tissues outside of the labeled limits of tissue thickness. The labeling must provide appropriate warnings regarding how to avoid known hazards associated with device use, including avoidance of obstructions to the creation of a staple line (*e.g.,* clips) and the unintended stapling of other anatomic structures; avoidance of clamping and unclamping of delicate tissue structures (*e.g.,* venous structures and bile ducts) to prevent tissue damage; avoidance of use of the stapler on large blood vessels, such as the aorta; establishing and maintaining proximal control of blood vessels prior to stapling; appropriate measures to take if a stapler malfunction occurs while applying staples across a blood vessel, such as clamping or ligating the vessel before releasing the stapler, while the stapler is still closed on the tissue; and ensuring stapler compatibility with staples, unless information is provided demonstrating that the warnings do not apply to a particular device. Usability testing and a labeling comprehension study must demonstrate that the clinician can correctly select and use the device for its indicated use based on the information in the labeling.

To mitigate the risk of complications associated with device failure or device malfunction, adequate performance testing is needed to ensure that the stapler with compatible staples performs as intended under anticipated conditions of use. FDA believes that adequate performance testing must include an evaluation of staple formation characteristics in the maximum and minimum tissue thicknesses for each staple type; measurement of the worst-case deployment pressures on stapler firing force; and a measurement of staple line strength. Performance testing must also demonstrate confirmation of staple line integrity (*e.g.,* through the absence of vertically contiguous malformed staples), as well as in vivo confirmation of staple line hemostasis following staple deployment.[1]

FDA believes that the inclusion of important technical characteristics and device performance parameters in the labeling will also help mitigate use error and device malfunctions by informing end users on device limitations. Therefore, FDA believes that the labeling must identify key technical characteristics and performance parameters of the surgical stapler and compatible staples needed for safe use of the device. Key technical characteristics include stapler specifications (*e.g.,* jaw length, shaft length, jaw opening, and angles of articulation), as well as compatible staple specifications (*e.g.,* open and closed staple heights). Key technical characteristics also include identification of any safety mechanisms of the stapler, such as a color-firing zone and/or lock-out mechanism. Examples of key performance parameters include information on firing the stapler, such as the firing force, pre-fire compression time, and maximum number of consecutive firings, and information relevant to creating a staple line, such as the percentage of properly formed staples, number of incremental firings required to complete a staple line, and maximum number of reloads.

FDA believes that the device must be demonstrated to be biocompatible because the risk of adverse tissue reaction may result from contact of the materials of the device with the body. Additionally, because the risk of infection can arise from a contaminated device, sterility testing must demonstrate the sterility of the device. If any components of the device are reusable, the labeling must include validated methods and instructions for cleaning and sterilization of these reusable components. Validation of cleaning and sterilization instructions must demonstrate that any reusable device components can be safely and effectively reprocessed per the recommended cleaning and sterilization protocol in the labeling.

In addition, loss of package integrity can result in compromised sterility and compromised device performance over time. Therefore, shelf-life testing must demonstrate that the device maintains its performance characteristics and the packaging of the device maintains its integrity for the duration of the proposed shelf-life. Finally, the labeling must also specify an expiration date to inform users of the shelf-life of the device based on the shelf-life testing.

Table 1 shows how FDA believes each risk to health described in section V would be mitigated by the proposed special controls.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR SURGICAL STAPLERS FOR INTERNAL USE

Identified risks to health	Mitigation measures
Complications associated with device failure/malfunction	Performance testing and Labeling.
Complications associated with use error/improper device selection and use.	Usability testing, Labeling comprehension study, and Labeling.
Adverse Tissue Reaction	Biocompatibility evaluation.

[1] FDA supports the principles of the ''3Rs,'' to reduce, refine, and replace animal use in testing when feasible. FDA encourages sponsors to consult with FDA if they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. FDA will consider if such an alternative method could be assessed for equivalency to an animal test method.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR SURGICAL STAPLERS FOR INTERNAL USE—Continued

Identified risks to health	Mitigation measures
Infection	Labeling, Sterility testing, and Shelf-Life testing.

If finalized, the reclassification of surgical staplers for internal use into class II would subject these devices to premarket notification under section 510(k) of the FD&C Act and part 807, subpart E, and the identified special controls in this order. FDA believes that the proposed reclassification would provide reasonable assurance of safety and effectiveness of surgical staplers for internal use.

IX. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed order contains no new collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520) is not required. This proposed order refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

XI. Proposed Effective Date

FDA proposes that any final order based on this proposed order become effective on its date of publication in the **Federal Register**.

- Surgical staplers for internal use that have not been offered for sale prior to the effective date of the final order or have been offered for sale but are required to submit a new 510(k) under 21 CFR 807.81(a)(3): Manufacturers would have to obtain 510(k) clearance before marketing their devices after the effective date of the order. If a manufacturer markets such a device without receiving 510(k) clearance, then FDA would consider taking action against such a manufacturer under its usual enforcement policies.
- Surgical staplers for internal use that have been offered for sale prior to the effective date of the final order and do not already have 510(k) clearance: FDA does not intend to enforce compliance with the 510(k) requirement or special controls until 180 days after the effective date of the final order. After that date, if a manufacturer continues to market such a device but does not have 510(k) clearance or FDA determines that the device is not substantially equivalent or not compliant with special controls, then FDA would consider taking action against such manufacturer under its usual enforcement policies.

For surgical staplers for internal use that have prior 510(k) clearance, FDA would accept a new 510(k) and would issue a new clearance letter, as appropriate, indicating substantial equivalence and special controls compliance. These devices could serve as predicates for new devices. These clearance letters would be made publicly available in FDA's 510(k) database, and compliance with special controls at the time of clearance would also be stated in the publicly available 510(k) Summary posted in this database. FDA believes that our public database is a transparent tool allowing users to confirm that their devices have been submitted under a new 510(k) and demonstrated conformance to applicable special controls.

XII. Codification of Orders

Prior to the amendments by FDASIA, section 513(e) of the FD&C Act provided for FDA to issue regulations to reclassify devices. Although section 513(e) as amended requires FDA to issue final orders rather than regulations, it also provides for FDA to revoke previously issued regulations by order. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as changes to codified classification determinations or as newly codified orders. Therefore, under section 513(e)(1)(A)(i), as amended by FDASIA, in the proposed order, we are proposing to revoke the classification of surgical staplers in § 878.4800 and to codify surgical staplers in the new 21 CFR 878.4740, under which surgical staplers for internal use would be reclassified into class II and surgical staplers for external use would remain in class I.

XIII. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; references with website addresses are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 878 be amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l*, 371.

■ 2. Add § 878.4740 to subpart E to read as follows:

§ 878.4740 Surgical stapler.

(a) *Surgical stapler for external use.* (1) *Identification.* A surgical stapler for external use is a specialized prescription device used to deliver compatible staples to skin during surgery.

(2) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

(b) *Surgical stapler for internal use.* (1) *Identification.* A surgical stapler for internal use is a specialized prescription device used to deliver compatible staples to internal tissues during surgery for resection, transection, and creating anastomoses.

(2) *Classification.* Class II (special controls). The special controls for this device are:

(i) Performance testing must demonstrate that the stapler, when used with compatible staples, performs as intended under anticipated conditions of use. Performance testing must include the following:

(A) Evaluation of staple formation characteristics in the maximum and minimum tissue thicknesses for each staple type;

(B) Measurement of the worst-case deployment pressures on stapler firing force;

(C) Measurement of staple line strength;

(D) Confirmation of staple line integrity; and

(E) In vivo confirmation of staple line hemostasis.

(ii) Usability testing and a labeling comprehension study must demonstrate that the clinician can correctly select and use the device, as identified in the labeling, based on reading the directions for use.

(iii) The elements of the device that may contact the patient must be demonstrated to be biocompatible.

(iv) Performance data must demonstrate the sterility of the device.

(v) Validation of cleaning and sterilization instructions must demonstrate that any reusable device components can be safely and effectively reprocessed per the recommended cleaning and sterilization protocol in the labeling.

(vi) Performance data must support the shelf life of the device by demonstrating continued device functionality, sterility, and package integrity over the identified shelf life.

(vii) Labeling of the device must include the following:

(A) Unless data demonstrates the safety of doing so, contraindications must be identified regarding use of the device on tissues for which the risk of stapling outweighs any reasonably foreseeable benefit due to known complications, including the stapling of necrotic or ischemic tissues and tissues outside of the labeled limits of tissue thickness.

(B) Unless available information demonstrates that the specific warnings do not apply, the labeling must provide appropriate warnings regarding how to avoid known hazards associated with device use including:

(*i*) Avoidance of obstructions to the creation of the staple line and the unintended stapling of other anatomic structures;

(*ii*) Avoidance of clamping and unclamping of delicate tissue structures to prevent tissue damage;

(*iii*) Avoidance of use of the stapler on large blood vessels, such as the aorta;

(*iv*) Establishing and maintaining proximal control of blood vessels prior to stapling;

(*v*) Appropriate measures to take if a stapler malfunction occurs while applying staples across a blood vessel, such as clamping or ligating the vessel before releasing the stapler, while the stapler is still closed on the tissue; and

(*vi*) Ensuring stapler compatibility with staples.

(C) Specific user instructions for proper device use including measures associated with the prevention of device malfunction, evaluation of the appropriateness of the target tissue for stapling, and evaluation of the resultant staple line.

(D) List of staples with which the stapler has been demonstrated to be compatible.

(E) Identification of key performance parameters and technical characteristics of the stapler and the compatible staples needed for safe use of the device.

(F) Information regarding tissues on which the stapler is intended to be used.

(G) Identification of safety mechanisms of the stapler.

(H) Validated methods and instructions for reprocessing of any reusable device components.

(I) An expiration date/shelf life.

(viii) Package labels must include critical information and technical characteristics necessary for proper device selection.

■ 3. In § 878.4800, revise paragraph (a) to read as follows:

§ 878.4800 Manual surgical instrument for general use.

(a) *Identification.* A manual surgical instrument for general use is a nonpowered, hand-held, or hand-manipulated device, either reusable or disposable, intended to be used in various general surgical procedures. The device includes the applicator, clip applier, biopsy brush, manual dermabrasion brush, scrub brush, cannula, ligature carrier, chisel, clamp, contractor, curette, cutter, dissector, elevator, skin graft expander, file, forceps, gouge, instrument guide, needle guide, hammer, hemostat, amputation hook, ligature passing and knot-tying instrument, knife, blood lancet, mallet, disposable or reusable aspiration and injection needle, disposable or reusable suturing needle, osteotome, pliers, rasp, retainer, retractor, saw, scalpel blade, scalpel handle, one-piece scalpel, snare, spatula, disposable or reusable stripper, stylet, suturing apparatus for the stomach and intestine, measuring tape, and calipers. A surgical instrument that has specialized uses in a specific medical specialty is classified in separate regulations in parts 868 through 892 of this chapter.

* * * * *

Dated: April 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–08260 Filed 4–23–19; 8:45 am]

BILLING CODE 4164–01–P

POSTAL SERVICE

39 CFR Part 551

Definition of Private Carrier for Premium PO Box Delivery

AGENCY: Postal Service™.

ACTION: Advanced Notice of Proposed Rulemaking.

SUMMARY: The Postal Service seeks customer and other stakeholder feedback to define the phrase ''packages from private carriers,'' as used in connection with PO Box Street Addressing. The Postal Service is contemplating an amendment to *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM®) to clarify the Street Addressing Additional Service available at many Premium Post Office Box Service locations.

DATES: Comments must be received on or before June 24, 2019.

ADDRESSES: Mail or deliver written comments to the Manager, Product Classification, U.S. Postal Service, 475 L'Enfant Plaza SW, Room 4446, Washington, DC 20260–5015. Email comments and questions to *ProductClassification@usps.gov* using the subject line ''Street Addressing at Premium PO Box Service Locations.'' Faxed comments will not be accepted.

FOR FURTHER INFORMATION CONTACT: Derek F. Hatten, Sr. Retail Services Specialist, Retail Partners and Services, 202–268–6919, *derek.f.hatten@usps.gov.*

SUPPLEMENTARY INFORMATION: On June 17, 2010, the Postal Regulatory Commission (PRC) approved the initial request of the Postal Service to transfer some Post Office Box (PO Box™) Service locations from the market dominant list to the competitive product list (see Order No. 473, Order Approving Request to Transfer Selected Post Office Box Service Locations to the Competitive Product List, PRC Docket No. MC2010–20). Additional locations were transferred following PRC approval in subsequent Order No. 780, Order Approving Request to Transfer Additional Post Office Box Service Locations to the Competitive Product List, PRC Docket No. MC2011–25 (Jul. 29, 2011). At these locations, the Postal Service now provides some of the same services offered by its competitors. These ''Additional Services,'' which are available at Premium PO Box service locations (formerly referred to as ''Move To Competitive'' locations) for no additional fee above the PO Box fees, include a service called ''Street Addressing.''

On February 14, 2013, language was added to the Mail Classification Schedule (MCS) describing the Street Addressing feature, including the option of receiving ''packages from private carriers'' (see Order No. 1657, Order on Elective Filing Regarding Post Office Box Service Enhancements, PRC Docket

No. MC2012–26; MCS § 2640.1.g). In related proceedings, the Postal Service explained that the delivery of private carrier packages would provide a service frequently requested by its customers, addressing a concern posed by the fact that some eCommerce merchants will not ship to a PO Box address (See *id.* at 6). A description of the Street Addressing feature was subsequently added to DMM 508.4.5.4.a, which states that customers who choose to use the street addressing designation also have the option of receiving packages from private carriers at the customer's Post Office Box address, if the packages conform to the maximum standards of 70 pounds in weight and 130 inches in combined length and girth. The street addressing feature may be used when the merchant or retailer does not accept the PO Box address format as a deliverable address.

When the Postal Service first introduced PO Box Street Addressing, there were very few private carriers or delivery competitors who would deliver packages to a PO Box customer. This made it simple for Premium PO Box Post Offices to accept and deliver packages that bore the street address equivalent of the PO Box address. They could easily recognize a private carrier, and accept and deliver the PO Box customer's packages with little concern as to whether the carrier was legitimate or the customer actually had requested that the package be delivered to the PO Box. However, as the shipping and delivery industry has evolved, so has the competition for last mile delivery.

Since the introduction of PO Box Street Addressing, a number of pilot efforts have aimed to reduce the delivery time of packages to the customer. These efforts include, but are not limited to, employees delivering packages using their personally owned vehicles, online retailers creating their own delivery operations, and retailers using crowdsourcing or taxi services to deliver packages. Where once the term ''private carriers'' would be commonly understood to include traditional shipping providers such as UPS and FedEx, now there are many more delivery options, including ''regional'' delivery companies such as LaserShip and localized or crowdsourced delivery startups such as PostMates and Deliv. Not all employees or persons who might deliver a package to a PO Box wear uniforms or are readily identified as being associated with a legitimate ''private carrier.'' Nor do all items submitted for delivery meet the traditional definition of a ''package'' according to Postal Service mailability standards. As one example, some Post Offices have been asked to accept open, tote-style shopping bags containing merchandise, in lieu of a sealed box or envelope. Others have been presented with packages labeled only with the customer's name but without the street address, and delivered by employees or contractors of a merchant with no clear indication of where the package originated.

As a practical matter, the advances in last mile delivery have created confusion as to who may deliver packages to a Premium PO Box customer when the customer uses the street address equivalent of their PO Box address to order merchandise. Therefore, the Postal Service seeks input on how the term ''private carriers,'' as used in DMM 508.4.5.4.a, should be defined, and how best to clarify that only properly sealed items mailed as a ''package'' may be delivered. These clarifications are necessary to ensure that Postal Service employees follow proper procedures, which helps prevent fraud and ensures the safety and security of customers and Postal Service personnel.

We will publish an appropriate amendment to 39 CFR part 551 if the Postal Service adopts any changes to the definition of ''packages from private carriers,'' as used in connection with Street Addressing, in DMM 508.4.5.4.a.

Ruth B. Stevenson,

Attorney, Federal Compliance.

[FR Doc. 2019–08222 Filed 4–23–19; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2019–0036; FRL–9992–64–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Infrastructure Requirements for the 2015 Ozone National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a state implementation plan (SIP) revision submittal from the State of Maryland for the 2015 ozone national ambient air quality standard (NAAQS or standard). Whenever EPA promulgates a new or revised NAAQS, states are required to make a SIP submission showing how the existing approved SIP has all the provisions necessary to meet the requirements of the new or revised NAAQS, or to add any needed provisions necessary to meet the revised NAAQS. The SIP revision is required to address basic program elements, including, but not limited to, regulatory structure, monitoring, modeling, legal authority, and adequate resources necessary to assure attainment and maintenance of the standards. These elements are referred to as infrastructure requirements. Maryland has made a submittal addressing the infrastructure requirements for the 2015 ozone NAAQS. EPA is proposing to approve Maryland's SIP revision addressing the infrastructure requirements for the 2015 ozone NAAQS in accordance with the requirements of section 110(a) of the Clean Air Act (CAA).

DATES: Written comments must be received on or before May 24, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R03–OAR–2019–0036 at *http://www.regulations.gov,* or via email to *spielberger.susan@epa.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Ellen Schmitt, Planning and Implementation Branch (3AD30), Air and Radiation Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814–5787. Ms. Schmitt can also be reached via

electronic mail at *schmitt.ellen@epa.gov.*

SUPPLEMENTARY INFORMATION: On October 11, 2018, the Maryland Department of the Environment (MDE) submitted a revision to its SIP to satisfy the requirements of section 110(a) of the CAA for the 2015 ozone NAAQS.

I. Background

On October 26, 2015, EPA issued a final rule revising both the primary and secondary NAAQS for ozone based on 8-hour average concentrations to 0.070 parts per million (ppm). Pursuant to section 110(a)(1) of the CAA, states are required to submit SIPs meeting the applicable requirements of section 110(a)(2) within three years after promulgation of a new or revised NAAQS or within such shorter period as EPA may prescribe. Section 110(a)(1) of the CAA provides the procedural and timing requirements for SIPs, while section 110(a)(2) lists specific elements that states must meet for infrastructure SIP requirements related to a newly established or revised NAAQS. Section 110(a)(2) requires states to address basic SIP elements such as requirements for monitoring, basic program requirements and legal authority that are designed to assure attainment and maintenance of the NAAQS. Section 110(a) imposes the obligation upon states to make a SIP submission to EPA for a new or revised NAAQS, but the contents of that submission may vary depending upon the facts and circumstances. In particular, the data and analytical tools available at the time the state develops and submits the SIP for a new or revised NAAQS affects the content of the submission. The content of such SIP submissions may also vary depending upon what provisions the state's existing SIP already contains. In the case of the 2015 ozone NAAQS, states typically have met the basic program elements required in section 110(a)(2) through earlier SIP submissions in connection with the 1997 and 2008 ozone NAAQS.

II. Summary of SIP Revision and EPA Analysis

On October 11, 2018, EPA received a SIP revision submittal from MDE to satisfy the requirements of section 110(a) of the CAA for the 2015 ozone NAAQS (Maryland's submittal). Maryland's submittal addressed the following infrastructure elements, or portions thereof, for the 2015 ozone NAAQS: CAA section 110(a)(2)(A), (B), (C), D(i)(II), D(ii), (E), (F), (G), (H), (J), (K), (L), and (M). EPA is proposing to make a determination that the submittal meets the requirements of section 110(a)(2)(A), (B), (C), D(i)(II), D(ii), (E), (F), (G), (H), (J), (K), (L), and (M), or portions thereof, of the CAA. Following EPA guidance, which was issued on September 13, 2013 (2013 guidance),[1] Maryland's October 11, 2018 SIP submittal did not address the portion of section 110(a)(2)(C) pertaining to permit programs, known as nonattainment new source review (NNSR), under part D, title I of the CAA, and section 110(a)(2)(I), referred to as element (I), also pertaining to the nonattainment requirements of part D, title I of the CAA. Both element (I) and the NNSR portion of element (C) pertain to SIP revisions that are collectively referred to as a nonattainment SIP or an attainment plan and, if required due to an area being designated nonattainment, would be due by the dates statutorily prescribed under subparts 2 through 5 under part D of the CAA. Because the CAA directs states to submit these plan elements on a separate schedule, EPA does not believe it is necessary for states to include these elements in the infrastructure SIP submission due three years after adoption or revision of a NAAQS.

Maryland's submittal also did not include a portion to address section 110(a)(2)(D)(i)(I) (significant contribution to nonattainment or interference of maintenance through interstate transport of air emissions). Therefore, EPA will take later, separate action on section 110(a)(2)(D)(i)(I) for the 2015 ozone NAAQS, once this portion has been submitted.

A detailed summary of EPA's review and rationale for approving Maryland's submittal may be found in the technical support document (TSD) for this proposed rulemaking action which is available online at *www.regulations.gov,* docket number EPA–R03–OAR–2019–0036.

III. EPA's Approach To Review Infrastructure SIPs

Pursuant to EPA's interpretation of section 110(a) of the CAA, states must provide SIP revisions addressing relevant infrastructure SIP elements from section 110(a)(2)(A) through (M) or provide certification that the existing SIP contains provisions adequately addressing these elements for the 2015 ozone NAAQS.

Due to ambiguity in some of the language of section 110(a)(2) of the CAA, EPA believes that it is appropriate to interpret these provisions in the specific context of acting on infrastructure SIP submissions. EPA has previously provided comprehensive guidance on the application of these provisions through a guidance document for infrastructure SIP submissions and through regional actions on infrastructure submissions.[2] In addition, in the context of acting on such infrastructure submissions, EPA evaluates the submitting state's SIP for facial compliance with statutory and regulatory requirements, not for the state's implementation of its SIP.[3] EPA has other authority to address any issues concerning a state's implementation of the rules, regulations, consent orders, etc. that comprise its SIP.

IV. Proposed Action

EPA is proposing to approve Maryland's October 11, 2018 SIP revision which provides the basic program elements, or portions thereof, specified in section 110(a)(2)(A), (B), (C), (D)(i)(II), (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M) necessary to implement, maintain, and enforce the 2015 ozone NAAQS. This proposed rulemaking is not taking action on section 110(a)(2)(I) nor on the NNSR permitting program requirements of section 110(a)(2)(C), which pertain to the nonattainment planning requirements of part D, title I of the CAA. Such SIP revisions are required when an area is designated nonattainment and, if required, would be due to EPA by the dates statutorily prescribed in CAA part D, subparts 2 through 5. Because the CAA directs states to submit these plan elements on a separate schedule, EPA does not believe it is necessary for states to include these elements in the infrastructure SIP submission due three years after adoption or revision of a NAAQS. Additionally, EPA is not taking action on CAA section 110(a)(2)(D)(i)(I) (significant contribution to nonattainment or interference of maintenance through interstate transport of air emissions) for the 2015 ozone NAAQS because Maryland's submission did not include this element. EPA will take later, separate

[1] ''Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)(2).'' Memorandum from Stephen D. Page, September 13, 2013.

[2] EPA explains and elaborates on these ambiguities and its approach to address them in its September 13, 2013 Infrastructure SIP Guidance (available at *https://www3.epa.gov/airquality/urbanair/sipstatus/docs/Guidance_on_Infrastructure_SIP_Elements_MultiPollutant_FINAL_Sept_2013.pdf*), as well as in numerous agency actions, including EPA's prior action on Maryland's infrastructure SIP to address the 2008 ozone NAAQS (79 FR 25054 (May 2, 2014).

[3] See U.S. Court of Appeals for the Ninth Circuit decision in Montana Environmental Information Center v. EPA, No. 16–71933 (Aug. 30, 2018).

action on this element once it has been submitted.

EPA is seeking public comment on whether Maryland's SIP revision meets the infrastructure requirements in 110(a)(2). These comments will be considered before taking final rulemaking action. Please refer to the TSD for this rulemaking which is available online at *www.regulations.gov,* docket number EPA–R03–OAR–2019–0036, for further discussion of each element being associated with this approval.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 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 proposed action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed rule, pertaining to Maryland's section 110(a) infrastructure requirements for the 2015 ozone NAAQS, does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: April 12, 2019.

Cosmo Servidio,

Regional Administrator, Region III.

[FR Doc. 2019–08165 Filed 4–23–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2018–0822; FRL–9992–58–Region 4]

Air Plan Approval; KY; Jefferson County Existing and New Miscellaneous Metal Parts and Products Surface Coating Operations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve two revisions to the Jefferson County portion of the Kentucky State Implementation Plan (SIP), provided by the Commonwealth of Kentucky, through the Kentucky Division of Air Quality (KDAQ), through a letter dated March 15, 2018. The revisions were submitted by KDAQ on behalf of the Louisville Metro Air Pollution Control District (LMAPCD) (also referred to herein as Jefferson County) and add a recordkeeping provision for certain sources of volatile organic compounds (VOC) along with other administrative changes. EPA is proposing to approve the changes because they are consistent with the Clean Air Act (CAA or Act).

DATES: Comments must be received on or before May 24, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2018–0822 at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Evan Adams of the Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9009. Mr. Adams can also be reached via electronic mail at *adams.evan@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What action is EPA proposing?

Through a letter dated March 15, 2018, KDAQ submitted SIP revisions to EPA for approval that include changes to the Jefferson County portion of the Kentucky SIP.[1] In this action EPA is proposing to approve the changes to Jefferson County Regulation 6.31, *Standards of Performance for Existing Miscellaneous Metal Parts and Products Surface Coating Operations,* and Regulation 7.59, *Standards of Performance for New Miscellaneous Metal Parts and Products Surface*

[1] EPA notes that the Agency received these SIP revisions on March 23, 2018, along with other revisions to the Jefferson County portion of the Kentucky SIP. EPA will be considering action for those SIP revisions in a separate rulemaking.

Coating Operations. The SIP revisions update the current SIP-approved versions of Regulation 6.31 (Version 5) and Regulation 7.59 (Version 5) to Version 6 of each. The changes that are being proposed for approval in this rulemaking, and EPA's rationale for proposing approval, are described in more detail below.

II. Background

EPA has found that surface coatings of miscellaneous metal parts and products operations emit hazardous air pollutants (HAP). *See, e.g.,* 69 FR 129. Regulation of these sources protects air quality and promotes the public health by reducing emissions of HAP into the environment. The organic HAP emitted by surface coatings of miscellaneous metal parts and products operations are VOC as defined by 40 CFR 51.100(s).[2]

Tropospheric ozone, commonly known as smog, occurs when VOC and nitrogen oxides (NOx) react in the atmosphere. Because of the harmful health effects of ozone, EPA limits the VOC and NOx emissions that can be released into the atmosphere. VOC are compounds of carbon excluding carbon monoxide, carbon dioxide, carbonic acid, metallic carbides, or carbonates, and ammonium carbonate, which participates in atmospheric photochemical reactions, including in the formation of ozone. The compounds of carbon (or organic compounds) have different levels of photochemical reactivity, therefore, they do not form ozone to the same extent.[3]

Jefferson County Air Quality Regulations 6.31 and 7.59 address VOC emitted by miscellaneous metal parts and products surface coating operations at existing and new facilities, respectively. Regulation 6.31, *Standards of Performance for Existing Miscellaneous Metal Parts and Products Surface Coating Operations,* as amended in Version 6, applies to each affected facility ''that was in being or commenced construction, modification, or reconstruction before May 20, 1981.'' Regulation 7.59, *Standards of Performance for New Miscellaneous Metal Parts and Products Surface Coating Operations,* applies to newer affected facilities.

In this action, EPA is proposing to approve changes to Regulations 6.31 and 7.59. In Section 6, *Recordkeeping,* of each regulation, a recordkeeping requirement for otherwise-exempt facilities has been added. Previously, facilities that qualified for an exemption according to Paragraph 5.1 of Section 5, *Exemptions,* were not subject to the requirements of the regulation, and facilities that qualified for an exemption according to Paragraph 5.2 of Section 5 were not subject to the requirements in Section 3, *Standards for Volatile Organic Compounds.* The new recordkeeping provision improves the regulations by requiring facilities to maintain records on an annual basis that support their exemption status.

EPA is also proposing to approve a minor, administrative change to Regulation 6.31, Section 1, *Applicability,* that clarifies the regulation's applicability based on the date that a facility was in existence or commenced construction, modification, or reconstruction.

III. Why is EPA proposing this action?

The March 15, 2018, SIP revisions that are the primary subject of this proposed rulemaking strengthen Regulations 6.31 and 7.59 by requiring facilities claiming an exemption to maintain records supporting that claim. In Section 6, *Recordkeeping,* a detailed description of the recordkeeping parameters is outlined in Paragraphs 6.1 through 6.4. Paragraph 6.5 is added and applies to any facility claiming an exemption pursuant to Section 5, *Exemptions.* Paragraph 6.5 requires the previously exempt facilities to keep records sufficient to demonstrate the applicability of the claimed exemption. For the facilities specifically claiming exemption pursuant to Paragraph 5.2, the records shall include, but not be limited to, the potential VOC emissions from all processes or process operations subject to this regulation prior to any add-on controls on a rolling twelve-month basis. The additional provision will provide more detailed information to the State concerning the emissions of the exempt process. They are not required to be monitored like larger sources but must be able to prove their exemption yearly by following the criteria in Section 3, *Standards of Volatile Organic Compounds.* EPA is preliminarily determining that these changes strengthen the regulations for miscellaneous metal parts and products coating operations. EPA views these changes as being consistent with the CAA and does not believe that these changes will result in a change in emissions.

The change to Section 1, *Applicability,* of Regulation 6.31, clarifies the facilities to which the regulation applies based on when the facilities were ''in being or commenced construction, modification, or reconstruction.'' EPA views this minor, administrative change as consistent with the CAA and does not believe that these changes will result in a change in emissions.

IV. Incorporation by Reference

In this action, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference Louisville Metro Air Pollution Control District portion of the Kentucky SIP at Regulation 6.31, *Standards of Performance for Existing Miscellaneous Metal Parts and Products Surface Coating Operations,* Version 6, and Regulation 7.59 *Standards of Performance for New Miscellaneous Metal Parts and Products Surface Coating Operations,* Version 6, state effective January 17, 2018. EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 4 office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Proposed Action

EPA is proposing to approve the aforementioned changes to the Jefferson County portion of the Kentucky SIP because the changes are consistent with section 110 of the CAA and meet the regulatory requirements. The amendments include the addition of a recordkeeping provision in Section 5, *Recordkeeping,* of both Regulations 6.31 and 7.59, as well as the clarification of Section 1, *Applicability,* in Regulation 6.31.

VI. Statutory and Executive Order Reviews

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

[2] Specifically, the organic HAP emitted by these operations include xylenes, toluene, methyl ethyl ketone (MEK), phenol, cresols/cresylic acid, glycol ethers (including ethylene glycol monobutyl ether (EGBE)), styrene, methyl isobutyl ketone (MIBK), and ethyl benzene. *See* 69 FR 129. The aforementioned compounds are identified as VOC in 40 CFR 51.100(s)(1).

[3] The Commonwealth of Kentucky has made similar changes to the Kentucky SIP defining VOC to be consistent with the Federal definitions in 40 CFR 51.100(s). *See* 72 FR 52282 for Kentucky.

• Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);

• Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;

• Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);

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

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

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

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

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

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

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Ozone, Volatile organic compounds.

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

Dated: April 11, 2019.

Mary S. Walker,

Acting Regional Administrator, Region 4.

[FR Doc. 2019–08164 Filed 4–23–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2018–0176; FRL–9991–12–Region 6]

Air Plan Approval; New Mexico; Albuquerque/Bernalillo County; Minor New Source Review (NSR) Preconstruction Permitting Program Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to convert its June 29, 2017 conditional approval of revisions to the New Mexico State Implementation Plan (SIP) for the City of Albuquerque-Bernalillo County minor New Source Review (NSR) program to full approval. The January 18, 2018 SIP submittal satisfies New Mexico's commitment which was the basis of our conditional approval of the minor NSR Preconstruction Permitting Program. Final approval of this SIP submittal will convert our earlier conditional approval to full approval. We are taking this action in accordance with the Clean Air Act (CAA, the Act) requirements.

DATES: Written comments must be received on or before May 24, 2019.

ADDRESSES: Submit your comments, identified by Docket No. EPA–R06–OAR–2018–0176, at *https://www.regulations.gov* or via email to *cox.kyndall@epa.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact Ms. Kyndall Cox, 214–665–8567, *cox.kyndall@epa.gov.* For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www2.epa.gov/dockets/commenting-epa-dockets.*

Docket: The index to the docket for this action is available electronically at *www.regulations.gov* and in hard copy at the EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material), and some may not be publicly available at either location (*e.g.,* CBI).

FOR FURTHER INFORMATION CONTACT: Ms. Kyndall Cox, Air Permits Section, EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, TX 75202, (214) 665–8567, *cox.kyndall@epa.gov.* To inspect the hard copy materials, please schedule an appointment with Kyndall Cox.

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, we mean the EPA.

I. Background

The CAA at section 110(a)(2)C) requires states to develop and submit to the EPA for approval into the SIP, preconstruction review and permitting programs applicable to certain new and modified stationary sources of air pollutants for attainment/unclassifiable and nonattainment areas that cover both major and minor new sources and modifications, collectively referred to as the new source review (NSR) SIP. The CAA NSR SIP program is composed of three separate programs: Prevention of Significant Deterioration (PSD), Nonattainment New Source Review (NNSR), and minor New Source Review (MNSR). The minor NSR SIP program addresses construction or modification activities that do not emit, or have the potential to emit, beyond certain major source/major modification thresholds and thus do not qualify as ''major'' and applies regardless of the designation of the area in which a source is located. The EPA regulations governing the criteria that states must satisfy for EPA approval of the NSR programs as part of the SIP are contained in 40 CFR 51.160–51.166. The minor NSR regulations are contained in 40 CFR 51.160–51.164.

The City of Albuquerque-Bernalillo County submitted revisions to their minor NSR program on July 26, 2013, and subsequently provided supplemental information on April 21,

2016; July 5, 2016; September 19, 2016; and December 20, 2016. In our final rulemaking action, June 29, 2017 (82 FR 29421), we determined that portions of the City of Albuquerque-Bernalillo County SIP submittal were inconsistent with the applicable Federal regulations. Specifically, we found the portions pertaining to accelerated permitting procedures, technical permit revisions, and conflict of interest were not consistent with the required elements of minor NSR programs at 40 CFR 51.160–51.164.

In a letter dated December 22, 2016, the City of Albuquerque committed to adopt enforceable revisions to 20.11.41 NMAC to address these concerns and submit these revisions to the EPA as a SIP revision within one year of the EPA's conditional approval. The January 18, 2018 SIP revision is the City's fulfillment of this commitment.

II. Evaluation

The January 18, 2018 SIP submittal addresses and corrects the deficiencies of the City of Albuquerque-Bernalillo County minor NSR program identified in our June 29, 2017, (82 FR 29421), final conditional approval as summarized below. The EPA's Technical Support Document for this action is available in the rulemaking docket and includes a detailed analysis of the submitted revisions to the New Mexico SIP for the City of Albuquerque-Bernalillo County minor NSR program.

In our June 29, 2017 final rule, we found that the abbreviated public notice process established by 20.11.41.13 NMAC for technical permit revisions was inconsistent with the requirements of 40 CFR 51.161 since it did not meet the applicable prominent advertisement requirements. The County adopted a single revision to 20.11.41.13 NMAC, Application for Permit, which removed the abbreviated public participation process for technical permit revisions that the EPA had determined was inconsistent with the requirements found in 40 CFR 51.161.

The County revised and clarified the technical permit provisions in 20.11.41.28 NMAC, Administrative and Technical Permit Revisions. In our June 29, 2017 final rule (82 FR 29421), we noted that the Section 28 provisions were inconsistent with federal regulations for public notice since technical permit revisions potentially allowed permittees to conduct changes that may could result in up to a one pound per hour increase of a NAAQS pollutant or NMAAQS pollutant and such changes require the County and permittee to follow the public notice requirements listed in 40 CFR 51.161. The January 18, 2018 revision satisfies the EPA's concern with the technical permit revision authorizing any emission increases: The proposed language in 20.11.41.28(B)(1)(b) NMAC clearly states that technical permit revisions have no potential increase in emissions and 20.11.41.28(B)(1)(e) NMAC clarifies that any new covered equipment will not result in an emissions increase.

In our June 29, 2017 final rule (82 FR 29421), we conditionally approved the accelerated review provision found in 20.11.41.32 NMAC since it did not comply with the requirement in 40 CFR 51.161 to make the permittee's application, and the County's evaluation of that application, public. The proposed revision to 20.11.41.32 NMAC, Accelerated Review of Application, revised the requirements of public notice to be consistent with federal requirements related to public availability of information and public notice in 40 CFR 51.161 by correcting the citation in 20.11.41.32(B) NMAC.

In our June 29, 2017 final rule, we also conditionally approved the definitions of ''conflict of interest'' at 20.11.41.7.J NMAC, the references to ''technical permit revisions'' in the definition for ''permit'' at 20.11.41.7.EE NMAC, and the definition of ''technical permit revision or technical revision'' at 20.11.41.7.RR NMAC because these definitions referenced or applied to the underlying provisions for accelerated review and technical permit revisions that were conditionally approved. Because we are proposing to fully approve the revisions to the accelerated review process and technical permit revision, we are also proposing to fully approve the cited definitions as consistent with federal requirements for minor NSR permitting.

In addition to satisfying all elements of our conditional approval, the January 18, 2018 submitted revision to 20.11.41.14 NMAC, Public Notice by Department—Public Participation, removed the requirement to provide public notice in a newspaper and authorized electronic notice on the City of Albuquerque website. The revision to Section 14 is consistent with the EPA's October 18, 2016, 81 FR 71613, publication that authorized electronic notice for the EPA and permitting authorities implementing federal permitting rules. Additionally, the County proposed to increase the timeframe from ten (10) to thirty (30) days for public hearings in 20.11.41.15 NMAC, Public Information Hearing. We find this to be consistent with federal requirements related to public availability of information and public notice (40 CFR 51.161).

Our analysis of the January 18, 2018 submitted revisions indicates that the SIP revision package was developed in accordance with the CAA and the State provided reasonable notice and public hearing. The revisions to 20.11.41 NMAC update the regulations so that the City of Albuquerque-Bernalillo County minor NSR permit program is consistent with federal requirements. Under section 110(l) of the CAA, the EPA finds that these submitted revisions will not interfere with any applicable requirement concerning attainment and reasonable further progress, or any other applicable requirement of the CAA.

III. Proposed Action

We are proposing to approve the January 18, 2018 submitted revisions to the New Mexico SIP for the City of Albuquerque-Bernalillo County. We have determined that the submitted revisions were developed in accordance with the CAA and EPA's regulations, policy and guidance for minor NSR permitting. Additionally, we propose to find that the January 18, 2018 submittal satisfies New Mexico's obligation under the March 10, 2017 (82 FR 13270) conditional approval, and to convert the June 29, 2017 (82 FR 29421) rulemaking to full approval. Therefore, under section 110 of the Act, the EPA proposes approval of the following revisions to the New Mexico SIP for the City of Albuquerque-Bernalillo County:

- 20.11.41.13 NMAC, Application for Permit;
- 20.11.41.14 NMAC, Public Notice by Department—Public Participation;
- 20.11.41.15 NMAC, Public Information Hearing (PIH);
- 20.11.41.28 NMAC, Administrative and Technical Permit Revisions; and
- 20.11.41.32 NMAC, Accelerated Review of Application.

IV. Incorporation by Reference

In this action, we are proposing to include in a final rule regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, we are proposing to incorporate by reference of the revisions to the New Mexico's regulations, as described in the Proposed Action Section above. The EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and in hard copy at the EPA Region 6 office.

V. Statutory and Executive Order Reviews

Under the 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 Act. Accordingly, this action merely proposes to approve 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 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, 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 proposed 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).

List of Subjects in 40 CFR Part 52

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

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

Dated: April 10, 2019.

David Gray,

Acting Regional Administrator, Region 6.

[FR Doc. 2019–07583 Filed 4–23–19; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

48 CFR Part 1419

[190D0102DM DS62500000 DLSN00000.000000 DX62501; DOI–2018–0018]

RIN 1090–AB22

Acquisition Regulation: Removal of Outdated References

AGENCY: Office of Small and Disadvantaged Business Utilization, Interior.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of the Interior is issuing a proposed rule amending the Department of the Interior Acquisition Regulation (DIAR) to implement Section 15(k) of the Small Business Act and remove outdated references and/or obsolete information.

DATES: Comments must be received on or before June 24, 2019.

ADDRESSES: You may submit comments on the rulemaking on Docket Number DOI–2018–0018 through the Federal eRulemaking Portal at *https://www.regulations.gov.* Please use Regulation Identifier Number (RIN) 1090–AB22 in your message. Follow the instructions on the website for submitting comments.

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Bell, Procurement Analyst, Office of Small and Disadvantaged Small Business, Department of the Interior, 1849 C Street NW, Mail Stop 4262 MIB, Washington, DC 20240; telephone (202) 208–3458 or email *christopher_bell@ios.doi.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This proposed rule will revise the Department of the Interior Acquisition Regulation (DIAR) in order to update references to other Federal and Departmental directives, remove obsolete material and remove obsolete references.

On November 24th, 2015, the DOI Office of Acquisition and Property Management (PAM) issued a class deviation to DIAR 1419.2, to revise the content in 1419.201 and 1419.202. This proposed rule intends to update the DIAR with changes from the deviation and rescind the class deviation.

The content of DIAR 1419.201 related to setting goals for small business contracting, the role of the Office of Small and Disadvantaged Business Utilization (OSDBU) and the appointment of Small Business Specialists and was out of date and inconsistent with statutory requirements and the Federal Acquisition Regulation (FAR). The deviation ensured that DOI manages our small business goals in full compliance with SBA's procedures and adhered to FAR requirements regarding the role of the OSDBU and Small Business Specialists. This proposed rule ensures that the role of the Director of the OSDBU is consistent with the Small Business Act 15 U.S.C. 644(k).

The proposed rule simplifies DIAR 1419.202 to allow the OSDBU Director responsibility for issuing policy on the use and content of the Form DI–1886 ''Acquisition Screening and Review Form''.

The proposed rule further intends to remove the following from DIAR 1419:

Remove DIAR 1419.505, ''Rejecting Small Business Administration recommendations.'' The Department has determined that the procedures in FAR 19.505 are sufficient for documenting the rejection of Small Business Administration's recommendation and that further supplemental guidance in the DIAR is duplicative and redundant;

Remove DIAR 1419.506, ''Withdrawing or modifying small business set-asides.'' The Department has determined that the procedures in FAR 19.506 are sufficient for withdrawing or modifying small business set-asides and that further supplemental guidance in the DIAR is duplicative and redundant;

Remove DIAR 1419.7, ''The Small Business Subcontracting Program'', in its entirety. The DOI has determined that the procedures in FAR 19.7 are

sufficient for managing the DOI's small business subcontracting program;

Remove DIAR 1419.803, Selecting acquisitions for the 8(a) program;

Remove DIAR 1419.9, ''Contracting Opportunities for Women-Owned Small Businesses'', in its entirety. The Executive Order 12138 supporting the regulation has been superseded by the Women Owned Small Business program established under 15 U.S.C 637(m);

Remove DIAR 1419.10, ''Small Business Competitiveness Demonstration Program'', in its entirety. FAR 19.10 was established to meet the requirements of the Business Opportunity Development Reform Act of 1988 (Pub. L. 100–656). Section 1335 of the Small Business Jobs Act of 2010 (Pub. L. 111–240) amended the Business Opportunity Development Reform Act of 1988 and repealed the Small Business Competitiveness Demonstration Program.

II. Required Determinations

1. *Regulatory Planning and Review (Executive Orders 12866 and 13563).* Executive Order (E.O.) 12866 provides that the Office of Information and Regulatory Affairs (OIRA) will review all significant rules. OIRA has determined that this proposed rule is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The Executive Order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public, where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this proposed rule in a manner consistent with these requirements.

2. *Regulatory Flexibility Act.* The Secretary certifies that the adoption of this proposed rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Therefore, under 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

3. *Small Business Regulatory Enforcement Fairness Act.* This proposed rule is not a major rule under the Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 804(2)). This proposed rule does not have an annual effect on the economy of $100 million or more. This proposed rule will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. This proposed rule does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

4. *Unfunded Mandates Reform Act.* This proposed rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on State, local, or tribal governments, or the private sector nor does the rule impose requirements on State, local, or tribal governments. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

5. *Takings (E.O. 12630).* This proposed rule does not affect a taking of private property or otherwise have taking implications under Executive Order 12630. A takings implication assessment is not required.

6. *Federalism (E.O. 13132).* Under the criteria in section 1 of E.O. 13132, this proposed rule does not have sufficient Federalism implications to warrant the preparation of a Federalism summary impact statement. It would not substantially and directly affect the relationship between the Federal and state governments. A Federalism summary impact statement is not required.

7. *Civil Justice Reform (E.O. 12988).* This proposed rule complies with the requirements of E.O. 12988. Specifically, this rule (1) meets the criteria of section 3(a) of this E.O. requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and (2) meets the criteria of section 3(b)(2) of this E.O. requiring that all regulations be written in clear language and contain clear legal standards.

8. *Consultation with Indian tribes (E.O. 13175).* The Department strives to strengthen its government-to-government relationship with Indian tribes through a commitment to consultation and recognition of their right to self-governance and tribal sovereignty. We have evaluated this rule under the Department's consultation policy and under the criteria in E.O. 13175 and have determined that it has no substantial direct effect on Federally recognized Indian tribes and that consultation under the Department's tribal consultation policy is not required. This rule does not apply to tribal awards made in accordance with the Indian Self-Determination and Education Assistance Act (Pub. L. 93–638, 88 Stat. 2204), as amended.

9. *Paperwork Reduction Act,* 44 U.S.C. 3501, *et seq.* This proposed rule does not contain information collection requirements, and a submission to the Office of Management and Budget under the Paperwork Reduction Act (PRA) is not required.

10. *National Environmental Policy Act.* This proposed rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act of 1969 (NEPA) is not required because the rule is covered by the categorical exclusion listed in 43 CFR 46.210(c). We have also determined that the rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

11. *Effects on the Energy Supply (E.O. 13211)* This proposed rule is not a significant energy action under the definition in E.O. 13211. A Statement of Energy Effects is not required.

12. *Clarity of this Regulation.* We are required by Executive Orders 12866 (section 1(b)(12)), and 12988 (section 3(b)(1)(B)), and 13563 (section 1(a)), and the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must (1) be logically organized; (2) use the active voice to address readers directly; (3) use common, everyday words and clear language rather than jargon; (4) be divided into short sections and sentences; and (5) use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **FOR FURTHER INFORMATION CONTACT** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the number of section or paragraphs that you find unclear, which section or sentences are too long, the sections where you feel lists or tables would be useful, etc.

13. *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 publically 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.

List of Subjects in 48 CFR Part 1419

Government procurement, Small business.

For the reasons set out in the preamble, DOI proposes to revise 48 CFR, chapter 7, part 1419 to read as follows:

PART 1419—SMALL BUSINESS PROGRAMS

Subpart 1419.1—[Reserved]

Subpart 1419.2—Policies

Sec.
1419.201 General Policy.
1419.202 Specific policies.

Subpart 1419.3—[Reserved]

Subpart 1419.4—[Reserved]

Subpart 1419.5—Set-Asides for Small Business

1419.503 Setting aside a class of acquisitions.
1419.503–70 Class set-aside for construction acquisitions.

Subpart 1419.6—Certificates of Competency and Determinations of Responsibility

1419.602 Procedures.
1419.602–1 Referral.

Subpart 1419.7—[Reserved]

Subpart 1419.8—Contracting with the Small Business Administration (The 8(a) Program)

1419.803 [Reserved]
1419.810 SBA appeals.

Subpart 1419.9—[Reserved]

Subpart 1419.10—[Reserved]

Authority: Sec. 205(c); 63 Stat. 390; 40 U.S.C. 486(c); and 5 U.S.C. 301.

Subpart 1419.1—[Reserved]

Subpart 1419.2—Policies

1419.201 General Policy.

The Director of the Office of Small Disadvantaged Business Utilization (OSDBU) is responsible for the following;

(a) Developing and maintaining policies, procedures, regulations, and guidelines for the effective administration of the Department's small business and disadvantaged business programs;

(b) The appointment of Small Business Specialists to ensure compliance with all applicable law, regulation, and policy; and

(c) The negotiation of annual small business and subcontracting goals with the Small Business Administration (SBA). The purpose of these goals is to increase participation of small business and disadvantaged small businesses in contract and subcontract opportunities.

1419.202 Specific policies

1419.202–70 Acquisition screening and Small Business Specialist recommendations.

The Director of the OSDBU is responsible for issuing policy for use of the DI Form 1886 and determining the content of Form DI–1886 ''Acquisition Screening and Review Form.''

Subpart 1419.3—[Reserved]

Subpart 1419.4—[Reserved]

Subpart 1419.5—Set-Asides for Small Business

1419.503 Setting aside a class of acquisitions.

1419.503–70 Class set-aside for construction acquisitions.

(a) Acquisitions for construction (as defined in FAR 2.101) estimated to cost $2 million or less must be set-aside on a class basis for exclusive participation by small business or disadvantaged business concerns. This class set-aside does not apply when:

(1) The acquisition is procured using simplified acquisition procedures;

(2) A non-competitive acquisition has been approved under the procedures of FAR 6.3;

(3) Work is to be performed outside the U.S.; or

(4) The Bureau Procurement Chief determines that adequate competition is not likely to be obtained if the acquisition is restricted to small business concerns.

(b) [Reserved].

Subpart 1419.6—Certificates of Competency and Determinations of Responsibility

1419.602 Procedures.

1419.602–1 Referral.

The contracting officer must obtain approval from the Chief of the Contracting Office for all determinations documenting a responsive small business' lack of responsibility prior to submission to the appropriate SBA office. A copy of the determination must be sent to OSDBU within 5 working days of the approval date of the determination.

Subpart 1419.7—[Reserved]

Subpart 1419.8—Contracting with the Small Business Administration (The 8(a) Program)

1419.803 [Reserved]

1419.810 SBA appeals.

Assistant Secretary of Policy Management and Budget, without the power of redelegation, is authorized to issue the decision on an SBA appeal of a Contracting Officer's Section 8(a) decision.

Subpart 1419.9—[Reserved]

Subpart 1419.10—[Reserved]

Susan Combs,

Senior Advisor to the Secretary, Exercising the Authority of the Assistant Secretary for Policy, Management and Budget.

[FR Doc. 2019–07814 Filed 4–23–19; 8:45 am]

BILLING CODE 4334–63–P

Notices

Federal Register
Vol. 84, No. 79
Wednesday, April 24, 2019

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

Office of the Chief Financial Officer; Notice of Request for Extension and Revision of a Currently Approved Collection

AGENCY: Office of the Chief Financial Officer, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), this notice announces the Office of the Chief Financial Officer intention to request an extension and revision of a currently approved collection.

DATES: Comments on this notice must be received by June 24, 2019 to be assured of consideration.

ADDRESSES: Office of the Chief Financial Officer invites interested persons to submit comments on this notice. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Go to *http://www.regulations.gov.* Follow the on-line instructions at that site for submitting comments.
- *Mail, including CD—ROMs, etc.:* Send to U.S. Department of Agriculture, Office of the Chief Financial Officer, Fiscal Policy Division, Room 3414, 1400 Independence Avenue SW, Washington, DC 20250.
- *Hand- or courier-delivered submittals:* Deliver to Iris Roseboro, U.S. Department of Agriculture, Office of the Chief Financial Officer, Fiscal Policy Division, Room 3414, 1400 Independence Avenue SW, Washington, DC 20250.

Instructions: All items submitted by mail or electronic mail must include the Agency name, Office of the Chief Financial Officer. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *http://www.regulations.gov.*

Docket: For access to background documents or comments received, go to the Office of the Chief Financial Officer, Room 3414, 1400 Independence Avenue SW, Washington, DC 20250–3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Iris Roseboro, U.S. Department of Agriculture, Office of the Chief Financial Officer, Fiscal Policy Division, Room 3414, 1400 Independence Avenue SW, Washington, DC 20250.

SUPPLEMENTARY INFORMATION:

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), this notice announces the intention of Office of the Chief Financial Officer to request approval for an extension and revision of a currently approved collection.

Title: Supplier Credit Audit Recovery.

OMB Number: 0505–0026.

Expiration Date of Approval: July 31, 2019.

Type of Request: Extension and revision of a currently approved information collection.

Abstract: The Department of Agriculture (USDA) believes that there are many program recipients and service providers who may be carrying a credit balance in their financial records due to possible overpayments. In fiscal year 2012, the USDA implemented a Supplier Credit Recovery Audit Program. The Supplier Credit Recovery Audit contractor sends out a letter to USDA vendors on an annual basis requesting account and payment information as to whether the vendor currently has a credit on their books due back to the USDA.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 2 hours per response.

Respondents: Vendors, contractors, program recipients, and any entity receiving funds from USDA.

Estimated Number of Respondents: 10,514.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 21,028 hours.

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. Comments may be sent to Iris Roseboro, U.S. Department of Agriculture, Office of the Chief Financial Officer, Fiscal Policy Division, Room 3414, 1400 Independence Avenue SW, Washington, DC 20250. All comments received will be available for public inspection during regular business hours at the same address. All responses to this notice will be summarized and included in the request for the Office of Management and Budget approval. All comments will become a matter of public record.

Ethel M. Butler,

Acting Director, Fiscal Policy Division.

[FR Doc. 2019–08130 Filed 4–23–19; 8:45 am]

BILLING CODE 3410–KS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–909]

Certain Steel Nails From the People's Republic of China: Final Results of Antidumping Duty Administrative Review, and Final Determination of No Shipments; 2016–2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that certain steel nails (nails) from the People's Republic of China (China) were sold in the United States at less than normal value (NV) during the period of review (POR), August 1, 2016, through July 31, 2017.

DATES: Applicable April 24, 2019.

FOR FURTHER INFORMATION CONTACT: Susan Pulongbarit or Benito Ballesteros,

AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone (202) 482–4031 or (202) 482–7425, respectively.

SUPPLEMENTARY INFORMATION:

Background

On September 11, 2018, Commerce published in the **Federal Register** the *Preliminary Results* of the administrative review of the antidumping duty order on nails from China.[1] Commerce conducted verification of Dezhou Hualade Hardware and Products Co. Ltd. (Dezhou Hualude) and its producers Tianjin Lingyu Metal Products Co., Ltd. (Tianjin Lingyu) and Tianjin Yongchang Metal Products Co., Ltd. (Tianjin Yongchang) from October 29, 2018, through November 8, 2018.

In accordance with 19 CFR 351.309, we invited parties to comment on our *Preliminary Results.* On February 13, 2019, Zhangjiagang Lianfeng Metals Products Co., Ltd.; Tianjin Jinghai County Hongli Industry & Business Co., Ltd., Tianjin Jinchi Metal Products Co., Ltd., Tianjin Zhonglian Metals Ware Co., Ltd., Shanghai Yueda Nails Industry Co., Ltd. aka Shanghai Yueda Nails Co., Ltd., and Shanxi Tianli Industries Co., Ltd.; The Stanley Works (Langfang) Fastening Systems Co., Ltd. and Stanley Black & Decker, Inc. (collectively, Stanley); Tianjin Huixinshangmao Co., Ltd., SDC International Aust. PTY. LTD., S-Mart (Tianjin) Technology Development Co., Ltd., Shanxi Hairui Trade Co., Ltd., Shanxi Pioneer Hardware Industry Co., Ltd., and Shanxi Yuci Broad Wire Products Co., Ltd.; National Nail Corp.; Mid Continent Steel & Wire, Inc. (the petitioner); and Dezhou Hualude, submitted timely filed case briefs. Between February 19, 2019, and February 21, 2019, National Nail Corp., the petitioner, Dezhou Hualude, and Stanley submitted timely rebuttal briefs pursuant to our regulations. On February 25, 2018, in response to Commerce's instructions, National Nail Corp. re-filed its rebuttal brief with untimely new factual information redacted.

On December 21, 2019, Commerce postponed the deadline for the final results of this review until March 8, 2019.[2] Commerce exercised its discretion to toll all deadlines affected by the partial federal government closure from December 22, 2018, through the resumption of operations on January 28, 2019. If the new deadline falls on a non-business day, in accordance with Commerce's practice, the deadline will become the next business day. Accordingly, the deadline for the final results of this review was revised to April 17, 2019.[3]

Scope of the Order

The merchandise covered by the order includes certain steel nails having a shaft length up to 12 inches. Certain steel nails subject to the order are currently classified under the Harmonized Tariff Schedule of the United States (HTSUS) subheadings 7317.00.55, 7317.00.65, 7317.00.75, and 7907.00.6000,[4] 7318.29.0000, and 8206.00.0000.[5] While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order, which is contained in the accompanying Issues and Decision Memorandum (I&D Memo), is dispositive.[6]

Analysis of Comments Received

We addressed all issues raised in the case and rebuttal briefs by parties to this review in the I&D Memo. Attached to this notice, in Appendix II, is a list of the issues which parties raised. The I&D Memo is a public document and is on file in the Central Records Unit (CRU), Room B8024 of the main Department of Commerce building, as well as electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and in the CRU. In addition, a complete version of the I&D Memo can be accessed directly on the internet at *http://enforcement.trade.gov/frn/index.html.* The signed I&D Memo and the electronic versions of the I&D Memo are identical in content.

Changes Since the *Preliminary Results*

Based on a review of the record and comments received from interested parties regarding our *Preliminary Results,* and for the reasons explained in the I&D Memo, we revised the margin calculation for Stanley and Dezhou Hualude. Accordingly, for the final results, Commerce updated the sample rate to be assigned to the non-selected companies, which is based on an average of the rates of the three mandatory respondents, Stanley, Dezhou Hualude, and Shandong Dinglong Import & Export Co., Ltd. (Shandong Dinglong), as discussed in the I&D Memo. The Surrogate Values Memorandum contains further explanation of our changes to the surrogate values selected for Stanley's factors of production.[7] For a list of all issues addressed in these final results, please refer to Appendix II accompanying this notice.

Final Determination of No Shipments

In the *Preliminary Results,* Commerce determined that nine companies, Astrotech Steels Pvt. Ltd., Hebei Minmetals Co. Ltd., Nanjing Caiqing Hardware Co., Ltd., Najing Toua Hardware & Tools Co., Ltd., Region Industries Co., Ltd., Region System Sdn. Bhd., Shandong Oriental Cherry Hardware Import & Export Co. Ltd., Shandong Qingyun Hongyi Hardware Co. Ltd., Shanghai Jade Shuttle Hardware Tools Co. Ltd., did not have any reviewable transactions during the POR. Consistent with Commerce's assessment practice in non-market economy (NME) cases, we completed the review with respect to the above-named companies. Based on the certifications submitted by the aforementioned companies, and our analysis of U.S. Customs and Border

[1] *See Certain Steel Nails from the People's Republic of China: Preliminary Results of the Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2015–2017,* 83 FR 45883 (September 11, 2018) (*Preliminary Results*).

[2] *See* Memorandum, ''Certain Steel Nails from the People's Republic of China: Extension of Deadline for Final Results of Antidumping Duty Administrate Review,'' dated December 21, 2018.

[3] *See* Memorandum to the Record from Gary Taverman, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, ''Deadlines Affected by the Partial Shutdown of the Federal Government,'' dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

[4] Commerce added the Harmonized Tariff Schedule category 7907.00.6000, ''Other articles of zinc: Other,'' to the language of the *Order. See* Memorandum to Gary Taverman, Senior Advisor for Antidumping and Countervailing Duty Operations, through James C. Doyle, Director, Office VAntidumping and Countervailing Duty Operations, regarding ''Certain Steel Nails from the People's Republic of China: Cobra Anchors Co. Ltd. Final Scope Ruling,'' (September 19, 2013).

[5] Commerce added the HTS categories 7318.29.000 and 8206.00.0000 per a request by U.S. Customs and Border Protection on February 24, 2017.

[6] For a full description of the scope of the Order, *see* Memorandum, ''Certain Steel Nails from the People's Republic of China: Issues and Decision Memorandum for the Final Results of the Ninth Antidumping Duty Administrative Review'' (April 17, 2019), which is adopted by this notice.

[7] *See* Memorandum, ''Eigth Antidumping Administrative Review of Certain Steel Nails from the People's Republic of China: Surrogate Values for the Final Results,'' dated concurrently with and hereby adopted by this notice (Surrogate Values Memorandum).

Protection (CBP) information, we continue to determine that these companies did not have any reviewable transactions during the POR. As noted in the ''Assessment Rates'' section below, Commerce intends to issue appropriate instructions to CBP for the above-named companies based on the final results of this review.

Separate Rates

In the *Preliminary Results,* we determined that 19 companies, in addition to the three mandatory respondents, met the criteria for separate rate status. We have not received any information since the issuance of the *Preliminary Results* that provides a basis for reconsidering this preliminary determination. Therefore, Commerce continues to find that these companies meet the criteria for a separate rate for the final results.

Rate for Non-Selected Companies

As noted above, for the final results, the calculated rates for two of the mandatory respondents have changed from the *Preliminary Results.* Accordingly, for the final results, Commerce has updated the sample rate to be assigned to the non-selected companies, which is based on an average of the rates of the three mandatory respondents, as discussed in the I&D Memo.

China-Wide Entity

In the *Preliminary Results,* we found that 114 companies for which a review was requested had not established eligibility for a separate rate and, thus, were considered to be part of the China-wide entity.[8] We have not received any information since the issuance of the *Preliminary Results* that provides a basis for reconsidering this preliminary determination. Therefore, Commerce continues to find that these companies will remain a part of the China-wide entity.[9]

Final Results of Administrative Review

The weighted-average dumping margins for the administrative review are as follows:

Exporter/producer	Weighted-average dumping margin
Dezhou Hualade Hardware and Products Co. Ltd	75.79
Shandong Dinglong Import & Export Co., Ltd	118.04
The Stanley Works (Langfang) Fastening Systems Co., Ltd. and Stanley Black & Decker, Inc	3.94
Hebei Canzhou New Century Foreign Trade Co. Ltd	44.48
Mingguang Ruifeng Hardware Products Co. Ltd	44.48
Qingdao D&L Group Ltd	44.48
SDC International Australia Pty. Ltd	44.48
Shandong Oriental Cherry Hardware Group Co. Ltd	44.48
Shanghai Curvet Hardware Products Co. Ltd	44.48
Shanghai Yueda Nails Co. Ltd	44.48
Shanxi Hairui Trade Co., Ltd	44.48
Shanxi Pioneer Hardware Industrial Co. Ltd	44.48
Shanxi Tianli Industries Co. Ltd	44.48
S-Mart (Tianjin) Technology Development Co. Ltd	44.48
Suntec Industries Co. Ltd	44.48
Tianjin Huixingshangmao Co. Ltd	44.48
Tianjin Jinchi Metal Products Co. Ltd	44.48
Tianjin Jinghai County Hongli Industry and Business Co. Ltd	44.48
Tianjin Universal Machinery Imp. & Exp	44.48
Tianjin Zhonglian Metals Ware Co. Ltd	44.48
Xi'An Metals and Minerals Imp. & Exp. Co. Ltd	44.48
Zhangjiagang Lianfeng Metals Products Co. Ltd	44.48

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.212(b), Commerce has determined, and CBP shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. Commerce intends to issue appropriate assessment instructions directly to CBP 15 days after publication of the final results of this administrative review.

Where the respondent reported reliable entered values, we calculated importer- (or customer-) specific *ad valorem* rates by aggregating the dumping margins calculated for all U.S. sales to each importer (or customer) and dividing this amount by the total entered value of the sales to each importer (or customer).[10] Where Commerce calculated a weighted-average dumping margin by dividing the total amount of dumping for reviewed sales to that party by the total sales quantity associated with those transactions, Commerce will direct CBP to assess importer-specific assessment rates based on the resulting per-unit rates.[11] Where an importer- (or customer-) specific *ad valorem* or per-unit rate is greater than *de minimis* (*i.e.,* 0.50 percent), Commerce will instruct CBP to collect the appropriate duties at the time of liquidation.[12] Where an importer- (or customer-) specific *ad valorem* or per-unit rate is zero or *de minimis,* Commerce will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[13] We intend to instruct CBP to liquidate entries containing subject merchandise exported by the China-wide entity at the China-wide rate.

Pursuant to Commerce's assessment practice, for entries that were not reported in the U.S. sales databases submitted by companies individually examined during this review, Commerce will instruct CBP to liquidate such entries at the China-wide entity rate. Additionally, if Commerce determines that an exporter had no shipments of the subject merchandise, any suspended entries that entered under that exporter's case number (*i.e.,* at that exporter's rate) will be liquidated at the China-wide entity rate.[14]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For the exporters listed above, the cash deposit rate will be the rate established in the final results of review (except, if the rate is zero or *de minimis,* a zero cash deposit rate will be required for that company); (2) for previously investigated or reviewed China and non-China exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (3) for all China exporters of subject merchandise which have not been found to be entitled to a separate rate, the cash deposit rate will be the China-Wide rate of 118.04 percent; and (4) for all non-China exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the China

[8] *See Preliminary Results* at Appendix I.

[9] *See* Appendix I.

[10] *See* 19 CFR 351.212(b)(1).

[11] *Id.*

[12] *Id.*

[13] *See* 19 CFR 351.106(c)(2).

[14] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

exporters that supplied that non-China exporter. The deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure

We intend to disclose the calculations performed regarding these final results within five days of the date of publication of this notice to parties in this proceeding in accordance with 19 CFR 351.224(b).

Notification to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Administrative Protective Orders

This notice also serves as a 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), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing these final results of administrative review in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.221(b)(5).

Dated: April 17, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I—China-Wide Entity

1 Air It on Inc.
2 A-Jax Enterprises Ltd.
3 A-Jax International Co. Ltd.
4 Anhui Amigo Imp.& Exp. Co. Ltd.
5 Anhui Tea Imp. & Exp. Co. Ltd.
6 Beijing Catic Industry Ltd.
7 Beijing Qin-Li Jeff Trading Co., Ltd.
8 Bodi Corporation.
9 Cana (Rizhou) Hardward Co. Ltd.
10 Cangzhou Xinqiao Int'l Trade Co. Ltd.
11 Certified Products Taiwan Inc.
12 Changzhou Kya Trading Co. Ltd.
13 Chia Pao Metal Co. Ltd.
14 China Dinghao Co. Ltd.
15 China Staple Enterprise Co. Ltd.
16 Chinapack Ningbo Imp. & Exp. Co. Ltd.
17 Chite Enterprise Co. Ltd.
18 Crelux Int'l Co. Ltd.
19 Daejin Steel Co. Ltd.
20 Dingzhou Baota Metal Products Co. Ltd.
21 Dong E Fuqiang Metal Products Co. Ltd.
22 Ejen Brother Limited.
23 Faithful Engineering Products Co. Ltd.
24 Fastening Care.
25 Fastgrow International Co. Inc.
26 Foshan Hosontool Development Hardware Co. Ltd.
27 Glori-Industry Hong Kong Inc.
28 Guangdong Meite Mechanical Co. Ltd.
29 Hangzhou Spring Washer Co. Ltd.
30 Hebei Handform Plastic Products Co. Ltd.
31 Hebei Minghao Imp. & Exp. Co. Ltd.
32 Hengtuo Metal Products Co. Ltd
33 Hongyi (HK) Hardware Products Co. Ltd.
34 Huaiyang County Yinfeng Plastic Factory.
35 Huanghua Yingjin Hardware Products.
36 Inmax Industries Sdn. Bhd.
37 Jade Shuttle Enterprise Co. Ltd.
38 Jiangsu General Science Technology Co. Ltd.
39 Jiangsu Huaiyin Guex Tools.
40 Jiaxing TSR Hardware Inc.
41 Jinhai Hardware Co. Ltd.
42 Jinsco International Corp.
43 Jinsheung Steel Corporation.
44 Koram Inc.
45 Korea Wire Co. Ltd.
46 Liaocheng Minghui Hardware Products.
47 Maanshan Lilai International Trade. Co. Ltd.
48 Mingguang Abundant Hardware Products Co. Ltd.
49 Nailtech Co. Ltd.
50 Nanjing Nuochun Hardware Co. Ltd.
51 Nanjing Tianxingtong Electronic Technology Co. Ltd.
52 Nanjing Tianyu International Co. Ltd.
53 Nanjing Zeejoe International Trade.
54 Ningbo Adv. Tools Co. Ltd.
55 Ningbo Fine Hardware Production Co. Ltd.
56 Overseas Distribution Services Inc.
57 Overseas International Steel Industry.
58 Paslode Fasteners Co. Ltd.
59 Patek Tool Co. Ltd.
60 President Industrial Inc.
61 Promising Way (Hong Kong) Ltd.
62 Qingda Jisco Co. Ltd.
63 Qingdao D&L Hardware Co. Ltd.
64 Qingdao Gold Dragon Co. Ltd.
65 Qingdao Hongyuan Nail Industry Co. Ltd.
66 Qingdao Meijialucky Industry and Co.
67 Qingdao MST Industry and Commerce Co. Ltd.
68 Qingdao Top Steel Industrial Co. Ltd.
69 Qingdao Uni-Trend International.
70 Quzhou Monsoon Hardware Co. Ltd.
71 Rise Time Industrial Ltd.
72 Romp Coil Nail Industries Inc.
73 R-Time Group Inc.
74 Shandong Liaocheng Minghua Metal Pvt. Ltd.
75 Shanghai Haoray International Trade Co. Ltd.
76 Shanghai Pioneer Speakers Co. Ltd.
77 Shanghai Seti Enterprise Int'l Co. Ltd.
78 Shanxi Easyfix Trade Co. Ltd.
79 Shaoxing Chengye Metal Producing Co. Ltd.
80 Shenzhen Xinjintal Hardware Co. Ltd.
81 Suzhou Xingya Nail Co. Ltd.
82 Taizhou Dajiang Ind. Co. Ltd.
83 Theps International.
84 Tianji Hweschun Fasteners Manufacturing Co. Ltd.
85 Tianjin Baisheng Metal Products Co. Ltd.
86 Tianjin Bluekin Indusries Ltd.
87 Tianjin Coways Metal Products Co. Ltd.
88 Tianjin Dagang Jingang Nail Factory.
89 Tianjin Evangel Imp. & Exp. Co. Ltd.
90 Tianjin Fulida Supply Co. Ltd.
91 Tianjin Jin Xin Sheng Long Metal Products Co. Ltd.
92 Tianjin Jinghai Yicheng Metal Pvt.
93 Tianjin Jinlin Pharmaceutical Factory.
94 Tianjin Jinmao Imp. & Exp. Corp. Ltd.
95 Tianjin Lianda Group Co. Ltd.
96 Tianjin Tianhua Environmental Plastics Co. Ltd.
97 Tianjin Yong Sheng Towel Mill.
98 Tianjin Yongye Furniture Co. Ltd.
99 Tianjin Zhonglian Times Technology.
100 Tianjin Zhongsheng Garment Co. Ltd.
101 Unicore Tianjin Fasteners Co. Ltd.
102 Win Fasteners Manufactory (Thailand) Co. Ltd.
103 Wulian Zhanpeng Metals Co. Ltd.
104 Yongchang Metal Product Co.
105 Yuyao Dingfeng Engineering Co. Ltd.
106 Zhangjiagang Longxiang Industries Co. Ltd.
107 Zhaoqing Harvest Nails Co. Ltd.
108 Zhejiang Best Nail Industry Co. Ltd.
109 Zhejiang Jihengkang (JHK) Door Ind. Co. Ltd.
110 Zhejiang Yiwu Yongzhou Imp. & Exp. Co. Ltd.
111 Zhong Shan Daheng Metal Products Co. Ltd.
112 Zhong Shan Shen Neng Metals Products Co. Ltd.
113 Zhucheng Jinming Metal Products Co. Ltd.
114 Zhucheng Runfang Paper Co. Ltd.

Appendix II—Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Discussion of the Issues
General Issues
Comment 1: Sample Rate Calculation Methodology
Comment 2: Surrogate Financial Ratios
Comment 3: Changes to Surrogate Financial Ratios
Dezhou Hualude Issues
Comment 4: Application of Partial Facts Available with Adverse Inferences to Tianjin Lingyu
Comment 5: Incorporate FOP database which includes missing CONNUMs
Comment 6: Application of Partial AFA for Tianjin Lingyu's FOP for Water Coating
Comment 7: Materials Classified as Factory Overhead
Comment 8: Labor Cost
Comment 9: Adjust Dezhou Hualude's U.S. Price for International Freight and Marine Insurance Expenses
Comment 10: Use Invoice Data as Dezhou Hualude's U.S. Date of Sale
Comment 11: Dezhou Hualude's Minor Corrections
Stanley Issues
Comment 12: Collating Wire Surrogate Value

Comment 13: Small Glass Balls Surrogate Value
Comment 14: Sealing Tape Surrogate Value
Comment 15: Treatment of Stanley's Rubber Bands
Comment 16: Black Liquor and Passivation Liquid Surrogate Values
Comment 17: Transportation Distances for Stanley's Packing Materials
Comment 18: Treatment of Irrecoverable VAT
Comment 19: Correction of a Transposition Error for Zinc Phosphate
V. Recommendation

[FR Doc. 2019–08273 Filed 4–23–19; 8:45 a.m.]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[Application No. 14–5A004]

Export Trade Certificate of Review

ACTION: Notice of Issuance of an Export Trade Certificate of Review to DFA of California (''DFA''), Application No. 14–5A004.

SUMMARY: The Secretary of Commerce, through the Office of Trade and Economic Analysis (''OTEA''), issued an amended Export Trade Certificate of Review Certificate to DFA on April 12, 2019.

FOR FURTHER INFORMATION CONTACT: Joseph Flynn, Director, OTEA, International Trade Administration, by telephone at (202) 482–5131 (this is not a toll-free number) or email at *etca@trade.gov.*

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. Sections 4001–21) (''the Act'') authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. An Export Trade Certificate of Review protects the holder and the members identified in the Certificate from State and Federal government antitrust actions and from private treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. The regulations implementing Title III are found at 15 CFR part 325 (2018). OTEA is issuing this notice pursuant to 15 CFR 325.6(b), which requires the Secretary of Commerce to publish a summary of the certification in the **Federal Register**. Under Section 305(a) of the Act and 15 CFR 325.11(a), any person aggrieved by the Secretary's determination may, within 30 days of the date of this notice, bring an action in any appropriate district court of the United States to set aside the determination on the ground that the determination is erroneous.

Description of Certified Conduct

DFA's Export Trade Certificate of Review has been amended to:

1. Add the following two new Members of the Certificate within the meaning of section 325.2(1) of the Regulations (15 CFR 325.2(1)):

- The DeRousi Group LLC—DBA DeRousi Nut
- Santa Clara Nut Company

DFA's amendment of its Export Trade Certificate of Review results in the following membership list:

1. Alpine Pacific Nut Company, Hughson, CA
2. Andersen & Sons Shelling, Vina, CA
3. Avanti Nut Company, Inc., Stockton, CA
4. Berberian Nut Company, LLC, Chico, CA
5. Carriere Family Farms, Inc., Glenn, CA
6. California Almond Packers and Exporters, Inc. (CAPEX), Corning CA
7. California Walnut Company, Inc., Los Molinos, CA
8. Chico Nut Company, Chico, CA
9. Continente Nut LLC, Oakley, CA
10. C. R. Crain & Sons, Inc., Los Molinos, CA
11. Crain Walnut Shelling, Inc., Los Molinos, CA
12. Diamond Foods, LLC, Stockton, CA
13. Empire Nut Company, Colusa, CA
14. Fig Garden Packing, Inc., Fresno, CA
15. Gold River Orchards, Inc., Escalon, CA
16. Grower Direct Nut Company, Hughson, CA
17. Guerra Nut Shelling Company, Hollister, CA
18. Hill View Packing Company Inc., Gustine, CA
19. John B. SanFilippo & Son, Inc.
20. Mariani Nut Company, Winters, CA
21. Mariani Packing Company, Inc., Vacaville, CA
22. Mid Valley Nut Company Inc., Hughson, CA
23. Morada Nut Company, LP, Stockton, CA
24. National Raisin Company, Fowler, CA
25. O–G Nut Company, Stockton, CA
26. Omega Walnut, Inc., Orland, CA
27. Pearl Crop, Inc., Stockton, CA
28. Poindexter Nut Company, Selma, CA
29. Prima Noce Packing, Linden, CA
30. RPC Packing Inc., Porterville, CA
31. Sacramento Packing, Inc., Yuba City, CA
32. Sacramento Valley Walnut Growers, Inc., Yuba City, CA
33. San Joaquin Figs, Inc., Fresno, CA
34. Santa Clara Nut Company, San Jose, CA
35. Shoei Foods USA Inc., Olivehurst, CA
36. Stapleton-Spence Packing, Gridley, CA
37. Sun-Maid Growers of California, Kingsburg, CA
38. Sunsweet Growers Inc., Yuba City, CA
39. Taylor Brothers Farms, Inc., Yuba City, CA
40. The DeRousi Group LLC—DBA DeRousi Nut, Escalon, CA
41. T.M. Duche Nut Company, Inc., Orland, CA
42. Wilbur Packing Company, Inc., Live Oak, CA
43. Valley Fig Growers, Fresno, CA

The effective date of the amended certificate is December 18, 2018, the date on which DFA's application to amend was deemed submitted.

Dated: April 19, 2019.

Joseph Flynn,

Director, Office of Trade and Economic Analysis, International Trade Administration, U.S. Department of Commerce.

[FR Doc. 2019–08286 Filed 4–23–19; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–122–866]

Sodium Sulfate Anhydrous From Canada: Initiation of Less-Than-Fair-Value Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable April 17, 2019.

FOR FURTHER INFORMATION CONTACT: Scott Hoefke or Daniel Deku at (202) 482–4947 or (202) 482–5075, respectively; AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

The Petition

On March 28, 2019, the U.S. Department of Commerce (Commerce) received an antidumping duty (AD) petition concerning imports of sodium sulfate anhydrous (sodium sulfate) from Canada, filed in proper form, on behalf of Cooper Natural Resources, Inc.; Elementis Global LLC; and Searles Valley Minerals, Inc. (collectively, the petitioners).[1]

[1] *See* Petitioners' Letter, ''Petition for the Imposition of Antidumping Duties: Sodium Sulfate

Between April 1 and April 5, 2019, Commerce requested supplemental information pertaining to certain aspects of the Petition.[2] The petitioners filed responses to these requests on April 3 and April 9, 2019.[3]

In accordance with section 732(b) of the Act, the petitioners allege that imports of sodium sulfate from Canada are being, or are likely to be, sold in the United States at less than fair value (LTFV) within the meaning of section 731 of the Act, and that such imports are materially injuring, or threatening material injury to, the domestic industry producing sodium sulfate in the United States. Consistent with section 732(b)(1) of the Act, the Petition is accompanied by information reasonably available to the petitioners supporting their allegations.

Commerce finds that the petitioners filed the Petition on behalf of the domestic industry, because the petitioners are interested parties as defined in section 771(9)(C) of the Act. Commerce also finds that the petitioners demonstrated sufficient industry support with respect to the initiation of the requested AD investigation.[4]

Period of Investigation

Because the Petition was filed on March 28, 2019,[5] the period of investigation (POI) for the investigation is January 1, 2018, through December 31, 2018.[6]

Scope of the Investigation

The product covered by this investigation is sodium sulfate from Canada. For a full description of the scope of this investigation, *see* the Appendix to this notice.

Comments on Scope of the Investigation

During our review of the Petition, Commerce issued questions to, and received responses from, the petitioners pertaining to the proposed scope, to ensure that the scope language in the Petition is an accurate reflection of the products for which the domestic industry is seeking relief.[7] No modifications were made to the scope of the Petition as a result of these exchanges.

As discussed in the *Preamble* to Commerce's regulations, we are setting aside a period for interested parties to raise issues regarding product coverage (scope).[8] Commerce will consider all comments received from interested parties and, if necessary, will consult with interested parties prior to the issuance of the preliminary determinations. If scope comments include factual information,[9] all such factual information should be limited to public information. To facilitate preparation of its questionnaires, Commerce requests that all interested parties submit such comments by 5:00 p.m. Eastern Time (ET) on May 7, 2019, which is 20 calendar days from the signature date of this notice.[10] Any rebuttal comments, which may include factual information, must be filed by 5:00 p.m. ET on May 17, 2019, which is 10 calendar days from the initial comment deadline.

Commerce requests that any factual information parties consider relevant to the scope of the investigation be submitted during this period. However, if a party subsequently finds that additional factual information pertaining to the scope of the investigation may be relevant, the party may contact Commerce and request permission to submit the additional information on the record the investigation.

Filing Requirements

All submissions to Commerce must be filed electronically using Enforcement and Compliance's Antidumping Duty and Countervailing Duty Centralized Electronic Service System (ACCESS).[11] An electronically filed document must be received successfully in its entirety by the time and date it is due. Documents exempted from the electronic submission requirements must be filed manually (*i.e.,* in paper form) with Enforcement and Compliance's APO/Dockets Unit, Room 18022, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, and stamped with the date and time of receipt by the applicable deadlines.

Comments on Product Characteristics for AD Questionnaires

Commerce is providing interested parties an opportunity to comment on the appropriate physical characteristics of sodium sulfate to be reported in response to Commerce's AD questionnaires. This information will be used to identify the key physical characteristics of the merchandise under consideration in order to report the relevant costs of production accurately as well as to develop appropriate product-comparison criteria.

Interested parties may provide any information or comments that they feel are relevant to the development of an accurate list of physical characteristics. Specifically, they may provide comments as to which characteristics are appropriate to use as: (1) General product characteristics; and (2) product-comparison criteria. We note that it is not always appropriate to use all product characteristics as product comparison criteria. We base product comparison criteria on meaningful commercial differences among products. In other words, although there may be some physical product characteristics utilized by manufacturers to describe sodium sulfate, it may be that only a select few product characteristics take into account commercially meaningful physical characteristics. In addition, interested parties may comment on the order in which the physical characteristics should be used in matching products. Generally, Commerce attempts to list the most important physical characteristics first and the least important characteristics last.

Anhydrous from Canada,'' dated March 27, 2019 (the Petition). The Petition was filed with Commerce and the U.S. International Trade Commission (ITC) on March 27, 2019, after 12:00 noon, and pursuant to 19 CFR 207.10(a), is deemed to have been filed with the ITC on the next business day, March 28, 2019. Because section 732(b)(2) of the Tariff Act of 1930, as amended (the Act) requires simultaneous filing of the petition with Commerce and the ITC, Commerce deemed the petition to have been filed with Commerce on March 28, 2019. *See* Memorandum, ''Decision Memorandum Concerning the Filing Date of the Petition,'' dated April 1, 2019 (Petition Filing Memo).

[2] *See* Commerce's Letter, ''Petition for the Imposition of Antidumping Duties on Imports of Sodium Sulfate Anhydrous from Canada: Supplemental Questions'' (Petition Supplemental Questionnaire), dated April 1, 2019; *see also* Memorandum, ''Phone Call with Counsel to the Petitioners,'' dated April 5, 2019.

[3] *See* Petitioners' Letter, ''Petitioners' Responses to Department of Commerce Deficiency Questions: Sodium Sulfate Anhydrous from Canada,'' dated April 3, 2019 (General Issues and AD Supplement); *see also* Petitioners' Letter, ''Petitioners' Supplemental Responses to Department of Commerce Deficiency Questions: Sodium Sulfate Anhydrous from Canada,'' dated April 9, 2019 (Second General Issues and AD Supplement).

[4] *See* the ''Determination of Industry Support for the Petition'' section, *infra.*

[5] *See* Petition Filing Memo.

[6] *See* 19 CFR 351.204(b)(1).

[7] *See* Petition Supplemental Questionnaire, at 3; *see also* General Issues and AD Supplement, at 2.

[8] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[9] *See* 19 CFR 351.102(b)(21) (defining ''factual information'').

[10] *See* 19 CFR 351.303(b).

[11] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011); *see also Enforcement and Compliance; Change of Electronic Filing System Name,* 79 FR 69046 (November 20, 2014) for details of Commerce's electronic filing requirements, effective August 5, 2011. Information on help using ACCESS can be found at *https://access.trade.gov/help.aspx* and a handbook can be found at *https://access.trade.gov/help/Handbook%20on%20Electronic%20Filling%20Procedures.pdf.*

In order to consider the suggestions of interested parties in developing and issuing the AD questionnaires, all product characteristics comments must be filed by 5:00 p.m. ET on May 7, 2019, which is 20 calendar days from the signature date of this notice.[12] Any rebuttal comments must be filed by 5:00 p.m. ET on May 17, 2019. All comments and submissions to Commerce must be filed electronically using ACCESS, as explained above.

Determination of Industry Support for the Petition

Section 732(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 732(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) At least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 732(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, Commerce shall: (i) Poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the ''industry.''

Section 771(4)(A) of the Act defines the ''industry'' as the producers, as a whole, of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs Commerce to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both Commerce and the ITC must apply the same statutory definition regarding the domestic like product,[13] they do so for different purposes and pursuant to a separate and distinct authority. In addition, Commerce's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.[14]

Section 771(10) of the Act defines the domestic like product as ''a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation'' (*i.e.,* the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition).

With regard to the domestic like product, the petitioners do not offer a definition of the domestic like product distinct from the scope of the Petition.[15] Based on our analysis of the information submitted on the record, we have determined that sodium sulfate, as defined in the scope, constitutes a single domestic like product, and we have analyzed industry support in terms of that domestic like product.[16]

In determining whether the petitioners have standing under section 732(c)(4)(A) of the Act, we considered the industry support data contained in the Petition with reference to the domestic like product as defined in the ''Scope of the Investigation,'' in the Appendix to this notice. To establish industry support, the petitioners provided their own production of the domestic like product in 2018.[17] The petitioners compared their own production to the estimated total production of the domestic like product for the entire domestic industry.[18] We relied on data the petitioners provided for purposes of measuring industry support.[19]

Our review of the data provided in the Petition, the General Issues and AD Supplement, the Second General Issues and AD Supplement, and other information readily available to Commerce indicates that the petitioners have established industry support for the Petition.[20] First, the Petition established support from domestic producers (or workers) accounting for more than 50 percent of the total production of the domestic like product and, as such, Commerce is not required to take further action in order to evaluate industry support (*e.g.,* polling).[21] Second, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(i) of the Act, because the domestic producers (or workers) who support the Petition account for at least 25 percent of the total production of the domestic like product.[22] Finally, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(ii) of the Act, because the domestic producers (or workers) who support the Petition account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petition.[23] Accordingly, Commerce determines that the Petition was filed on behalf of the domestic industry within the meaning of section 732(b)(1) of the Act.

Allegations and Evidence of Material Injury and Causation

The petitioners allege that the U.S. industry producing the domestic like product is being materially injured, or is threatened with material injury, by reason of the imports of the subject merchandise sold at LTFV. In addition, the petitioners allege that subject imports exceed the negligibility threshold provided for under section 771(24)(A) of the Act.[24]

The petitioners contend that the industry's injured condition is illustrated by a significant and increasing volume of subject imports; increased market share of subject imports; underselling and price depression or suppression; lost sales and revenues; the magnitude of the alleged dumping margins; and a decline in the domestic industry's U.S.

[12] *See* 19 CFR 351.303(b).

[13] *See* section 771(10) of the Act.

[14] *See USEC, Inc.* v. *United States,* 132 F. Supp. 2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd.* v. *United States,* 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989)).

[15] *See* Volume I of the Petition, at 11–14; *see also* General Issues and AD Supplement, at 1 and Exhibit 1.

[16] For a discussion of the domestic like product analysis as applied to this case and information regarding industry support, *see* Antidumping Duty Investigation Initiation Checklist: Sodium Sulfate Anhydrous from Canada (AD Initiation Checklist), at Attachment II, Analysis of Industry Support for the Antidumping Duty Petition Covering Sodium Sulfate Anhydrous from Canada (Attachment II). This checklist is dated concurrently with this notice and on file electronically via ACCESS. Access to documents filed via ACCESS is also available in the Central Records Unit, Room B8024 of the main Department of Commerce building.

[17] *See* Volume I of the Petition, at 4 and Exhibit 1.

[18] *See* Volume I of the Petition, at 4 and Exhibit 1; *see also* General Issues and AD Supplement, at 2–3 and Exhibit 3; *see also* Second General Issues and AD Supplement, at 1 and Exhibit 8.

[19] *See* Volume I of the Petition, at 4 and Exhibit 1; *see also* Second General Issues and AD Supplement, at 1 and Exhibit 8. For further discussion, *see* Attachment II of the AD Initiation Checklist.

[20] *See* Attachment II of the AD Initiation Checklist.

[21] *Id.; see also* section 732(c)(4)(D) of the Act.

[22] *See* Attachment II of the AD Initiation Checklist.

[23] *Id.*

[24] *See* Volume I of the Petition, at 19 and Exhibit 15.

shipments and financial performance.[25] We have assessed the allegations and supporting evidence regarding material injury, threat of material injury, causation, as well as negligibility, and we have determined that these allegations are properly supported by adequate evidence, and meet the statutory requirements for initiation.[26]

Allegations of Sales at Less Than Fair Value

The following is a description of the allegations of sales at LTFV upon which Commerce based its decision to initiate an AD investigation of imports of sodium sulfate from Canada. The sources of data for the deductions and adjustments relating to U.S. price and normal value (NV) are discussed in greater detail in the initiation checklist.

Export Price

The petitioners based EP on pricing information for sodium sulfate produced in, and exported from, Canada and sold or offered for sale in the United States.[27] Where appropriate, the petitioners made deductions from U.S. price for foreign brokerage and handling, rail hopper car leasing expenses, and U.S. inland freight, consistent with the terms of sale.[28]

Normal Value

The petitioners based NV on a home market price they obtained for sodium sulfate produced and sold in Canada during the POI.[29] The petitioners calculated a net home market price, adjusted for freight expenses, consistent with the terms of sale.[30] The petitioners provided information indicating that the home market price was below the cost of production (COP) and, therefore, the petitioners also calculated NV based on constructed value (CV), pursuant to section 773(a)(4) of the Act.[31]

Normal Value Based on Constructed Value

Pursuant to section 773(e) of the Act, CV consists of the cost of manufacturing (COM), selling, general and administration (SG&A) expenses, financial expenses, packing and profit.

The petitioners calculated the COM based on a domestic producer's input factors of production and usage rates for raw materials, labor, energy and factory overhead. The petitioners valued the input factors of production using publicly available data on costs specific to Canada during the POI. Specifically, the petitioners calculated raw material cost as the mineral royalty rate paid for extracting lake brine.[32] The petitioners valued labor and energy costs using publicly available sources for Canada.[33] The petitioners calculated factory overhead based on a U.S. producer's experience. The petitioners calculated SG&A expenses, financial expenses, and profit for Canada based on the experience of a Canadian producer of comparable merchandise (*i.e.,* potash).[34]

Fair Value Comparisons

Based on the data provided by the petitioners, there is reason to believe that imports of sodium sulfate from Canada are being, or are likely to be, sold in the United States at LTFV. Based on comparisons of EP to NV in accordance with sections 772 and 773 of the Act, the estimated dumping margins for sodium sulfate from Canada range from 43.37 to 170.08 percent.[35]

Initiation of LTFV Investigation

Based upon the examination of the Petition and supplements to the Petition, we find that the Petition meets the requirements of section 732 of the Act. Therefore, we are initiating an AD investigation to determine whether imports of sodium sulfate from Canada are being, or are likely to be, sold in the United States at LTFV. In accordance with section 733(b)(1)(A) of the Act and 19 CFR 351.205(b)(1), unless postponed, we will make our preliminary determination no later than 140 days after the date of this initiation.

Identification of Respondents

The petitioners named two producers of sodium sulfate in Canada (*i.e.,* Saskatchewan Mining and Minerals Inc. (SSM) and TODA Advanced Materials, Inc. (TODA)).[36] Following standard practice in AD investigations involving market economy countries, if necessary, Commerce intends to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports under the appropriate HTSUS numbers listed with the ''Scope of the Investigation,'' in the Appendix.

On April 15, 2019, Commerce released CBP data on imports of sodium sulfate from Canada under APO to all parties with access to information protected by APO and indicated that interested parties wishing to comment on the CBP data must do so within three business days of the publication date of the notice of initiation of this investigation.[37] We further stated that we will not accept rebuttal comments.

Distribution of Copies of the Petition

In accordance with section 732(b)(3)(A) of the Act and 19 CFR 351.202(f), copies of the public version of the Petition have been provided to the Government of Canada *via* ACCESS. To the extent practicable, we will attempt to provide a copy of the public version of the Petition to each exporter named in the Petition, as provided under 19 CFR 351.203(c)(2).

ITC Notification

We will notify the ITC of our initiation, as required by section 732(d) of the Act.

Preliminary Determinations by the ITC

The ITC will preliminarily determine, within 45 days after the date on which the Petition was filed, whether there is a reasonable indication that imports of sodium sulfate from Canada are materially injuring, or threatening material injury to, a U.S. industry.[38] A negative ITC determination will result in the investigation being terminated.[39] Otherwise, the investigation will proceed according to statutory and regulatory time limits.

Submission of Factual Information

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by Commerce; and (v) evidence other than factual information described in (i)–(iv). 19 CFR 351.301(b) requires any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being

[25] *See* Volume I of the Petition, at 15–30 and Exhibits 4 and 7 through 13.

[26] *See* Canada AD Initiation Checklist, at Attachment III, Analysis of Allegations and Evidence of Material Injury and Causation for the Antidumping Duty Petition Covering Sodium Sulfate Anhydrous from Canada (Attachment III).

[27] *See* Canada AD Initiation Checklist.

[28] *Id.*

[29] *Id.*

[30] *Id.*

[31] In accordance with section 773(b)(2) of the Act, for this investigation, Commerce will request information necessary to calculate the CV and cost of production (COP) to determine whether there are reasonable grounds to believe or suspect that sales of the foreign like product have been made at prices that represent less than the COP of the product.

[32] *See* Canada AD Initiation Checklist.

[33] *Id.*

[34] *Id.*

[35] *See* Canada AD Initiation Checklist.

[36] *See* Volume 2 of the Petition at 3.

[37] *See* Memoranda, ''Less-Than-Fair-Value Investigation of Sodium Sulfate Anhydrous from Canada: Release of U.S. Customs and Border Protection Data,'' dated April 16, 2019.

[38] *See* section 733(a) of the Act.

[39] *Id.*

submitted [40] and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct.[41] Time limits for the submission of factual information are addressed in 19 CFR 351.301, which provides specific time limits based on the type of factual information being submitted. Interested parties should review the regulations prior to submitting factual information in this investigation.

Particular Market Situation Allegation

Section 504 of the Trade Preferences Extension Act of 2015 amended the Act by adding the concept of particular market situation (PMS) for purposes of CV under section 773(e) of the Act.[42] Section 773(e) of the Act states that ''if a particular market situation exists such that the cost of materials and fabrication or other processing of any kind does not accurately reflect the cost of production in the ordinary course of trade, the administering authority may use another calculation methodology under this subtitle or any other calculation methodology.'' When an interested party submits a PMS allegation pursuant to section 773(e) of the Act, Commerce will respond to such a submission consistent with 19 CFR 351.301(c)(2)(v). If Commerce finds that a PMS exists under section 773(e) of the Act, then it will modify its dumping calculations appropriately.

Neither section 773(e) of the Act nor 19 CFR 351.301(c)(2)(v) set a deadline for the submission of PMS allegations and supporting factual information. However, in order to administer section 773(e) of the Act, Commerce must receive PMS allegations and supporting factual information with enough time to consider the submission. Thus, should an interested party wish to submit a PMS allegation and supporting new factual information pursuant to section 773(e) of the Act, it must do so no later than 20 days after submission of a respondent's initial section D questionnaire response.

Extensions of Time Limits

Parties may request an extension of time limits before the expiration of a time limit established under 19 CFR 351.301, or as otherwise specified by the Secretary. In general, an extension request will be considered untimely if it is filed after the expiration of the time limit established under 19 CFR 351.301. For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. ET on the due date. Under certain circumstances, we may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, we will inform parties in a letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, stand-alone submission; under limited circumstances we will grant untimely filed requests for the extension of time limits. Parties should review *Extension of Time Limits; Final Rule,* 78 FR 57790 (September 20, 2013), available at *http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm,* prior to submitting factual information in this investigation.

Certification Requirements

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information.[43] Parties must use the certification formats provided in 19 CFR 351.303(g).[44] Commerce intends to reject factual submissions if the submitting party does not comply with the applicable revised certification requirements.

Notification to Interested Parties

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305. On January 22, 2008, Commerce published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures,* 73 FR 3634 (January 22, 2008). Parties wishing to participate in this investigation should ensure that they meet the requirements of these procedures (*e.g.,* the filing of letters of appearance as discussed at 19 CFR 351.103(d)).

This notice is issued and published pursuant to sections 732(c)(2) and 777(i) of the Act, and 19 CFR 351.203(c).

Dated: April 17, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix—Scope of the Investigation

The scope of this investigation covers sodium sulfate (Na_2SO_4) (Chemical Abstracts Service (CAS) Number 7757–82–6) that is anhydrous (*i.e.,* containing no water), regardless of purity, grade, color, production method, and form of packaging, in which the percentage of particles between 20 mesh and 100 mesh, based on U.S. mesh series screens, ranges from 10–95% and the percentage of particles finer than 100 mesh, based on U.S. mesh series screens, ranges from 5–90%.

Excluded from the scope of this investigation are specialty sodium sulfate anhydrous products, which are products whose particle distributions fall outside the described ranges. Glauber's salt ($Na_2SO_4 \cdot 10H_2O$), also known as sodium sulfate decahydrate, an intermediate product in the production of sodium sulfate anhydrous that has no known commercial uses, is not included within the scope of the investigation, although some end-users may mistakenly refer to sodium sulfate anhydrous as Glauber's salt. Other forms of sodium sulfate that are hydrous (*i.e.,* containing water) are also excluded from the scope of the investigation.

The merchandise subject to this investigation is classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheading 2833.11.5010. Subject merchandise may also be classified under 2833.11.1000, 2833.11.5050, and 2833.19.0000. Although the HTSUS subheadings and CAS registry number are provided for convenience and customs purposes, the written description of the scope of the investigation is dispositive.

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[40] *See* 19 CFR 351.301(b).

[41] *See* 19 CFR 351.301(b)(2).

[42] *See Trade Preferences Extension Act of 2015,* Public Law 114–27, 129 Stat. 362 (2015).

[43] *See* section 782(b) of the Act.

[44] *See also Certification of Factual Information to Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (*Final Rule*). Answers to frequently asked questions regarding the *Final Rule* are available at *http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

DEPARTMENT OF COMMERCE

International Trade Administration

Environmental Technologies Trade Advisory Committee (ETTAC) Public Meeting

AGENCY: International Trade Administration, DOC.

ACTION: Notice of an open meeting of a Federal Advisory Committee.

SUMMARY: This notice sets forth the schedule and proposed agenda of a meeting of the Environmental Technologies Trade Advisory Committee (ETTAC).

DATES: The meeting is scheduled for May 15, 2019, from 8:45 a.m. to 3:30 p.m. Eastern Daylight Time (EDT). The deadline for members of the public to register or to submit written comments for dissemination prior to the meeting is 5:00 p.m. EDT on Friday, May 3, 2019.

The deadline for members of the public to request auxiliary aids is 5:00 p.m. EDT on Friday, May 3, 2019.

ADDRESSES: The meeting will take place in the Research Library at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230. To register and obtain call-in information; submit comments; or request auxiliary aids, please contact: Ms. Amy Kreps, Office of Energy & Environmental Industries (OEEI), International Trade Administration, Room 28018, 1401 Constitution Avenue NW, Washington, DC 20230 or email: *amy.kreps@trade.gov*

FOR FURTHER INFORMATION CONTACT: Ms. Amy Kreps, Office of Energy & Environmental Industries (OEEI), International Trade Administration, Room 28018, 1401 Constitution Avenue NW, Washington, DC 20230 (Phone: 202–482–3835; Fax: 202–482–5665; email: *amy.kreps@trade.gov*)

SUPPLEMENTARY INFORMATION: The meeting will take place on May 15, 2019, from 8:45 a.m. to 3:30 p.m. EDT. The general meeting is open to the public, and time will be permitted for public comment from 3:00–3:30 p.m. EDT. Members of the public seeking to attend the meeting are required to register in advance. Those interested in attending must provide notification by Friday, May 3, at 5:00 p.m. EDT, via the contact information provided above. This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to OEEI at (202) 482–3835 no less than one week prior to the meeting. Requests received after this date will be accepted, but it may not be possible to accommodate them.

Written comments concerning ETTAC affairs are welcome any time before or after the meeting. To be considered during the meeting, written comments must be received by Friday, May 3, 2019, at 5:00 p.m. EDT to ensure transmission to the members before the meeting. Minutes will be available within 30 days of this meeting.

Topics to be considered: During the May 15 meeting, which is the second in-person meeting of the current charter term, the ETTAC will receive briefings from ITA as well as the interagency and will discuss its priorities and objectives for potential recommendations to the interagency through the Secretary of Commerce. Topics to be considered during the afternoon subcommittee breakout session will fall under the three themes of Trade Policy and Trade Negotiations, Trade Promotion and Export Market Development and Cooperation on Standards, Certifications and Regulations. OEEI will make the final agenda available to the public one week prior to the meeting. Please email *amy.kreps@trade.gov* or contact 202–482–3835 for a copy.

Background: The ETTAC is mandated by Section 2313(c) of the Export Enhancement Act of 1988, as amended, 15 U.S.C. 4728(c), to advise the Environmental Trade Working Group of the Trade Promotion Coordinating Committee, through the Secretary of Commerce, on the development and administration of programs to expand U.S. exports of environmental technologies, goods, services, and products. The ETTAC was most recently re-chartered until August 2020.

Dated: April 18, 2019.

Amy Kreps,

Designated Federal Officer, ETTAC.

[FR Doc. 2019–08199 Filed 4–23–19; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–552–819]

Certain Steel Nails From the Socialist Republic of Vietnam: Rescission of Countervailing Duty Administrative Review; 2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is rescinding the administrative review of the countervailing duty (CVD) order on certain steel nails (steel nails) from the Socialist Republic of Vietnam (Vietnam) for the period January 1, 2017, through December 31, 2017.

DATES: Applicable April 24, 2019.

FOR FURTHER INFORMATION CONTACT: Yasmin Bordas, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3813.

SUPPLEMENTARY INFORMATION:

Background

On July 3, 2018, Commerce published a notice of opportunity to request an administrative review of the CVD order on steel nails from Vietnam for the period January 1, 2017, through December 31, 2017.[1] On July 31, 2018, Commerce received a timely request, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), from Mid Continent Steel & Wire Inc. (the petitioner) to conduct an administrative review of this CVD order with respect to 12 companies.[2] Based upon this request, on September 10, 2018, in accordance with section 751(a) of the Act, Commerce published in the **Federal Register** a notice of initiation of administrative review for this CVD order.[3] On November 5, 2018, the petitioner timely withdrew its request for an administrative review for each of the 12 companies.[4]

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), the Secretary 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 of the requested review. As noted above, the petitioner withdrew its request for review by the 90-day deadline. No other party requested an administrative review. Accordingly, we are rescinding the administrative review of the CVD order on steel nails from Vietnam covering the period January 1, 2017, to December 31, 2017.

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess CVDs on all appropriate entries at a rate equal to the cash deposit of estimated CVDs required at the time of entry, or withdrawal from warehouse, for consumption, during the period January 1, 2017, to December 31, 2017, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions directly to CBP 15 days after publication of this notice in the **Federal Register**.

Notification to Importers

This notice serves as the only reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of countervailing duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 83 FR 31121 (July 3, 2018).

[2] *See* Letter from the petitioner re: Certain Steel Nails from Vietnam: Request for Administrative Reviews, dated July 31, 2018.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 45596 (September 10, 2018) (*Initiation Notice*).

[4] *See* Letter from the petitioner re: Certain Steel Nails from Vietnam: Withdrawal of Request for Administrative Reviews, dated November 5, 2018.

result in the presumption that reimbursement of the countervailing duties occurred and the subsequent assessment of doubled countervailing duties.

Notification Regarding Administrative Protective Order

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under an 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 violation which is subject to sanction. This notice is issued and published in accordance with sections 751(a)(1) of the Act and 19 CFR 351.213(d)(4).

Dated: April 16, 2019.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2019–08271 Filed 4–23–19; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG993

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The North Pacific Fishery Management Council (Council) Social Science Planning Team will meet May 7, 2019 through May 9, 2019.

DATES: The meeting will be held on Tuesday May 7, 2019 through Thursday May 9, 2019, from 9 a.m. to 5 p.m. Alaska Daylight Time.

ADDRESSES: The meeting will be held at the Hilton Hotel in the Fireweed Room, 500 W 3rd Ave, Anchorage, AK 99501. Teleconference number is (907) 271–2896.

Council address: North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501–2252; telephone: (907) 271–2809.

FOR FURTHER INFORMATION CONTACT: Sarah Marrinan, Council staff; telephone: (907) 271–2809.

SUPPLEMENTARY INFORMATION:

Agenda

Tuesday, May 7, 2019 Through Thursday, May 9, 2019

The meeting agenda will include the following topics:

- Data Gap Analysis v3
- Economic Data Reports discussion paper and next steps
- Highlight new or underrepresented research published in the North Pacific relevant to the SSPT and fisheries management
- Qualitative information in fisheries management
- Update on Fishery Ecosystem Plan Local Knowledge and Climate Change action modules

The agenda is subject to change. More details on meeting topics and schedule will be posted at *https://www.npfmc.org/committees/social-science-planning-team/*.

Public Comment

Public comment letters will be accepted and should be submitted either electronically to *meetings.npfmc.org* or through the mail: North Pacific Fishery Management Council, 605 W 4th Ave., Suite 306, Anchorage, AK 99501–2252. In-person oral public testimony will be accepted at the discretion of the chair.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Shannon Gleason at (907) 271–2809 at least 7 working days prior to the meeting date.

Dated: April 19, 2019.

Tracey L. Thompson,

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

[FR Doc. 2019–08297 Filed 4–23–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG980

New England Fishery Management Council; Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Habitat Committee to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Thursday, May 9, 2019 at 10 a.m.

ADDRESSES: The meeting will be held at the Hampton Inn & Suites, 2 Foxborough Blvd., Foxborough, MA 02035; phone: (508) 623–0555.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The committee will review the Habitat Plan Development Team (PDT) report on research planning efforts for the Great South Channel HMA, including priorities and general research framework with a briefing on specific proposals in development as appropriate. They will also review the PDT report on the Fishing Effects model and discuss applications and next steps. The committee will receive a staff update on offshore energy-related issues; discuss any upcoming comment opportunities plus other follow up items resulting from the April 18, 2019 Council meeting. Also on the agenda is planning for development of Council policies on non-fishing activities that may affect fisheries and fish habitats (offshore energy policies approved last year). Other business will be discussed as necessary.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the date. This meeting will be recorded.

Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

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

Dated: April 19, 2019.

Tracey L. Thompson,

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

[FR Doc. 2019–08295 Filed 4–23–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG967

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting (webinar).

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Ad Hoc Climate and Communities Core Team (CCCT) will hold a webinar, which is open to the public.

DATES: The webinar meeting will be held on Thursday, May 9, 2019, from 2 p.m. until 4:30 p.m.

ADDRESSES: The meeting will be held via webinar. A public listening station is available at the Pacific Council office (address below). To attend the webinar (1) join the meeting by visiting this link *https://global.gotomeeting.com/join/73822157,* (2) enter the Webinar ID: 738–221–157, and (3) enter your name and email address (required). After logging in to the webinar, please (1) dial this TOLL number 1–224–501–3412, (2) enter the attendee phone audio access code 738–221–157, and (3) then enter your audio phone pin (shown after joining the webinar). *Note:* We have disabled Mic/Speakers as an option and require all participants to use a telephone or cell phone to participate. Technical Information and system requirements: PC-based attendees are required to use Windows® 10, 8, 7, Vista, or XP; Mac®-based attendees are required to use Mac OS® X 10.5 or newer; Mobile attendees are required to use iPhone®, iPad®, Android™ phone or Android tablet (See the *https://www.gotomeeting.com/meeting/ipad-iphone-android-apps*). You may send an email to Mr. Kris Kleinschmidt at *Kris.Kleinschmidt@noaa.gov* or contact him at (503) 820–2280, extension 411 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220.

FOR FURTHER INFORMATION CONTACT: Dr. Kit Dahl, Pacific Council; telephone: (503) 820–2422.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is for the Scenario Planning Core Team to receive an overview of climate change scenario planning processes, begin discussing the Team's assignment, and review topics for a to-be-scheduled workshop.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt, (503) 820–2411, at least 10 business days prior to the meeting date.

Dated: April 19, 2019.

Tracey L. Thompson,

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

[FR Doc. 2019–08292 Filed 4–23–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG991

Gulf of Mexico Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting (webinar).

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) will hold a meeting via webinar of its Reef Fish Advisory Panel (AP).

DATES: The meeting will convene via webinar on Thursday, May 9, 2019; 10 a.m. to 12 p.m., EDT.

ADDRESSES: You may register for the webinar by visiting *www.gulfcouncil.org* and click on the AP meeting on the calendar.

Council address: Gulf of Mexico Fishery Management Council, 4107 W Spruce Street, Suite 200, Tampa, FL 33607; telephone: (813) 348–1630.

FOR FURTHER INFORMATION CONTACT: Dr. Lisa Hollensead, Fishery Biologist, Gulf of Mexico Fishery Management Council; *lisa.hollensead@gulfcouncil.org,* telephone: (813) 348–1630.

SUPPLEMENTARY INFORMATION: The following items are on the agenda, though agenda items may be addressed out of order (changes will be noted on the Council's website when possible.)

Thursday, May 9, 2019; 10 a.m.–12 p.m.

The Reef Fish AP will hold introductions of members, adoption of agenda, and approval of minutes from the October 4–5, 2016 meeting. Staff will review the Scope of Work with the members; which is to provide input on a single action draft framework to modify the Gulf Greater Amberjack commercial trip limit. The AP is charged with discussing and providing comments on the framework draft.

—Meeting Adjourns

The agenda is subject to change, and the latest version along with other meeting materials will be posted on *www.gulfcouncil.org* as they become available.

Although other non-emergency issues not on the agenda may come before the group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during this meeting. Actions will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take action to address the emergency.

Dated: April 19, 2019.

Tracey L. Thompson,

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

[FR Doc. 2019–08296 Filed 4–23–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG979

Gulf of Mexico Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council will hold a meeting via webinar of its Standing, Reef Fish, Red Drum and Socioeconomic Scientific and Statistical Committees (SSC).

DATES: The meeting will convene via webinar on Thursday, May 9, 2019; 2 p.m.–5 p.m., EDT.

ADDRESSES: You may register for the webinar by visiting *www.gulfcouncil.org* and clicking on the SSC meeting on the calendar.

Council address: Gulf of Mexico Fishery Management Council, 4107 W Spruce Street, Suite 200, Tampa, FL 33607; telephone: (813) 348–1630.

FOR FURTHER INFORMATION CONTACT: Ryan Rindone, Fishery Biologist, Gulf of Mexico Fishery Management Council; *ryan.rindone@gulfcouncil.org,* telephone: (813) 348–1630.

SUPPLEMENTARY INFORMATION:

Thursday, May 9, 2019; 2 p.m.–5 p.m., EDT

The meeting will begin with Introductions, Adoption of Agenda, and Approval of Scientific and Statistical Committees (SSC) Minutes from the March 13–14, 2019 Standing, Reef Fish, Mackerel, Shrimp and Socioeconomic SSC meeting; and, selection of SSC representative to attend the June 3–6, 2019 Council meeting in Destin/Miramar, FL. The Committees will review carryover simulations updated to include overages, and will discuss any other business items.

—Meeting Adjourns

The Agenda is subject to change, and the latest version along with other meeting materials will be posted on *www.gulfcouncil.org* as they become available.

Although other non-emergency issues not on the agenda may come before the Scientific and Statistical Committee for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, those issues may not be the subject of formal action during this meeting. Actions of the Scientific and Statistical Committee will be restricted to those issues specifically identified in the agenda and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Pereira at the Gulf Council Office (see **ADDRESSES**), at least 5 working days prior to the meeting.

Dated: April 2019.

Tracey L. Thompson,

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

[FR Doc. 2019–08294 Filed 4–23–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG977

South Atlantic Fishery Management Council; Public Meeting

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

ACTION: Notice of a meeting of the Regional Fishery Management Councils' (RFMC) Council Coordination Committee (CCC).

SUMMARY: The South Atlantic Fishery Management Council (SAFMC) will host a meeting of the RFMC CCC, in Charleston, SC.

DATES: The CCC meeting will be held from 1:30 p.m. on Tuesday, May 14, 2019 until 12 p.m. on Thursday, May 16, 2019.

ADDRESSES:

Meeting address: The meeting will be held at the Francis Marion Hotel, 387 King Street, Charleston, SC 29403; phone: (843) 722–0600.

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; phone: (843) 302–8440 or toll free (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION: The Council Coordination Committee (CCC) consists of the chairs, vice-chairs, and executive directors from each regional fishery management council, or their respective proxies; only council staff or council members may serve as proxies. The CCC meets twice each year to discuss issues relevant to all councils, including issues related to the implementation of the Magnuson-Stevens Act (MSA). Additional information about the regional fishery management councils and the CCC meeting is available at *fisherycouncils.org.*

The items of discussion for the meeting are as follows:

Tuesday, May 14, 2019; 1:30 p.m. Until 5:15 p.m.

The CCC will receive an update from NOAA Fisheries on agency priorities for Fiscal Year (FY) 2019, an overview on legislative affairs and reauthorization of the MSA, and a Legislative Work Group report. The CCC will also receive an update on aquaculture issues, Ecosystem-Based Fishery Management regional implementation, and Electronic Technology and Implementation Plans.

Wednesday, May 15, 2019; 8:30 a.m. Until 5:30 p.m.

The CCC will receive an overview of SAFMC activities, a presentation from the Atlantic Coastal Cooperative Statistics Program on the use of unique trip identifiers for fishery management purposes, an update on the Net Gains Alliance, and discuss Best Scientific Information Available (BSIA) guidance. The CCC will receive an update on the development of Geographic Plans as part of NOAA's Strategic Plan, a Management and Budget update, receive a presentation on Shifting Distributions and Changing Productivity and discuss a relevant technical memo, and discuss a proposed rule addressing Council member voting and financial disclosure. The CCC will also discuss the timing of review for the Regional Fishery Management Councils' Standard Operating, Policy and Procedures (SOPPs), technical guidance on implementing National Standard 1, and consultation with regional fishery management councils on developing U.S. positions regarding the United Nation's Convention of Law of the Sea.

Thursday, May 16, 2019; 8:30 a.m. Until 12 p.m.

The CCC will discuss continued council member and staff development for regional fishery management councils and NOAA Fisheries, receive reports from CCC sub-committees and

work groups, and a report of the 33rd session of the Food and Agriculture Organization's Committee on Fisheries (COFI 33).

The CCC will discuss other business, new timing for CCC meetings, actions/wrap up from this meeting and upcoming meetings and take action as necessary.

Public comment on agenda items will be accepted at the beginning of the meeting on Tuesday, May 14, 2019. The CCC Chair, based on the number of individuals wishing to comment, will determine the amount of time provided to each commenter; total time available for all public comments will not exceed 30 minutes. Written comments will also be accepted on agenda items. Written comments should be addressed to Gregg Waugh, Executive Director, SAFMC, 4055 Faber Place Drive, Suite 201, N Charleston, SC 20405 or via email at *Gregg.waugh@safmc.net.* Written comments must be received by 5 p.m. on May 13, 2019 to be considered by the CCC.

Documents regarding these issues are available from *http://www.fisherycouncils.org/ccc-meetings* or *https://www.fisheries.noaa.gov/national/partners/council-coordination-committee.*

Interested persons may also contact the SAFMC office (see **ADDRESSES**).

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 5 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: April 19, 2019.

Tracey L. Thompson,

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

[FR Doc. 2019–08293 Filed 4–23–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF ENERGY

Notice of Request for Information (RFI) on Research and Development Opportunities for Building Energy Modeling

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy (DOE).

ACTION: Request for information (RFI).

SUMMARY: The U.S. Department of Energy (DOE) invites public comment on its Request for Information (RFI). The Office of Energy Efficiency and Renewable Energy (EERE) Building Technologies Office (BTO) seeks input from the public about research and development opportunities in building energy modeling (BEM). In particular, BTO is interested in feedback on planned research and development initiatives and their prioritization, on program scope, and on data-sets, metrics and targets for assessing program effectiveness and impact.

DATES: Responses to the RFI must be received by 5:00 p.m. (ET) on June 3, 2019.

ADDRESSES: Interested parties are to submit comments electronically to *BTO_BEM_RDO@ee.doe.gov*. Include ''*DRAFT Research and Development Opportunities for Building Energy Modeling*'' in the subject of the title. Responses must be provided as attachments to an email. It is recommended that attachments with file sizes exceeding 25MB be compressed (*i.e.,* zipped) to ensure message delivery. Responses must be provided as a Microsoft Word (.docx) attachment to the email, and no more than 10 pages in length, 12 point font, 1 inch margins. Only electronic responses will be accepted. The complete RFI document is located at *https://eere-exchange.energy.gov/*.

Please identify your answers by responding to a specific question or topic if applicable. Within the Report, Topics, Barriers, and Initiatives are numbered. In your response, please include these numbers in your responses. Respondents may answer as many or as few questions as they wish.

BTO will not respond to individual submissions or publish publicly a compendium of responses.

A response to this RFI will not be viewed as a binding commitment to develop or pursue the project or ideas discussed.

Respondents are requested to provide the following information at the start of their response to this RFI:

- Institution name and website
- Institution type (*e.g.,* university, utility, non-profit organization, small business, etc.)
- BEM stakeholder type (*e.g.,* developer, user, client)
- Institution contact name and email address

FOR FURTHER INFORMATION CONTACT: Questions may be addressed to *BTO_BEM_RDO@ee.doe.gov* or Amir Roth, *Amir.Roth@EE.Doe.Gov,* (202) 287.1694. Further instruction can be found in the RFI document posted on EERE Exchange.

SUPPLEMENTARY INFORMATION: The purpose of this RFI is to solicit feedback from industry, academia, research laboratories, government agencies, and other stakeholders on BTO's BEM program and its future directions and priorities. To clarify these, BTO has developed a report that is structured around six focus areas (the BEM value proposition, predictive accuracy of BEM, core modeling capabilities, workflow integration and automation, the BEM data ecosystem, and BEM professionals). The report identifies barriers to the increased adoption of BEM and proposing a set of initiatives to address them. BTO is requesting feedback on each of these barriers, the associated initiatives, as well as barriers and initiatives that have not been identified. BTO is also requesting feedback on datasets, metrics, and targets for assessing the impact and progress of the BEM industry and its own BEM program. The RFI is available at: *https://eere-exchange.energy.gov/*.

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. Factors of interest to DOE when evaluating requests to treat submitted information as confidential include: (1) A description of the items; (2) whether and why such items are customarily treated as confidential within the industry; (3) whether the information is generally known by or available from other sources; (4) whether the information has previously been made available to others without

obligation concerning its confidentiality; (5) an explanation of the competitive injury to the submitting person that would result from public disclosure; (6) when such information might lose its confidential character due to the passage of time; and (7) why disclosure of the information would be contrary to the public interest.

Signed in Washington, DC on April 16, 2019.

David Nemtzow,

Director, Building Technologies Office.

[FR Doc. 2019–08266 Filed 4–23–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Notice of Request for Information (RFI) on Research and Development Opportunities for Innovations in Sensors and Controls for Building Energy Management

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy (DOE).

ACTION: Request for information (RFI).

SUMMARY: The U.S. Department of Energy (DOE) invites public comment on its Request for Information (RFI) on research and development opportunities for innovations in sensors and controls for building energy management. Through this RFI, the Office of Energy Efficiency and Renewable Energy (EERE) Building Technologies Office (BTO) seeks input on research and development opportunities for the integration and optimization of systems at the whole-building level through connected and controllable loads for increased energy affordability, improved occupant comfort, and enhanced provision of grid services that will strengthen the integration between buildings, other distributed energy resources, and the electric grid. This RFI will inform BTO's strategic planning moving forward in identifying early-stage and innovative technology solutions to meet these goals. Successful solutions will strengthen the affordability, reliability, and resiliency of the energy consumed by the buildings sector, contributing to DOE's priorities for the energy sector as a whole.

DATES: Responses to the RFI must be received by 5:00 p.m. (ET) on June 3rd, 2019.

ADDRESSES: Interested parties are to submit comments electronically to *BTO_SensorsControls_RDO@ee.doe.gov*. Include ''*Research and Development Opportunities for Innovations in Sensors and Controls for Building Energy Management*'' in the subject of the title. Responses must be provided as attachments to an email. It is recommended that attachments with file sizes exceeding 25MB be compressed (*i.e.,* zipped) to ensure message delivery. Responses must be provided as a Microsoft Word (.docx) attachment to the email, and no more than 10 pages in length, 12 point font, 1 inch margins. Only electronic responses will be accepted.

Please identify your answers by responding to a specific question or topic if applicable. Respondents may answer as many or as few questions as they wish.

EERE will not respond to individual submissions or publish publicly a compendium of responses. A response to this RFI will not be viewed as a binding commitment to develop or pursue the project or ideas discussed.

Respondents are requested to provide the following information at the start of their response to this RFI:

- Company/institution name;
- Company/institution contact;
- Contact's address, phone number, and email address.

The complete RFI document is located at *https://eere-exchange.energy.gov/*.

FOR FURTHER INFORMATION CONTACT: Question may be addressed to *BTO_SensorsControls_RDO@ee.doe.gov* or Marina Sofos, (202) 586–3492, *marina.sofos@hq.doe.gov.* or Erika Gupta, (202) 586–3152, *erika.gupta@ee.doe.gov*. Further instruction can be found in the RFI document posted on EERE Exchange.

SUPPLEMENTARY INFORMATION: The purpose of this RFI is to solicit feedback from industry, academia, research laboratories, government agencies, and other stakeholders on issues related to sensor and control technologies for optimizing building energy management. This information will be used by BTO to update its Sensors and Controls R&D strategy and supporting energy savings and cost reduction goals, as well as to inform future strategic planning and adjustments to its R&D portfolio. This is solely a request for information and not a Funding Opportunity Announcement (FOA). EERE is not accepting FOA applications. The RFI is available at: *https://eere-exchange.energy.gov/*.

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. Factors of interest to DOE when evaluating requests to treat submitted information as confidential include: (1) A description of the items; (2) whether and why such items are customarily treated as confidential within the industry; (3) whether the information is generally known by or available from other sources; (4) whether the information has previously been made available to others without obligation concerning its confidentiality; (5) an explanation of the competitive injury to the submitting person that would result from public disclosure; (6) when such information might lose its confidential character due to the passage of time; and (7) why disclosure of the information would be contrary to the public interest.

Signed in Washington, DC on April 16, 2019.

David Nemtzow,

Director, Building Technologies Office.

[FR Doc. 2019–08274 Filed 4–23–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Number: PR19–40–001.

Applicants: Cranberry Pipeline Corporation.

Description: Tariff filing per 284.123(b), (e)+(g): Amended Application for Rate Approval to be effective 4/18/2019.

Filed Date: 4/17/19.

Accession Number: 201904175128.

Comments Due: 5 p.m. ET 5/8/19.

284.123(g) Protests Due: 5 p.m. ET 5/8/19.

Docket Numbers: RP19–1129–000.

Applicants: Columbia Gas Transmission, LLC.

Description: § 4(d) Rate Filing: TCO VPSE Negotiated Rate Amendments to be effective 4/16/2019.

Filed Date: 4/16/19.

Accession Number: 20190416–5096.

Comments Due: 5 p.m. ET 4/29/19.

Docket Numbers: RP19–1130–000.

Applicants: MIGC LLC.

Description: § 4(d) Rate Filing: Gas Quality Update—Hydrogen Sulphide and Sulphur to be effective 5/17/2019.

Filed Date: 4/17/19.

Accession Number: 20190417–5000.

Comments Due: 5 p.m. ET 4/29/19.

Docket Numbers: RP19–1131–000.

Applicants: Trunkline Gas Company, LLC.

Description: § 4(d) Rate Filing: Administrative Revisions Filing to be effective 5/18/2019.

Filed Date: 4/17/19.

Accession Number: 20190417–5069.

Comments Due: 5 p.m. ET 4/29/19.

Docket Numbers: RP19–1132–000.

Applicants: El Paso Natural Gas Company, L.L.C.

Description: Penalty Crediting Report of El Paso Natural Gas Company, L.L.C. under RP19–1132.

Filed Date: 4/17/19.

Accession Number: 20190417–5096.

Comments Due: 5 p.m. ET 4/29/19.

Docket Numbers: RP19–1134–000.

Applicants: Tennessee Gas Pipeline Company, L.L.C.

Description: § 4(d) Rate Filing: Wells Fargo Commodities SP347736 to be effective 5/1/2019.

Filed Date: 4/17/19.

Accession Number: 20190417–5127.

Comments Due: 5 p.m. ET 4/29/19.

Docket Numbers: RP19–1135–000.

Applicants: Midcontinent Express Pipeline LLC.

Description: § 4(d) Rate Filing: Fuel Tracker Filing 4/18/19 to be effective 6/1/2019.

Filed Date: 4/18/19.

Accession Number: 20190418–5000.

Comments Due: 5 p.m. ET 4/30/19.

Docket Numbers: RP19–1136–000.

Applicants: Elba Express Company, L.L.C.

Description: § 4(d) Rate Filing: Fuel Tracker Filing—2019 to be effective 6/1/2019.

Filed Date: 4/18/19.

Accession Number: 20190418–5001.

Comments Due: 5 p.m. ET 4/30/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified date(s). Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 18, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–08238 Filed 4–23–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP19–151–000]

Enable Gas Transmission, LLC; Notice of Request Under Blanket Authorization

Take notice that on April 8, 2019, Enable Gas Transmission, LLC (Enable), 910 Louisiana St., Ste. 48040, Houston, Texas 77002, filed in Docket No. CP19–151–000 a prior notice request pursuant to sections 157.205 and 157.211 of the Commission's regulations under the Natural Gas Act (NGA), and Enable's blanket certificate issued in Docket Nos. CP82–384–000 and CP82–384–001, seeking authorization to modify its 4-inch-diameter lateral line connected to its 12-inch-diameter Line OT–27 in Sequoyah County, Oklahoma. Enable proposes to install a new delivery meter and appurtenant facilities that are designed to measure a maximum of 6,000 Dekatherms per day at 700-psig. Enable states that the facilities will constitute a bypass of Arkansas Oklahoma Gas Corporation, a Local Distribution Company, and that the purpose of the new meter is to provide natural gas service to Roland Development Authority (Roland). Enable avers that Roland will construct, own, and operate a lateral line to receive the gas delivery service to its facility from Enable's measurement facility. Enable estimates the cost of the Project to be $325,000, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing may also be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or TTY, contact (202) 502–8659.

Any questions concerning this application may be directed to Lisa Yoho, Senior Director, Regulatory and FERC Compliance, Enable Gas Transmission, LLC, 910 Louisiana Street, Ste. 48040, Houston, Texas, 77002, by telephone at (346)701–2539, or by email at *lisa.yoho@enablemidstream.com.*

Any person or the Commission's staff may, within 60 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to section 157.205 of the regulations under the NGA (18 CFR 157.205), a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the allowed time for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

Pursuant to section 157.9 of the Commission's rules (18 CFR 157.9), within 90 days of this Notice, the Commission staff will either: Complete its environmental assessment (EA) 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 EA for this proposal. The filing of the 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 EA.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters,

will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests, and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and seven copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

Dated: April 17, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–08214 Filed 4–23–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PF18–2–000]

Equitrans Midstream Corporation; Amended Notice of Intent To Prepare an Environmental Assessment for the Planned Tri-State Corridor Pipeline Project and Request for Comments on Environmental Issues

As previously noticed on February 20, 2018, and amended herein, the staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the Tri-State Corridor Pipeline Project involving construction and operation of facilities by Equitrans Midstream Corporation (Equitrans) in Washington County, Pennsylvania and Brooke County, West Virginia. The Commission will use this EA in its decision-making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of a second scoping period (due to pipeline route changes in the project design) the Commission will use to gather input from the public and interested agencies about issues regarding the project. The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from its action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires the Commission to discover concerns the public may have about proposals. This process is referred to as scoping. The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this notice, the Commission requests public comments on the scope of issues to address in the EA. To ensure that your comments are timely and properly recorded, please submit your comments so that the Commission receives them in Washington, DC on or before 5:00 p.m. Eastern Time on May 20, 2019.

You can make a difference by submitting your specific comments or concerns about the project. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the EA. Commission staff will consider all filed comments during the preparation of the EA.

If you sent comments on this project to the Commission before the opening of this docket on October 17, 2017, you will need to file those comments in Docket No. PF18–2–000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission's current environmental mailing list for this project, which includes newly identified affected landowners along the revised pipeline route and landowners who would no longer be affected by the previous pipeline route. State and local government representatives should notify their constituents of this planned project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the planned facilities. The company would seek to negotiate a mutually acceptable easement agreement. You are not required to enter into an agreement. However, if the Commission approves the project, that approval conveys with it the right of eminent domain. Therefore, if you and the company do not reach an easement agreement, the pipeline company could initiate condemnation proceedings in court. In such instances, compensation would be determined by a judge in accordance with state law.

A fact sheet prepared by the FERC entitled An Interstate Natural Gas Facility On My Land? What Do I Need To Know? is available for viewing on the FERC website (*www.ferc.gov*) at *https://www.ferc.gov/resources/guides/gas/gas.pdf.* This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings.

Public Participation

The Commission offers a free service called eSubscription which makes it easy to stay informed of all issuances and submittals regarding the dockets/projects to which you subscribe. These instant email notifications are the fastest way to receive notification and provide a link to the document files which can reduce the amount of time you spend researching proceedings. To sign up go to *www.ferc.gov/docs-filing/esubscription.asp.*

For your convenience, there are three methods you can use to submit your comments to the Commission. The Commission encourages electronic filing of comments and has staff available to assist you at (866) 208–3676 or *FercOnlineSupport@ferc.gov.* Please carefully follow these instructions so that your comments are properly recorded.

(1) You can file your comments electronically using the *eComment* feature, which is located on the Commission's website (*www.ferc.gov*) under the link to *Documents and Filings.* Using eComment is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the *eFiling* feature, which is located on the Commission's website (*www.ferc.gov*) under the link to *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; a comment on a particular project is considered a Comment on a Filing; or

(3) You can file a paper copy of your comments by mailing them to the following address. Be sure to reference the project docket number (PF18–2–000) with your submission: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426

Summary of the Planned Project

Since issuance of our February 20, 2018 notice, Equitrans has taken over the planned project from Brooke County Access I, LLC. Additionally Equitrans has modified approximately 60 percent of the original pipeline route and added or modified workspaces, access roads, and other project components.

Equitrans plans to construct and operate approximately 17 miles of new natural gas transmission line and new facilities in Washington County, Pennsylvania and Brooke County, West Virginia. The purpose of the project is to provide 140 million cubic feet of firm natural gas transportation service per day to a proposed Power Facility being constructed by ESC Brooke County Power I, LLC in Brooke County, West Virginia.

The Tri-State Corridor Pipeline Project would consist of constructing the following facilities:

- Approximately 16.7 miles of 16-inch-diameter pipeline in Washington County;
- approximately 0.3 mile of 16-inch-diameter pipeline in Brooke County;
- three interconnect/metering and regulating stations and mainline valves in Washington County;
- one metering and regulating station at the Power Facility in Brooke County; and
- new and existing temporary and permanent access roads and contractor/laydown yards.

The general location of the project facilities is shown in appendix 1.[1]

Land Requirements for Construction

Construction of the planned facilities would disturb about 260 acres of land for the aboveground facilities and the pipeline. Following construction, Equitrans would maintain about 104 acres for permanent operation of the project's facilities; the remaining acreage would be restored and revert to former uses. About 7 percent of the planned pipeline route parallels existing pipeline, utility, or road rights-of-way.

The EA Process

The EA will discuss impacts that could occur as a result of the construction and operation of the planned project under these general headings:

- Geology and soils;
- water resources and wetlands;
- vegetation and wildlife;
- threatened and endangered species;
- cultural resources;
- land use;
- air quality and noise;
- public safety; and
- cumulative impacts.

Commission staff will also evaluate possible alternatives to the planned project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

Although no formal application has been filed, Commission staff have already initiated a NEPA review under the Commission's pre-filing process. The purpose of the pre-filing process is to encourage early involvement of interested stakeholders and to identify and resolve issues before the Commission receives an application. As part of the pre-filing review, Commission staff will contact federal and state agencies to discuss their involvement in the scoping process and the preparation of the EA.

The EA will present Commission staffs' independent analysis of the issues. The EA will be available in electronic format in the public record through eLibrary[2] and the Commission's website (*https://www.ferc.gov/industries/gas/enviro/eis.asp*). If eSubscribed, you will receive instant email notification when the EA is issued. The EA may be issued for an allotted public comment period. Commission staff will consider all comments on the EA before making recommendations to the Commission. To ensure Commission staff have the opportunity to consider and address your comments, please carefully follow the instructions in the Public Participation section, beginning on page 2.

With this notice, the Commission is asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues related to this project to formally cooperate in the preparation of the EA.[3] Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice. Currently, the West Virginia Division of Natural Resources has expressed its intention to participate as a cooperating agency in the preparation of the EA.

Consultation Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, the Commission is using this notice to initiate consultation with the applicable State Historic Preservation Office(s), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the project's potential effects on historic properties.[4] The EA for this project will document our findings on the impacts on historic properties and summarize the status of consultations under section 106.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project. Commission staff will update the environmental mailing list as the analysis proceeds to ensure that Commission notices related to this environmental review are sent to all individuals, organizations, and government entities interested in and/or potentially affected by the planned project.

If the Commission issues the EA for an allotted public comment period, a *Notice of Availability* of the EA will be sent to the environmental mailing list and will provide instructions to access the electronic document on the FERC's website (*www.ferc.gov*). If you need to make changes to your name/address, or if you would like to remove your name from the mailing list, please return the attached ''Mailing List Update Form'' (appendix 2).

Becoming an Intervenor

Once Equitrans files its application with the Commission, you may want to become an intervenor which is an official party to the Commission's proceeding. Only intervenors have the right to seek rehearing of the Commission's decision and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 CFR 385.214). Motions

[1] The appendices referenced in this notice will not appear in the **Federal Register**. Copies of the appendices were sent to all those receiving this notice in the mail and are available at *www.ferc.gov* using the link called eLibrary or from the Commission's Public Reference Room, 888 First Street NE, Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary, refer to the last page of this notice.

[2] For instructions on connecting to eLibrary, refer to the last page of this notice.

[3] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.6.

[4] The Advisory Council on Historic Preservation regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

to intervene are more fully described at *http://www.ferc.gov/resources/guides/how-to/intervene.asp.* Please note that the Commission will not accept requests for intervenor status at this time. You must wait until the Commission receives a formal application for the project, after which the Commission will issue a public notice that establishes an intervention deadline.

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website (*www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on General Search and enter the docket number in the Docket Number field, excluding the last three digits (*i.e.,* PF18–2). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

Public sessions or site visits will be posted on the Commission's calendar located at *www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Dated: April 18, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–08216 Filed 4–23–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. EL19–64–000, QF19–907–002, QF19–908–002]

Rockville Solar I LLC, Rockville Solar II LLC, Rockville Solar I LLC, Rockville Solar II LLC; Notice of Petition for Declaratory Order

Take notice that on April 15, 2019, pursuant to Rule 207(a)(2) of the Commission's (Commission) Rules of Practice and Procedure,[1] Rockville Solar I LLC and Rockville Solar II LLC (collectively, the Applicants or Petitioners) filed a joint petition for declaratory order (petition) requesting that the Commission grant partial waivers of the filing requirement in section 292.203(a)(3) of the Commission's regulations (QF Filing Requirement)[2] for the time-period beginning April 9, 2014 for the Rockville Solar I solar project and beginning on August 19, 2014 for the Rockville Solar II solar project and ending on March 6, 2019, when each of the Applicants filed the required Form 556 self-certifications for each of the Projects to become a qualifying facility (the requested waiver period),[3] all as more fully explained in the petition.

Any person desiring to intervene or to protest in this proceeding must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioners.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern time on May 15, 2019.

Dated: April 17, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–08218 Filed 4–23–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL18–203–000]

Owensboro Municipal Utilities v. Louisville Gas and Electric Company and Kentucky Utilities Company; Notice of Filing

Take notice that on April 18, 2019, Louisville Gas and Electric Company and Kentucky Utilities Company submitted a Compliance Refund Report [OMU RS No. 402], pursuant to the Federal Energy Regulatory Commission's February 21, 2019 Order.[1]

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the eFiling link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the eLibrary link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or

[1] 18 CFR 385.207 (2018).

[2] 18 CFR 292.203(a)(3) (2018).

[3] *See* Rockville Solar I, Docket No. QF19–907–000 and Rockville Solar II, Docket No. QF19–908–000.

[1] *Owensboro Mun. Utilities* v. *Louisville Gas and Elec. Co., et al., 166 FERC ¶ 61,131 (2019).*

call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on May 9, 2019.

Dated: April 18, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–08240 Filed 4–23–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC19–79–000.

Applicants: Cobalt Power, L.L.C., Garrison Energy Center LLC, RockGen Energy LLC.

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act, et al. of Cobalt Power, L.L.C.

Filed Date: 4/18/19.

Accession Number: 20190418–5158.

Comments Due: 5 p.m. ET 5/9/19.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER18–1267–006.

Applicants: GridLiance High Plains LLC.

Description: Compliance filing: Supplemental Revisions to OATT Attchmt K and Resubmission of Attchmt Q to be effective 3/31/2018.

Filed Date: 4/18/19.

Accession Number: 20190418–5146.

Comments Due: 5 p.m. ET 5/9/19.

Docket Numbers: ER17–1743–003.

Applicants: Doswell Limited Partnership.

Description: Report Filing: Refund Report? Informational Filing to be effective N/A.

Filed Date: 4/17/19.

Accession Number: 20190417–5155.

Comments Due: 5 p.m. ET 5/8/19.

Docket Numbers: ER19–1600–000.

Applicants: Pacific Gas and Electric Company.

Description: § 205(d) Rate Filing: E&P Agreement for VP Development—es Volta to be effective 4/18/2019.

Filed Date: 4/17/19.

Accession Number: 20190417–5143.

Comments Due: 5 p.m. ET 5/8/19.

Docket Numbers: ER19–1601–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Cancellation: Notice of Cancellation of WMPA/SA No. 3656; Queue No. V4–022 to be effective 5/13/2019.

Filed Date: 4/17/19.

Accession Number: 20190417–5146.

Comments Due: 5 p.m. ET 5/8/19.

Docket Numbers: ER19–1602–000.

Applicants: Mirabito Power & Gas, LLC.

Description: Compliance filing: MBR baseline refile to be effective 3/31/2019.

Filed Date: 4/17/19.

Accession Number: 20190417–5151.

Comments Due: 5 p.m. ET 5/8/19.

Docket Numbers: ER19–1603–000.

Applicants: Lorenzo Wind, LLC.

Description: Market-Based Triennial Review Filing: Lorenzo Wind, LLC Triennial Amendment to Market-Based Rate Tariff to be effective 4/18/2019.

Filed Date: 4/17/19.

Accession Number: 20190417–5156.

Comments Due: 5 p.m. ET 5/8/19.

Docket Numbers: ER19–1604–000.

Applicants: Minco Wind IV, LLC.

Description: Market-Based Triennial Review Filing: Minco Wind IV, LLC Triennial Amendment to Market-Based Rate Tariff to be effective 4/18/2019.

Filed Date: 4/17/19.

Accession Number: 20190417–5157.

Comments Due: 5 p.m. ET 5/8/19.

Docket Numbers: ER19–1605–000.

Applicants: Minco Wind V, LLC.

Description: Market-Based Triennial Review Filing: Minco Wind V, LLC Triennial Amendment to Market-Based Rate Tariff to be effective 4/18/2019.

Filed Date: 4/17/19.

Accession Number: 20190417–5158.

Comments Due: 5 p.m. ET 5/8/19.

Docket Numbers: ER19–1606–000.

Applicants: Ninnescah Wind Energy, LLC.

Description: Market-Based Triennial Review Filing: Ninnescah Wind Energy, LLC Triennial Amendment to Market-Based Rate Tariff to be effective 4/18/2019.

Filed Date: 4/17/19.

Accession Number: 20190417–5162.

Comments Due: 5 p.m. ET 5/8/19.

Docket Numbers: ER19–1607–000.

Applicants: Osborn Wind Energy, LLC.

Description: Market-Based Triennial Review Filing: Osborn Wind Energy, LLC Triennial Amendment Market-Based Rate Tariff to be effective 4/18/2019.

Filed Date: 4/17/19.

Accession Number: 20190417–5163.

Comments Due: 5 p.m. ET 5/8/19.

Docket Numbers: ER19–1608–000.

Applicants: Pratt Wind, LLC.

Description: Market-Based Triennial Review Filing: Pratt Wind, LLC Triennial Amendment to Market-Based Rate Tariff to be effective 4/18/2019.

Filed Date: 4/17/19.

Accession Number: 20190417–5164.

Comments Due: 5 p.m. ET 5/8/19.

Docket Numbers: ER19–1609–000.

Applicants: Rush Springs Wind Energy, LLC.

Description: Market-Based Triennial Review Filing: Rush Springs Wind Energy, LLC Triennial Amendment to Market-Based Rate Tariff to be effective 4/18/2019.

Filed Date: 4/17/19.

Accession Number: 20190417–5165.

Comments Due: 5 p.m. ET 5/8/19.

Docket Numbers: ER19–1610–000.

Applicants: Louisville Gas and Electric Company.

Description: § 205(d) Rate Filing: OMU Amended NITSA Svc Agmt No 15 to be effective 3/20/2019.

Filed Date: 4/18/19.

Accession Number: 20190418–5002.

Comments Due: 5 p.m. ET 5/9/19.

Docket Numbers: ER19–1611–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Cancellation: Notice of Cancellation of WMPA/SA No. 4361; Queue No. AA1–096 to be effective 4/8/2019.

Filed Date: 4/18/19.

Accession Number: 20190418–5095.

Comments Due: 5 p.m. ET 5/9/19.

Docket Numbers: ER19–1612–000.

Applicants: California Independent System Operator Corporation.

Description: § 205(d) Rate Filing: 2019–04–18 EIM Agreement between CAISO and Seattle City Light Dept. to be effective 6/18/2019.

Filed Date: 4/18/19.

Accession Number: 20190418–5106.

Comments Due: 5 p.m. ET 5/9/19.

Docket Numbers: ER19–1613–000.

Applicants: Southwestern Public Service Company.

Description: § 205(d) Rate Filing: Hale Wind Project to be effective 6/1/2019.

Filed Date: 4/18/19.

Accession Number: 20190418–5116.

Comments Due: 5 p.m. ET 5/9/19.

Docket Numbers: ER19–1614–000.

Applicants: Minco IV & V Interconnection, LLC.

Description: Market-Based Triennial Review Filing: Minco IV & V Interconnection, LLC Triennial Amendment to MBR Tariff to be effective 4/19/2019.

Filed Date: 4/18/19.

Accession Number: 20190418–5118.

Comments Due: 5 p.m. ET 5/9/19.

Docket Numbers: ER19–1615–000.

Applicants: Palo Duro Wind Interconnection Services, LLC.

Description: Market-Based Triennial Review Filing: Palo Duro Wind

Interconnection Services, LLC Triennial Amendment to MBR Tariff to be effective 4/19/2019.

Filed Date: 4/18/19.

Accession Number: 20190418–5119.

Comments Due: 5 p.m. ET 5/9/19.

Docket Numbers: ER19–1616–000.

Applicants: Seiling Wind Interconnection Services, LLC.

Description: Market-Based Triennial Review Filing: Seiling Wind Interconnection Services, LLC Triennial Amendment to MBR Tariff to be effective 4/19/2019.

Filed Date: 4/18/19.

Accession Number: 20190418–5120.

Comments Due: 5 p.m. ET 5/9/19.

Docket Numbers: ER19–1617–000.

Applicants: Sholes Wind, LLC.

Description: Market-Based Triennial Review Filing: Sholes Wind, LLC Triennial Amendment to Market-Based Rate Tariff to be effective 4/19/2019.

Filed Date: 4/18/19.

Accession Number: 20190418–5121.

Comments Due: 5 p.m. ET 5/9/19.

Docket Numbers: ER19–1618–000.

Applicants: Steele Flats Wind Project, LLC.

Description: Market-Based Triennial Review Filing: Steele Flats Wind Project, LLC Triennial Amendment to Market-Based Rate Tariff to be effective 4/19/2019.

Filed Date: 4/18/19.

Accession Number: 20190418–5122.

Comments Due: 5 p.m. ET 5/9/19.

Docket Numbers: ER19–1619–000.

Applicants: Wildcat Ranch Wind Project, LLC.

Description: Market-Based Triennial Review Filing: Wildcat Ranch Wind Project, LLC Triennial Amendment to Market-Based Rate Tariff to be effective 4/19/2019.

Filed Date: 4/18/19.

Accession Number: 20190418–5123.

Comments Due: 5 p.m. ET 5/9/19.

Docket Numbers: ER19–1620–000.

Applicants: AEP Texas Inc.

Description: § 205(d) Rate Filing: AEPTX-Shakes Solar Interconnection Agreement Second Amend & Restated to be effective 4/4/2019.

Filed Date: 4/18/19.

Accession Number: 20190418–5153.

Comments Due: 5 p.m. ET 5/9/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 18, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–08237 Filed 4–23–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL19–63–000]

Office of the People's Counsel for the District of Columbia, Delaware Division of the Public Advocate, Citizens Utility Board, Indiana Office of Utility Consumer Counselor, Maryland Office of People's Counsel, Pennsylvania Office of Consumer Advocate, West Virginia Consumer Advocate Division, and PJM Industrial Customer Coalition v. PJM Interconnection, L.L.C.; Notice of Complaint

Take notice that on April 15, 2019, pursuant to Rule 206 and 212 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206 and 385.212, Office of the People's Counsel for the District of Columbia, Delaware Division of the Public Advocate, Citizens Utility Board, Indiana Office of Utility Consumer Counselor, Maryland Office of People's Counsel, Pennsylvania Office of Consumer Advocate, West Virginia Consumer Advocate Division, and PJM Industrial Customer Coalition (collectively, the Joint Consumer Advocates or Complainants) filed a formal complaint against PJM Interconnection, L.L.C., (Respondent) alleging that the current market seller offer cap that Respondent uses in its Reliability Price Model Base Residual Auction is unjust and unreasonable, all as more fully explained in the complaint.

The Complainants states that copies of the complaint were served on representatives of the Respondent.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on May 6, 2019.

Dated: April 17, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–08217 Filed 4–23–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP15–521–000]

Gulf LNG Liquefaction Company, LLC, Gulf LNG Energy, LLC, Gulf LNG Pipeline, LLC; Notice of Availability of the Final Environmental Impact Statement for the Proposed Gulf LNG Liquefaction Project

April 17, 2019.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared a final environmental impact statement (EIS) for the Gulf LNG Liquefaction Project, proposed by Gulf LNG Liquefaction

Company, LLC; Gulf LNG Energy, LLC; and Gulf LNG Pipeline, LLC (GLP) (collectively referred to as Gulf LNG) in the above-referenced docket. Gulf LNG requests authorization pursuant to Section 3(a) of the *Natural Gas Act* (NGA) to construct and operate onshore liquefied natural gas (LNG) liquefaction and associated facilities to allow export of LNG. Pursuant to Part 157.203 of Commission regulations, Gulf LNG intends to construct, own, operate, and maintain new interconnection and metering facilities for the existing Gulf LNG Pipeline in Jackson County, Mississippi. The proposed actions are referred to as the Gulf LNG Liquefaction Project (Project) and consist of the Gulf LNG Terminal Expansion (Terminal Expansion) and the GLP Pipeline Modifications.

The final EIS assesses the potential environmental effects of construction and operation of the Gulf LNG Liquefaction Project in accordance with the requirements of the National Environmental Policy Act (NEPA). The FERC staff concludes that approval of the proposed Project, with the mitigation measures recommended in the EIS, would have some adverse environmental impacts; however, these impacts would be avoided or reduced to less-than-significant levels.

U.S. Army Corps of Engineers; U.S. Coast Guard; U.S. Department of Energy, Office of Fossil Energy; the U.S. Department of Transportation's Pipeline and Hazardous Materials Safety Administration; U.S. Fish and Wildlife Service; National Oceanic and Atmospheric Administration, National Marine Fisheries Service; and U.S. Environmental Protection Agency participated as cooperating agencies in the preparation of the EIS. In addition, the Mississippi Office of the Secretary of State has jurisdiction over the wetland mitigation property and, therefore, is assisting us as a cooperating agency. Cooperating agencies have jurisdiction by law or special expertise with respect to resources potentially affected by the proposal and participate in the NEPA analysis. Although the cooperating agencies provided input to the conclusions and recommendations presented in the final EIS, the agencies will present their own conclusions and recommendations in their respective Records of Decision for the Project.

The final EIS addresses the potential environmental effects of the construction and operation of the following proposed facilities:

- Feed gas pre-treatment facilities, including a mercury removal system, an acid gas removal system (to remove carbon dioxide and hydrogen sulfide), a molecular sieve dehydration system (to remove water), and a heavy hydrocarbon removal system (to remove natural gas liquids);
- two separate propane precooled mixed refrigerant liquefaction trains that liquefy natural gas, each with a nominal liquefaction capacity of 5 million tonnes per annum (mtpa) and a maximum capacity of more than 5.4 mtpa of LNG;
- liquefaction facility utilities and associated systems, including two gas-fired turbine compressors per liquefaction train;
- storage facilities for condensate, ammonia and refrigerants;
- utilities systems, including instrument, plant air, and nitrogen;
- a truck loading/unloading facility to unload refrigerants and to load condensate produced during the gas liquefaction process;
- four flares (including one spare flare) in a single flare tower to incinerate excess gases associated with maintenance, startup/shutdown, and upset conditions during an emergency;
- two supply docks (North and South Supply Docks) designed to receive barges transporting materials and large equipment during construction, with one dock retained for use during operation;
- new in-tank LNG loading pumps in the existing LNG storage tanks to transfer LNG through the existing transfer lines to LNG marine carriers;
- new spill impoundment systems designed to contain LNG, refrigerants and other hazardous fluids;
- minor changes to piping at the existing berthing facility to permit bi-directional flow;
- a new concrete storm surge protection wall that connects to the existing storm surge protection wall near the southwest corner of the Terminal Expansion site and extends along the southern border of the Terminal Expansion site;
- a new earthen berm extending from the northeastern to the southeastern boundaries of the Terminal Expansion site, between the Terminal Expansion and the Bayou Casotte Dredged Material Management Site, and connecting to the new segments of the storm surge protection wall;
- six off-site construction support areas for use as staging and laydown areas, contractor yards, and parking;
- modifications to the existing metering stations at the existing Gulfstream Pipeline Company and Destin Pipeline Company interconnection facilities; and
- modifications to the existing Gulf LNG Pipeline at the existing Terminal to provide a connection to the inlet of the LNG liquefaction pre-treatment facilities.

The Commission mailed a copy of the *Notice of Availability* to federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American tribes; potentially affected landowners and other interested individuals and groups; and newspapers and libraries in the Project area. The final EIS is only available in electronic format. It may be viewed and downloaded from the FERC's website (*www.ferc.gov*), on the Environmental Documents page (*https://www.ferc.gov/industries/gas/enviro/eis.asp*). In addition, the final EIS may be accessed by using the eLibrary link on the FERC's website. Click on the eLibrary link (*https://www.ferc.gov/docs-filing/elibrary.asp*), click on General Search, and enter the docket number in the ''Docket Number'' field, excluding the last three digits (*i.e.* CP15–521). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Additional information about the Project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website (*www.ferc.gov*) using the eLibrary link. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription that allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp.*

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–08213 Filed 4–23–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2853–071]

Montana Dept. of Natural Resources and Conservation; Notice of Intent To File License Application, Filing of Pre-Application Document, Approving Use of the Traditional Licensing Process

a. *Type of Filing:* Notice of Intent to File License Application and Request to Use the Traditional Licensing Process.

b. *Project No.:* 2853–071.

c. *Date Filed:* February 21, 2019.

d. *Submitted By:* Montana Department of Natural Resources and Conservation (Montana DNRC).

e. *Name of Project:* Broadwater Hydroelectric Project.

f. *Location:* On the Missouri River in Broadwater County, Montana. The project occupies 44 acres of United States lands administered by U.S. Bureau of Land Management.

g. *Filed Pursuant to:* 18 CFR 5.3 of the Commission's regulations.

h. *Potential Applicant Contact:* Dave Lofftus, Hydro Power Program Manager, Department of Natural Resources and Conservation, State of Montana, 1424 9th Avenue, P.O. Box 201601, Helena, Montana 59620; (406) 444–6659; or email at *dlofftus@mt.gov.*

i. *FERC Contact:* Peter McBride at (202) 502–8132; or email at *peter.mcbride@ferc.gov.*

j. Montana DNRC filed its request to use the Traditional Licensing Process on February 21, 2019. Montana DNRC provided public notice of its request on February 15, 2019. In a letter dated April 18, 2019, the Director of the Division of Hydropower Licensing approved Montana DNRC's request to use the Traditional Licensing Process.

k. With this notice, we are initiating informal consultation with the U.S. Fish and Wildlife Service under section 7 of the Endangered Species Act and the joint agency regulations thereunder at 50 CFR, Part 402. We are also initiating consultation with the Montana State Historic Preservation Officer, as required by section 106, National Historic Preservation Act, and the implementing regulations of the Advisory Council on Historic Preservation at 36 CFR 800.2.

l. With this notice, we are designating Montana DNRC as the Commission's non-federal representative for carrying out informal consultation pursuant to section 7 of the Endangered Species Act; and consultation pursuant to section 106 of the National Historic Preservation Act.

m. Montana DNRC filed a Pre-Application Document (PAD; including a proposed process plan and schedule) with the Commission, pursuant to 18 CFR 5.6 of the Commission's regulations.

n. A copy of the PAD is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website (*http://www.ferc.gov*), using the eLibrary link. Enter the docket number, excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCONlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). A copy is also available for inspection and reproduction at the address in paragraph h.

o. The licensee states its unequivocal intent to submit an application for a new license for Project No. 2853. Pursuant to 18 CFR 16.8, 16.9, and 16.10 each application for a new license and any competing license applications must be filed with the Commission at least 24 months prior to the expiration of the existing license. All applications for license for this project must be filed by June 30, 2022.

p. Register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filing and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Dated: April 18, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–08215 Filed 4–23–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER19–1597–000]

AES Integrated Energy, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of AES Integrated Energy, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is May 8, 2019.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 18, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–08243 Filed 4–23–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Western Area Power Administration

Central Arizona Project, Colorado River Storage Project, Loveland Area Projects, Pacific Northwest-Pacific Southwest Intertie Project, and Parker-Davis Project—Rate Order No. WAPA–187

AGENCY: Western Area Power Administration, DOE.

ACTION: Extension of formula rates for use under the WestConnect Point-to-Point Regional Transmission Service Participation Agreement (WestConnect PA).

SUMMARY: The Under Secretary of Energy extends the existing formula rates for non-firm point-to-point transmission service provided under the WestConnect PA and will submit them to the Federal Energy Regulatory Commission (FERC) for confirmation and approval on a final basis. The existing formula rates under Rate Schedule WC–8 are scheduled to expire on May 31, 2019. This rate extension makes no change to the existing formula rates.

DATES: The extended formula rates under Rate Schedule WC–8 will be placed into effect on an interim basis on June 1, 2019.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas Hackett, Rates Manager, Colorado River Storage Project, (801) 524–5503 or email *hackett@wapa.gov*; Ms. Tina Ramsey, Rates Manager, Desert Southwest Region, (602) 605–2525 or email *dswpwrmrk@wapa.gov*; or Mrs. Sheila D. Cook, Rates Manager, Rocky Mountain Region, (970) 461–7211 or email *scook@wapa.gov*.

SUPPLEMENTARY INFORMATION: By Delegation Order No. 00–037.00B, effective November 19, 2016, the Secretary of Energy delegated: (1) The authority to develop power and transmission rates to the Western Area Power Administration's (WAPA) 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 to disapprove such rates, to FERC. In Delegation Order No. 00–002.00Q, effective November 1, 2018, the Secretary of Energy also delegated to the Under Secretary of Energy the authority to confirm, approve, and place into effect on an interim basis power and transmission rates for WAPA.

Following DOE's review of WAPA's proposal, I hereby approve Rate Order No. WAPA–187 on an interim basis, extending existing Rate Schedule WC–8 through May 31, 2024. Rate Order No. WAPA–187 will be submitted to FERC for confirmation and approval on a final basis.

Dated: April 17, 2019.

Mark W. Menezes,

Under Secretary of Energy.

DEPARTMENT OF ENERGY

DEPUTY SECRETARY

In the Matter of:
Western Area Power Administration
Extension of
Loveland Area Projects
Colorado River Storage Project
Pacific Northwest-Pacific Southwest Intertie Project
Central Arizona Project
Parker-Davis Project Transmission Service
Formula Rates
Rate Order No. WAPA-187

ORDER CONFIRMING, APPROVING, AND PLACING THE WESTERN AREA POWER ADMINISTRATION'S TRANSMISSION SERVICE FORMULA RATES FOR USE UNDER THE WESTCONNECT POINT-TO-POINT REGIONAL TRANSMISSION SERVICE PARTICIPATION AGREEMENT INTO EFFECT ON AN INTERIM BASIS

The transmission service formula rates set forth in this Rate Order are established in accordance with Section 302 of the Department of Energy (DOE) Organization Act (42 U.S.C. 7152). This Act transferred to and vested in the Secretary of Energy the power marketing functions of the Secretary of the Department of the Interior and the Bureau of Reclamation under the Reclamation Act of 1902 (ch. 1093, 32 Stat. 388), as amended and supplemented by subsequent laws, particularly section 9(c) of the Reclamation Project Act of 1939 (43 U.S.C. 485h(c)) and section 5 of the Flood Control Act of 1944 (16 U.S.C. 825s); and other acts that specifically apply to the projects involved.

By Delegation Order No. 00-037.00B, effective November 19, 2016, the Secretary of Energy delegated: (1) The authority to develop power and transmission rates to the Western Area Power Administration's (WAPA) Administrator; (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary of Energy; [1] and (3) the authority to confirm, approve, and place into effect on a final basis, or to remand or to disapprove such rates, to the Federal Energy Regulatory Commission (FERC). This extension is issued under the Delegation Order and DOE rate extension procedures found at 10 CFR 903.23(a).

BACKGROUND

On December 15, 2014, FERC approved Rate Schedule WC-8 under Rate Order No. WAPA-163 [2] for a five-year period through May 31, 2019. This schedule applies to WestConnect Regional, Non-Firm, Point-to-Point Transmission Service that uses one or more of the following WAPA transmission projects: Central Arizona Project, Colorado River Storage Project, Loveland Area Projects, Pacific Northwest-Pacific Southwest Intertie Project, and Parker-Davis Project. In accordance with 10 CFR 903.23(a), WAPA is extending the existing formula rates under Rate Schedule WC-8 for the period of June 1, 2019, through May 31, 2024. This rate extension makes no change to the existing formula rates.

DISCUSSION

In accordance with 10 CFR 903.23(a), WAPA filed a notice in the **Federal Register** on March 18, 2019, proposing to extend Rate Schedule WC-8 under Rate Order No. WAPA-187 (84 FR 9771). WAPA determined it was not necessary to hold public information or public comment forums on the proposed formula rate extension, but provided a 14-day consultation and comment period to give the public an opportunity to comment on the proposed extension. The consultation and comment period ended on April 1, 2019, and WAPA received no comments on the proposed formula rate extension.

ORDER

In view of the above and under the authority delegated to me, I hereby extend, on an interim basis, WAPA's existing formula rates under Rate Schedule WC-8, for use under WestConnect's Point-to-Point Regional Transmission Service Participation Agreement through May 31, 2024. This rate schedule shall remain in effect on an interim basis pending FERC's confirmation and approval of this extension, or substitute rates, on a final basis.

Dated: April 17, 2019.

Mark W. Menezes,

Under Secretary of Energy.

[FR Doc. 2019–08277 Filed 4–23–19; 8:45 am]

BILLING CODE 6450–01–P

[1] In Delegation Order No. 00-002.00Q, effective November 1, 2018, the Secretary of Energy also delegated to the Under Secretary of Energy the authority to confirm, approve, and place into effect on an interim basis power and transmission rates for WAPA.

[2] Order Confirming and Approving Rate Schedule on a Final Basis, FERC Docket No. EF14-8-000, 149 FERC ¶62,196 (2014).

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2015–0765; FRL–9992–33–ORD]

Board of Scientific Counselors Executive Committee Meeting—June 2019

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act the U.S. Environmental Protection Agency (EPA), Office of Research and Development (ORD), gives notice of a meeting of the Board of Scientific Counselors (BOSC) Executive Committee (EC).

DATES: The meeting will be held on Thursday, June 27, 2019, from 8:30 a.m. to 5:30 p.m., and Friday, June 28, 2019, from 8:30 a.m. until 2:00 p.m. All times noted are Eastern Time and approximate. The meeting may adjourn early if all business is finished. Attendees should register by June 20 at *https://www.eventbrite.com/e/us-epa-bosc-executive-committee-meeting-tickets-58436808066*. Requests for making oral presentations at the meeting will be accepted up to one business day before the meeting. Comments may be submitted through Tuesday, June 25, 2019.

ADDRESSES: The meeting will be held at the EPA's Research Triangle Park Main Campus Facility, Room C–112, 109 T.W. Alexander Drive, Research Triangle Park, North Carolina 27711. Submit your comments to Docket ID No. EPA–HQ–ORD–2015–0765 by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email:* Send comments by electronic mail (email) to: *ORD.Docket@epa.gov,* Attention Docket ID No. EPA–HQ–ORD–2015–0765.
- *Fax:* Fax comments to: (202) 566–0224, Attention Docket ID No. EPA–HQ–ORD–2015–0765.
- *Mail:* Send comments by mail to: Board of Scientific Counselors (BOSC) Executive Committee Docket, Mail Code: 2822T, 1301 Constitution Ave. NW, Washington, DC 20004, Attention Docket ID No. EPA–HQ–ORD–2015–0765.
- *Hand Delivery or Courier:* Deliver comments to: EPA Docket Center (EPA/DC), Room 3334, William Jefferson Clinton West Building, 1301 Constitution Ave. NW, Washington, DC, Attention Docket ID No. EPA–HQ–ORD–2015–0765. Note: This is not a mailing address. Deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov* including any personal information provided unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* website is an ''anonymous access'' system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. 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. 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's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/dockets/.*

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Board of Scientific Counselors Executive Committee Docket, EPA/DC, William Jefferson Clinton West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. 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, and the telephone number for the ORD Docket is (202) 566–1752.

FOR FURTHER INFORMATION CONTACT: The Designated Federal Officer (DFO) via mail at: Tom Tracy, Mail Code 8104R, Office of Science Policy, Office of Research and Development, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; via phone/voice mail at: (202) 564–6518; via fax at: (202) 565–2911; or via email at: *tracy.tom@epa.gov.*

SUPPLEMENTARY INFORMATION: *General Information:* The meeting is open to the public. Any member of the public interested in receiving a draft agenda, attending the meeting, or making a presentation at the meeting may contact Tom Tracy, the Designated Federal (DFO), via any of the contact methods listed in the **FOR FURTHER INFORMATION CONTACT** section above. Individuals making an oral presentation will be limited to a total of three minutes.

For security purposes, all attendees must provide their names to the DFO by registering online at *https://www.eventbrite.com/e/us-epa-bosc-executive-committee-meeting-tickets-58436808066* by June 25, 2019, and must go through a metal detector, sign in with the security desk, and show REAL ID Act-compliant government-issued photo identification to enter the building. Attendees are encouraged to arrive at least 15 minutes prior to the start of the meeting to allow enough time for security screening. Proposed agenda items for the meeting include but are not limited to the following: Overview of materials provided to the subcommittee, review of charge questions, overview and illustrations of SHC's draft Strategic Research Action Plan and research topics, and subcommittee deliberations.

Information on Services for Individuals with Disabilities: For information on access or services for individuals with disabilities, please contact Tom Tracy (202) 564–6518 or *tracy.tom@epa.gov.* To request accommodation of a disability, please contact Tom Tracy, preferably at least ten days prior to the meeting, to give the EPA as much time as possible to process your request.

Dated April 2, 2019.

Kathleen Deener,

Acting Director, Office of Science Policy.

[FR Doc. 2019–08301 Filed 4–23–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2015–0467; FRL–9992–32–ORD]

Board of Scientific Counselors (BOSC) Safe and Sustainable Water Resources Subcommittee Meeting—May 2019

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act the U.S. Environmental Protection Agency, Office of Research and Development (ORD), gives notice of a meeting of the Board of Scientific Counselors (BOSC) Safe and Sustainable Water Resources Subcommittee.

DATES: The meeting will be held on Tuesday, May 21, 2019, from 3 p.m. to 5 p.m. All times noted are Eastern Time. The meeting may adjourn early if all business is finished. Attendees should register by May 20, 2019. Requests for the draft agenda or for making oral presentations at the meeting will be accepted up to one business day before the meeting.

ADDRESSES: The meeting will be a conference call and the number will be provided following registration at *https://epa-bosc-sswr-teleconference.eventbrite.com.* Submit your comments to Docket ID No. EPA–HQ–ORD–2015–0467 by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email:* Send comments by electronic mail (email) to: *ORD.Docket@epa.gov,* Attention Docket ID No. EPA–HQ–ORD–2015–0467.
- *Fax:* Fax comments to: (202) 566–0224, Attention Docket ID No. EPA–HQ–ORD–2015–0467.
- *Mail:* Send comments by mail to: Board of Scientific Counselors (BOSC) Safe and Sustainable Water Resources Subcommittee Docket, Mail Code: 2822T, 1301 Constitution Ave. NW, Washington, DC 20004, Attention Docket ID No. EPA–HQ–ORD–2015–0467.
- *Hand Delivery or Courier:* Deliver comments to: EPA Docket Center (EPA/DC), Room 3334, William Jefferson Clinton West Building, 1301 Constitution Ave. NW, Washington, DC, Attention Docket ID No. EPA–HQ–ORD–2015–0467. Note: this is not a mailing address. Deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov* including any personal information provided unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* website is an ''anonymous access'' system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. 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. 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's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/dockets/.*

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Board of Scientific Counselors Executive Committee Docket, EPA/DC, William Jefferson Clinton West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. 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, and the telephone number for the ORD Docket is (202) 566–1752.

FOR FURTHER INFORMATION CONTACT: The Designated Federal Officer (DFO) via mail at: Tom Tracy, Mail Code 8104R, Office of Science Policy, Office of Research and Development, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; via phone/voice mail at: (202) 564–6518; via fax at: (202) 565–2911; or via email at: *tracy.tom@epa.gov.*

SUPPLEMENTARY INFORMATION: *General Information:* The meeting is open to the public. Any member of the public interested in receiving a draft agenda, attending the meeting, or making a presentation at the meeting may contact Tom Tracy, the Designated Federal (DFO), via any of the contact methods listed in the **FOR FURTHER INFORMATION CONTACT** section above. Individuals making an oral presentation will be limited to a total of three minutes. All attendees must register online at *https://epa-bosc-sswr-teleconference.eventbrite.com* by May 20, 2019. Proposed agenda items for the meeting include but not limited to the following: Review of charge questions, draft subcommittee report and Subcommittee discussion.

Information on Services for Individuals with Disabilities: For information on access or services for individuals with disabilities, please contact Tom Tracy (202) 564–6518 or *tracy.tom@epa.gov.* To request accommodation of a disability, please contact Tom Tracy, preferably at least ten days prior to the meeting, to give the EPA as much time as possible to process your request.

Dated April 9, 2019.

Kathleen Deener,

Acting Director, Office of Science Policy.

[FR Doc. 2019–08302 Filed 4–23–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2013–0118; FRL–9992–68–OAR]

Proposed Information Collection Request; Comment Request; Control of Evaporative Emissions From New and In-Use Portable Gasoline Containers (Renewal), ICR 2213.06, OMB 2060–0597

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), ''Control of Evaporative Emissions from New and In-Use Portable Gasoline Containers (Renewal)'', ICR 2213.06,

OMB 2060–0597 to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection request as described below. This notice is a proposed extension of the Portable Fuel Container ICR, which is currently approved through September 30, 2019. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before June 24, 2019.

ADDRESSES: Submit your comments, referencing the Docket ID No. EPA–HQ–OAR–2013–0118, to the EPA: Online using *www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Julia Giuliano, Compliance Division, Office of Transportation and Air Quality, U.S. Environmental Protection Agency, 2000 Traverwood, Ann Arbor, Michigan 48105; telephone number: 734–214–4865; fax number 734–214–4869; email address: *giuliano.julia@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting will be available in the public docket, EPA–HQ–OAR–2013–0118, for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: EPA is required under Section 183(e) of the Clean Air Act to regulate Volatile Organic Compound (VOC) emissions from the use of consumer and commercial products. Under regulations promulgated on February 26, 2007 (72 FR 8428) manufacturers of new portable gasoline containers are required to obtain certificates of conformity with the Clean Air Act, effective January 1, 2009. This ICR covers the burdens associated with this certification process. EPA reviews information submitted in a manufacturer's application for certification to determine if the gasoline container design conforms to applicable regulatory requirements and to verify that the required testing has been performed. The certificate holder is required to keep records on the testing and collect and keep warranty and defect information for annual reporting on in-use performance of their products. The respondent must also retain records on the units produced, apply serial numbers to individual containers, and track the serial numbers to their certificates of conformity. Any information submitted for which a claim of confidentiality is made is safeguarded according to EPA regulations at 40 CFR 2.201 *et seq.*

Form Numbers: None.

Respondents/affected entities: Manufacturers of new portable gasoline containers from 0.25 to 10.0 gallons in capacity.

Respondent's obligation to respond: Mandatory 40 CFR part 59, subpart F.

Estimated number of respondents: 8 (total).

Frequency of response: Yearly for warranty reports; at least once every five years for certificate renewals.

Total estimated burden: 206.9 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $22,028.90 (per year), includes $12,552 annualized capital or operation & maintenance costs.

Changes in Estimates: There is a reduction of 43.1 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This decrease of the estimated burden and cost estimates is due to a change in the estimated cost of labor and additional testing requirements for new portable fuel container families to comply with the requirements for evaporative testing promulgated in 40 CFR part 59.

Dated: April 17, 2019.

Byron Bunker,

Director, Compliance Division, Office of Transportation and Air Quality, U.S. Environmental Protection Agency.

[FR Doc. 2019–08307 Filed 4–23–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OLEM–2017–0657; FRL–9992–46–OLEM]

RIN 2050–ZA11

Planning for Natural Disaster Debris Guidance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is announcing the availability of a final guidance entitled, Planning for Natural Disaster Debris. The Planning for Natural Disaster Debris guidance is intended to assist communities in planning for debris management before a natural disaster occurs (also referred to as ''pre-incident debris management planning''). This guidance revises EPA's existing guidance document on planning for natural disaster debris that was published in 2008 under the same name. Pre-incident planning can significantly aid decision-making during a response and enhance a community's resiliency. Pre-incident planning can help communities recover faster, spend less money on cleanup and debris/waste management, and use fewer resources to rebuild and recover.

DATES: The announcement of the guidance is published in the **Federal Register** on April 24, 2019.

ADDRESSES: EPA has established a docket for this action under Docket ID

No. EPA–HQ–OLEM–2017–0657. All documents in this docket are listed in the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (CBI) or other information for which 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 at *www.regulations.gov* or in hard copy at the EPA Docket Center Reading Room. Please see *https://www.epa.gov/dockets/epa-docket-center-reading-room* or call (202) 566–1744 for more information on the Docket Center Reading Room.

FOR FURTHER INFORMATION CONTACT: Melissa Kaps, Office of Resource Conservation and Recovery (5304P), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: 703–308–6787; email address: *kaps.melissa@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Planning for Natural Disaster Debris Guidance

The U.S. Environmental Protection Agency's (EPA's) final Planning for Natural Disaster Debris guidance provides planning suggestions and considerations to assist the whole community (*i.e.,* all governmental, private, nonprofit, community, and other stakeholders) in preparing for debris management before a natural disaster occurs. Communities that may benefit from the advice presented in this document include those that are currently without a debris management plan, are in the beginning stages of the debris management planning process, or have existing debris management plans that are not comprehensive or have not been updated with new information. Plans should be updated regularly to keep the information current (*e.g.,* record reductions in existing disposal capacity, include innovative reuse or recycling opportunities), as well as exercised to ensure that the whole community remains familiar with their roles and responsibilities in the implementation of the disaster debris plan.

Updating the 2008 version of EPA's Planning for Natural Disaster Debris, this guidance adds information drawn from communities' experiences with natural disasters, including hurricanes, earthquakes, tornadoes, volcanoes, floods, wildfires, and winter storms, and provides more planning recommendations, resources, and lessons learned for managing natural disaster debris. Also, this guidance walks through EPA's pre-incident debris management planning process. This process has four steps to help prepare communities for effective debris management: (1) Conduct pre-planning activities; (2) develop a comprehensive pre-incident debris management plan; (3) keep the debris management plan updated; and (4) implement the debris management plan during a natural disaster.

Natural disasters generate large amounts of debris that communities must manage to fully recover from the disaster. Debris management is often one of the biggest costs for a response, and recovery is not complete until all debris has been managed. Pre-incident debris management planning can significantly aid decision-making during a natural disaster by allowing important analyses and considerations to be made in advance, *i.e.,* not during a disaster response. Pre-incident planning can also enhance a community's resiliency by, for example, identifying (and mitigating) potential debris sources in advance. In the event of a disaster, a more resilient community generates less debris to manage and contains fewer hazardous materials that may pose an increased risk to human health and the environment if released. Resilient communities recover faster, spend less money on cleanup and debris management, and use fewer resources to rebuild and recover. Effective planning addresses source reduction and hazard mitigation activities to reduce the amount and toxicity of debris generated by a natural disaster; strategies for reuse and recycling of materials to minimize the environmental and economic impact of debris management activities; and issues and considerations beyond initial debris removal [for example, characterizing and processing (*e.g.,* volume reduction, refrigerant removal) debris for proper management, tracking debris from the original deposited point to its final destination, communicating with the public about debris collection and other management activities]. For these reasons, EPA believes it is critical that communities include debris management planning in their overall preparation for natural disasters.

A copy of the final guidance can be found on EPA's website at *https://www.epa.gov/homeland-security-waste/guidance-about-planning-natural-disaster-debris.*

Dated: April 4, 2019.

Barnes Johnson,

Director, Office of Resource Conservation and Recovery.

[FR Doc. 2019–08305 Filed 4–23–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9992–27–OA]

Request for Nominations of Candidates for EPA's Science Advisory Board Computable General Equilibrium Model Review Panel

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The U.S. Environmental Protection Agency (EPA) Science Advisory Board (SAB) Staff Office invites nominations of environmental economists and other experts with expertise in computable general equilibrium (CGE) modeling to be considered for appointment to the SAB's CGE Model Review Panel.

DATES: Nominations should be submitted in time to arrive no later than May 15, 2019.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing further information regarding this Notice and Request for Nominations may contact Dr. Holly Stallworth, Designated Federal Officer (DFO), EPA Science Advisory Board Staff Office (1400R), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; by telephone at (202) 564–2073 or at *stallworth.holly@epa.gov.* General information concerning the EPA SAB can be found at the EPA SAB website at *http://www.epa.gov/sab.*

SUPPLEMENTARY INFORMATION:

Background: The SAB (42 U.S.C. 4365) is a chartered Federal Advisory Committee that provides independent scientific and technical peer review, advice and recommendations to the EPA Administrator on the technical basis for EPA actions. As a Federal Advisory Committee, the SAB conducts business in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2) and related regulations. The SAB CGE Model Review Panel will be an ad hoc panel of the SAB that provides advice through the chartered SAB. It will be charged with reviewing a CGE model developed by EPA's National Center for Environmental Economics (NCEE) for use by agency analysts for the economic analysis of environmental regulations. Experts

selected for the panel will be asked to review the model code and documentation, run the model and independently verify how it works to respond to NCEE's charge questions. Thus, the SAB Staff Office is seeking nominations of environmental economists and other experts with extensive experience building and using CGE models. The SAB CGE Model Review Panel will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies. The SAB CGE Model Review Panel will operate under the auspices of the SAB.

Request for Nominations: The SAB Staff Office is seeking nominations of environmental economists and other experts with CGE modeling experience.

Process and Deadline for Submitting Nominations: Any interested person or organization may nominate qualified individuals with CGE modeling experience for possible service on the SAB CGE Model Review Panel identified in this notice. Nominations should be submitted in electronic format (preferred) following the instructions for ''Nominating Experts to Advisory Panels and Ad hoc Committees Being Formed,'' provided on the SAB website (see the ''Nomination of Experts'' link under ''Current Activities'') at *http://www.epa.gov.sab.*

To receive full consideration, EPA's SAB Staff Office requests contact information about the person making the nomination; contact information about the nominee; the disciplinary and specific areas of expertise of the nominee; the nominee's resume or curriculum vitae; sources of recent grant and/or contract support; and a biographical sketch of the nominee indicating current position, educational background, research activities, and recent service on other national advisory committees or national professional organizations.

Persons having questions about the nomination procedures, or who are unable to submit nominations through the SAB website, should contact Dr. Holly Stallworth as indicated above in this notice. Nominations should be submitted in time to arrive no later than May 15, 2019. EPA values and welcomes diversity. All qualified candidates are encouraged to apply regardless of sex, race, disability, or ethnicity.

The EPA SAB Staff Office will acknowledge receipt of nominations. The names and biosketches of qualified nominees identified by respondents to this **Federal Register** notice, and additional experts identified by the SAB Staff, will be posted in a List of Candidates on the SAB website at *http://www.epa.gov/sab.* Public comments on the List of Candidates will be accepted for 21 days. The public will be requested to provide relevant information or other documentation on nominees that the SAB Staff Office should consider in evaluating candidates.

For the EPA SAB Staff Office, a balanced review panel includes candidates who possess the necessary domains of knowledge, the relevant scientific perspectives (which, among other factors, can be influenced by work history and affiliation), and the collective breadth of experience. The SAB Staff Office will consider public comments on the List of Candidates, information provided by the candidates themselves, and background information independently gathered by the SAB Staff Office. Selection criteria to be used for panel membership include: (a) Scientific and/or technical expertise, knowledge, and experience (primary factors), *e.g.* journal publications within the last ten years that rely on and discuss CGE model results; (b) availability and willingness to serve; (c) absence of financial conflicts of interest; (d) absence of an appearance of a loss of impartiality; and (e) skills working in panels and advisory committees; and, (f) for the panel as a whole, diversity of expertise and scientific points of view.

The SAB Staff Office's evaluation of an absence of financial conflicts of interest will include a review of the ''Confidential Financial Disclosure Form for Special Government Employees'' (EPA Form 3110–48). This confidential form allows government officials to determine whether there is a statutory conflict between a person's public responsibilities (which include membership on an EPA federal advisory committee) and private interests and activities, or the appearance of a loss of impartiality, as defined by federal regulation. The form may be viewed and downloaded from the following URL address *http://yosemite.epa.gov/sab/sabproduct.nsf/Web/ethics?OpenDocument.*

Dated: April 9, 2019.

Khanna Johnston,

Deputy Director, EPA Science Advisory Board Staff Office.

[FR Doc. 2019–08304 Filed 4–23–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2015–0635; FRL–9992–31–ORD]

Board of Scientific Counselors (BOSC) Chemical Safety for Sustainability Subcommittee Meeting—May 2019

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act the U.S. Environmental Protection Agency, Office of Research and Development (ORD), gives notice of a meeting of the Board of Scientific Counselors (BOSC) Chemical Safety for Sustainability (CSS) Subcommittee.

DATES: The meeting will be held on Friday, May 10, 2019, from 2 p.m. to 3:30 p.m. All times noted are Eastern Time. The meeting may adjourn early if all business is finished. Attendees should register by May 9, 2019. Requests for the draft agenda or for making oral presentations at the meeting will be accepted up to one business day before the meeting.

ADDRESSES: The meeting will be a conference call and the number will be provided following registration at *https://epa-bosc-css-hhra-teleconference.eventbrite.com.*

Submit your comments to Docket ID No. EPA–HQ–ORD–2015–0635 by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email:* Send comments by electronic mail (email) to: *ORD.Docket@epa.gov,* Attention Docket ID No. EPA–HQ–ORD–2015–0635.
- *Fax:* Fax comments to: (202) 566–0224, Attention Docket ID No. EPA–HQ–ORD–2015–0635.
- *Mail:* Send comments by mail to: Board of Scientific Counselors (BOSC) Chemical Safety for Sustainability Subcommittee Docket, Mail Code: 2822T, 1301 Constitution Ave. NW, Washington, DC 20004, Attention Docket ID No. EPA–HQ–ORD–2015–0635.
- *Hand Delivery or Courier:* Deliver comments to: EPA Docket Center (EPA/DC), Room 3334, William Jefferson Clinton West Building, 1301 Constitution Ave. NW, Washington, DC, Attention Docket ID No. EPA–HQ–ORD–2015–0635. Note: This is not a mailing address. Deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov* including any personal information provided unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* website is an ''anonymous access'' system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. 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. 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's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/dockets/.*

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Board of Scientific Counselors Executive Committee Docket, EPA/DC, William Jefferson Clinton West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. 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, and the telephone number for the ORD Docket is (202) 566–1752.

FOR FURTHER INFORMATION CONTACT: The Designated Federal Officer (DFO) via mail at: Tom Tracy, Mail Code 8104R, Office of Science Policy, Office of Research and Development, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; via phone/voice mail at: (202) 564–6518; via fax at: (202) 565–2911; or via email at: *tracy.tom@epa.gov.*

SUPPLEMENTARY INFORMATION:

General Information: The meeting is open to the public. Any member of the public interested in receiving a draft agenda, attending the meeting, or making a presentation at the meeting may contact Tom Tracy, the Designated Federal (DFO), via any of the contact methods listed in the **FOR FURTHER INFORMATION CONTACT** section above. Individuals making an oral presentation will be limited to a total of three minutes. All attendees must register online at *https://epa-bosc-css-hhra-teleconference.eventbrite.com* by May 9, 2019. Proposed agenda items for the meeting include but not limited to the following: Review of charge questions, draft subcommittee report and subcommittee discussion.

Information on Services for Individuals with Disabilities: For information on access or services for individuals with disabilities, please contact Tom Tracy (202) 564–6518 or *tracy.tom@epa.gov.* To request accommodation of a disability, please contact Tom Tracy, preferably at least ten days prior to the meeting, to give the EPA as much time as possible to process your request.

Dated April 9, 2019.

Kathleen Deener,

Acting Director, Office of Science Policy.

[FR Doc. 2019–08303 Filed 4–23–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9992–11–OA]

Notice of Meeting of the EPA Children's Health Protection Advisory Committee (CHPAC)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of meeting.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act, notice is hereby given that the next meeting of the Children's Health Protection Advisory Committee (CHPAC) will be held May 9 and 10, 2019 at 1615 @Dupont, located at 1615 New Hampshire Ave. NW, Third Floor, Washington, DC 20009. The CHPAC advises the Environmental Protection Agency (EPA) on science, regulations and other issues relating to children's environmental health.

DATES: May 9, 2019 from 9 a.m. to 5 p.m. and May 10, 2019 from 9 a.m. to 1 p.m.

ADDRESSES: 1615 New Hampshire Ave. NW, Third Floor, Washington, DC 20009.

FOR FURTHER INFORMATION CONTACT: Nica Louie, Office of Children's Health Protection, U.S. EPA, MC 1107T, 1200 Pennsylvania Avenue NW, Washington, DC 20460, (202) 564–7633 or *louie.nica@epa.gov.*

SUPPLEMENTARY INFORMATION: The meetings of the CHPAC are open to the public. An agenda will be posted to *https://www.epa.gov/children/childrens-health-protection-advisory-committee-chpac.*

Access and Accommodations: For information on access or services for individuals with disabilities, please contact Nica Louie at 202–564–7633 or *louie.nica@epa.gov.*

Dated: March 25, 2019.

Nica Louie,

Environmental Health Scientist.

[FR Doc. 2019–08300 Filed 4–23–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL MEDIATION AND CONCILIATION SERVICE

Submission for OMB Review; 30-Day Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Federal Mediation and Conciliation Service.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Federal Mediation and Conciliation Service (FMCS) has submitted to the Office of Management and Budget (OMB) a request for review and approval of a Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (Generic Clearance).

DATES: Written comments must be received on or before May 24, 2019.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for FMCS.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Jeannette Walters-Marquez, 202–606–5488, *jwmarquez@fmcs.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on February 13, 2019 (Vol. 84, No. 30) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The Federal Mediation and Conciliation Service may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised or implemented on or after October 1, 1995, unless it displays a current valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the FMCS has submitted to OMB a request for review and approval of the information collection below.

Proposed Collection: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

Need and Use of Information Collection: The information collection activity will garner qualitative customer and stakeholder feedback in an efficient manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,167.

Current Action: New collection of information.

Type of Review: New collection.

Affected Public: Individuals and Households, Businesses and Organizations, State, Local or Tribal Government.

Below we provide projected average annual estimates:

Estimated Number of Annual Respondents: 7,000.

Expected Annual Number of Activities: 1.

Number of Respondents per Activity: 1.

Annual Responses: 7,000.

Frequency of Response: Once per request.

Average Minutes per Response: 10.

Average Expected Annual Burden hours: 1,167 (7,000 responses × 10/60 minutes).

Dated: April 18, 2019.

Jeannette Walters-Marquez,

Deputy General Counsel, Federal Mediation and Conciliation Service.

[FR Doc. 2019–08235 Filed 4–23–19; 8:45 am]

BILLING CODE 6732–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (''Act'') (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than May 8, 2019.

A. Federal Reserve Bank of Minneapolis (Mark A. Rauzi, Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Penelope K. Lee, Alexandria, Minnesota, individually and as co-trustee of the Eleanor Kaiser Trust A for the benefit of Penelope K. Lee, the Eleanor Kaiser Trust B for the benefit of Penelope K. Lee, and the Eleanor Kaiser Irrevocable Trust for the benefit of Penelope K. Lee (together, the ''Trusts FBO Ms. Lee'' trustees Lake Elmo Bank, Oakdale, Minnesota (branch of Lake Elmo Bank, Lake Elmo, Minnesota), and Penelope K. Lee);* to retain control of the First National Agency of Bagley, Inc. (''Company'') and thereby indirectly retain control of First National Bank (''Bank''), both of Bagley, Minnesota. Additionally, Penelope K. Lee; Trusts FBO Ms. Lee; Whitney Lee, Minneapolis, Minnesota; Tammy Lee Morell, San Diego, California; and Kyle Lee, Cave Creek, Arizona, as a group acting in concert, to retain voting shares of Company and thereby indirectly retain shares of Bank.

2. *William C. Rosacker, Burnsville, Minnesota; William C. Rosacker II, Minnetonka, Minnesota; and Stephanie L. Forbes, Prior Lake, Minnesota;* as a group acting in concert, to retain shares of First National Agency of Bagley, Inc. and thereby indirectly retain shares of First National Bank, both of Bagley, Minnesota.

B. Federal Reserve Bank of Dallas (Robert L. Triplett III, Senior Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *James Samuel Reeves, Parkville, Missouri; Kristin Courtney Thurman, Austin, Texas; Brent Teague Thurman, Englewood, Colorado; Kimberly Colleen Bessent, Fort Worth, Texas; Mace Baxter Thurman, Spicewood, Texas; Miles Brandon Thurman, Richardson, Texas; Macayla Brooke Thurman, Austin, Texas; John Glynn Martino, Phillip Keen Martino, and Helen Leann Sanchez, all of Moody, Texas;* to apply for permission to join the Thurman Family Group, as a group acting in concert, and for the Thurman Family Group to retain voting shares of Reynolds, Teague, Thurman Financial Corp., and indirectly, The First National Bank of Moody, both of Moody, Texas.

Board of Governors of the Federal Reserve System, April 19, 2019.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2019–08244 Filed 4–23–19; 8:45 am]

BILLING CODE P

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Sunshine Act; Notice of Board Member Meeting

TIME AND DATE: 8:30 a.m., April 29, 2019.

PLACE: 77 K Street NE, 10th Floor, Washington, DC 20002.

STATUS: Parts of this meeting will be open to the public. The rest of the meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

Agenda

Federal Retirement Thrift Investment Board

In Person

Board Meeting Agenda

PORTIONS OPEN TO THE PUBLIC:

Open Session

1. Approval of the March 25, 2019 Board Meeting Minutes
2. Monthly Reports
   (a) Participant Activity Report
   (b) Legislative Report
3. Quarterly Reports
   (c) Investment Policy
   (d) Budget Review
   (e) Audit Status
4. OCFO Annual Report
5. Internal Audit
6. Annual Financial Audit—CLA
7. DOL Presentation
8. Withdrawal Project Update

PORTIONS CLOSED TO THE PUBLIC:

Executive Session

Material Covered by 5 U.S.C. 552b(c)(9)(B).

Adjourn

CONTACT PERSON FOR MORE INFORMATION: Kimberly Weaver, Director, Office of External Affairs, (202) 942–1640.

Dated: April 19, 2019.

Dharmesh Vashee,

Deputy General Counsel, Federal Retirement Thrift Investment Board.

[FR Doc. 2019–08221 Filed 4–22–19; 11:15 am]

BILLING CODE 6760–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10673]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by May 24, 2019.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, *Attention:* CMS Desk Officer, *Fax Number:* (202) 395–5806, *OR Email: OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html*

1. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

2. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration; *Use:* CMS plans to use this data to implement and test the MAQI Demonstration, with its associated research questions. More specifically, CMS would review the information collected in both forms to determine whether clinicians meet the conditions for waivers of MIPS reporting requirements and payment adjustments set forth in the Demonstration and therefore may receive the waiver afforded under the demonstration. Information collected as part of the Qualifying Payment Arrangement Submission Form would provide a basis for CMS to determine whether a clinician's contractual/payment arrangement is a Qualifying Payment Arrangement under the MAQI Demonstration. For example, the information collected could be reviewed against the Demonstration's standards for minimum financial risk. Information collected as part of the Threshold Data Submission Form would allow CMS to make the calculations necessary to determine whether the MAQI participant meets the threshold(s) required to receive waivers from MIPS reporting requirements and payment adjustments under the Demonstration.

While selection of qualifying clinicians would be the main use of these data, CMS might also use this information to inform monitoring and the evaluation of the MAQI Demonstration as needed and in conjunction with the MAQI Demonstration's research questions.

Finally, this data may be used by the Department of Justice, a court, or adjudicatory body, another federal agency investigating fraud, waste, and abuse, appropriate agencies in the case of a system breach, or the U.S. Department of Homeland Security in the event of a cybersecurity incident. *Form Number:* CMS–10673 (OMB control number: 0938–1354; *Frequency:* Annually; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 100,000; *Total Annual Responses:*

100,000; *Total Annual Hours:* 1,500,000. (For policy questions regarding this collection contact John Amoh at *john.amoh@cms.hhs.gov*.)

Dated: April 18, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–08194 Filed 4–23–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10261 and CMS–10079]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by June 24, 2019.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10261 Part C Medicare Advantage Reporting Requirements and Supporting Regulations in 42 CFR 422.516(a)

CMS–10079 Hospital Wage Index Occupational Mix Survey

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Part C Medicare Advantage Reporting Requirements and Supporting Regulations in 42 CFR 422.516(a); *Use:* Section 1852(m) of the Social Security Act (the Act) and CMS regulations at 42 CFR 422.135 allow Medicare Advantage (MA) plans the ability to provide ''additional telehealth benefits'' to enrollees starting in plan year 2020 and treat them as basic benefits. MA additional telehealth benefits are limited to services for which benefits are available under Medicare Part B but which are not payable under section 1834(m) of the Act. In addition, MA additional telehealth benefits are services that been identified by the MA plan for the applicable year as clinically appropriate to furnish through electronic information and telecommunications technology (or ''electronic exchange'') when the physician (as defined in section 1861(r) of the Act) or practitioner (as defined in section 1842(b)(18)(C) of the Act) providing the service is not in the same location as the enrollee. Per § 422.135(d), MA plans may only furnish MA additional telehealth benefits using contracted providers.

The changes for the 2020 Reporting Requirements will require plans to report Telehealth benefits. The data collected in this measure will provide CMS with a better understanding of the number of organizations utilizing Telehealth per contract and to also capture those specialties used for both in-person and Telehealth. This data will allow CMS to improve its policy and process surrounding Telehealth. In addition, the specialist and facility data we are collecting aligns with some of the provider and facility specialty types that organizations are required to include in their networks and to submit on their HSD tables in the Network Management Module in Health Plan Management System. *Form Number:* CMS–10261 (OMB control number: 0938–1054); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 594; *Total Annual Responses:* 4,752; *Total Annual Hours:* 187,926. (For policy questions regarding this collection contact Mark Smith at 410–786–8015.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of*

Information Collection: Hospital Wage Index Occupational Mix Survey; *Use:* Section 304(c) of Public Law 106–554 mandates an occupational mix adjustment to the wage index, requiring the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. The proposed data collection that is included in this submission complies with this statutory requirement. The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor. *Form Number:* CMS–10079 (OMB control number: 0938–0907); *Frequency:* Yearly; *Affected Public:* Business or Other for-Profits, Not-for-Profit Institutions; *Number of Respondents:* 3,300; *Total Annual Responses:* 3,300; *Total Annual Hours:* 1,584,000. (For policy questions regarding this collection contact Tehila Lipschutz at 410–786–1344.)

Estimated Total Annual Burden Hours: 1,834.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: April 18, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–08184 Filed 4–23–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; The Early Head Start Family and Child Experiences Survey (Baby FACES 2020; OMB #0970–0354)

AGENCY: Office of Planning, Research, and Evaluation; Administration for Children and Families; HHS.

ACTION: Request for Public Comment.

SUMMARY: The Administration for Children and Families (ACF) at the U.S. Department of Health and Human Services (HHS) seeks approval to collect descriptive information for the Early Head Start Family and Child Experiences Survey 2020 (Baby FACES 2020).

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *OPREinfocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: This information collection is to provide nationally representative data on Early Head Start (EHS) programs, centers, classrooms, staff, and families to guide program planning, technical assistance, and research. The proposed data collection builds upon a prior round of the study conducted in 2018 (Baby FACES 2018; OMB 0970–0354) that obtained information on EHS programs at a point in time to better understand how program processes support relationships (*e.g.,* between home visitors and parents, between parents and children, and between teachers and children) which are hypothesized to lead to improved child and family outcomes. Baby FACES 2020 has the same goals as Baby FACES 2018, but while the 2018 study focused on classroom-based relationships, the current study will take a closer look at home visiting processes.

Respondents: Early Head Start program directors, child care center directors, teachers and home visitors, and parents of enrolled children.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Classroom and home visitor sampling form (from EHS staff)	407	204	1	.17	35
Child roster form (from EHS staff)	252	126	1	.33	42
Parent consent form	2,495	1,248	1	.17	212
Parent survey	2,084	1,042	1	.50	521
Parent Child Report	2,008	1,004	1	.25	251
Staff survey (Teacher survey and Home Visitor survey)	1,317	659	1	.5	330
Staff Child Report	1,046	523	2.13	.25	279
Program director survey	120	60	1	.5	30
Center director survey	294	147	1	.33	49
Parent-child interaction	996	498	1	.17	85

Authority: Sec 640(a)(2)(D) and Sec 649 of the Improving Head Start for School Readiness Act Sec 645A and 649 of the

Improving Head Start for School Readiness Act of 2007 and the Consolidated Appropriations Act of 2017.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–08248 Filed 4–23–19; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Native Employment Works (NEW) Program Plan Guidance and Report Requirements, (OMB No.: 0970–0174)

AGENCY: Division of Tribal TANF Management, Office of Family Assistance, Administration for Children and Families, HHS.

ACTION: Request for Public Comment.

SUMMARY: The Administration for Children and Families (ACF) is requesting a three-year extension of the form OFA–0086, NEW Plan Guidance and NEW Program Report (OMB #0970–0174, expiration 7/31/2019). There are changes requested to these forms, including the deletion of guidance for NEW programs included in Public Law 102–477 programs.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *infocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The NEW program plan guidance documents specify the information needed to complete a NEW program plan and explains the process for plan submission every third year and to complete the annual program report. The program plan is the application for NEW program funding and documents how the grantee will carry out its NEW program. The program report provides HHS, Congress, and grantees information to document and assess the activities and accomplishments of the NEW program.

Respondents: Indian tribes and tribal coalitions that run NEW programs.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
NEW program plan guidance for non-477 Tribes	[1] 15	15	1	29	435
NEW program report	[2] 44	44	1	15	660

[1] We estimate that 44 of the 78 NEW grantees will not include their NEW programs in Public Law 102–477 projects. 44 grantees divided by 3 (because grantees submit the NEW plan once every 3 years) = 15.

[2] We estimate that 44 of the 78 NEW grantees will not include their NEW programs in Public Law 102–477 projects and therefore will submit the NEW program report to HHS.

Estimated Total Annual Burden Hours: 1095.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 612.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–08249 Filed 4–23–19; 8:45 am]

BILLING CODE 4184–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Continued Information Collection Activity; Evaluation of the Child Welfare Capacity Building Collaborative (OMB Number: 0970–0484)

AGENCY: Children's Bureau, Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) is requesting a three-year extension of the previously approved forms that include satisfaction surveys; a leadership interview protocol; a web-based collaboration survey; assessment tools; and service-specific feedback forms (OMB #0970–0484, expiration 8/31/2019). There are no changes to the forms.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *infocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The Evaluation of the Child Welfare Capacity Building Collaborative is sponsored by the Children's Bureau, Administration for Children and Families of the U.S. Department of Health and Human Services. The Capacity Building Collaborative includes three centers (Center for States, Center for Tribes,

Center for Courts) funded by the Children's Bureau to provide national child welfare expertise and evidence-informed training and technical assistance services to state, tribal and territorial public child welfare agencies and Court Improvement Programs (CIPs). The Centers offer a wide array of services including, but not limited to: Web-based content and resources, product development and dissemination, self-directed and group-based training, virtual learning and peer networking events, and tailored consultation and coaching. During the project period, Center services are evaluated by both Center-specific evaluations and a Cross-Center Evaluation. The Center-specific evaluations are designed to collect data on Center-specific processes and outcomes, which are used to support service delivery and continuous quality improvement. The Cross-Center Evaluation is designed to respond to a set of cross-cutting evaluation questions posed by the Children's Bureau. The Cross-Center Evaluation examines: How and to what extent key partners across and within Centers collaborate; whether Center capacity building service interventions are evaluable; the degree to which Centers follow common protocols; what service interventions are delivered and in what services do jurisdictions participate; how satisfied recipients are with services; what outcomes are achieved in jurisdictions receiving Center services and under what conditions are services effective; and what are the costs of services.

The Cross-Center Evaluation uses a longitudinal, mixed methods approach to evaluate Center services as they develop and mature over the course of the study. Multiple data collection strategies are used to efficiently capture quantitative and qualitative data to enable analyses that address each evaluation question. Cross-Center Evaluation data sources for this effort include (1) satisfaction surveys to assess recipient satisfaction with services, such as the Learning Experiences Satisfaction Survey; (2) a leadership interview used to assess perceptions of state child welfare directors, tribal child welfare directors, and CIP directors; and (3) a web-based collaboration survey used to assess perceptions of collaboration within and between the capacity building centers. Center-specific data sources for this effort include (1) assessment tools such as the Center for Tribes Needs and Fit Exploration Tools; and (2) service-specific feedback forms, such as the Center for States Intensive Projects instrument and the Center for Courts CQI Workshops instrument.

Respondents: Respondents of data collection instruments include (1) child welfare and judicial professionals who use the Collaborative's products and online courses, that participate in webinars, virtual or in-person trainings, or peer events, and that receive brief or intensive tailored services from the Centers; (2) all State child welfare directors, and Tribal child welfare directors, and CIP coordinators that receive services from the Centers; and (3) directors and staff of the three Capacity Building Centers.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Web Pages and Products Satisfaction Survey	6,240	2,080	1	.08	166
Learning Experiences Satisfaction Survey (single) [1]	2,000	666	1	.33	220
Learning Experiences Satisfaction Survey (intensive) [2]	3,600	1200	1	.08	96
Webinars, Events, and In-Person Meetings Satisfaction Survey	22,008	7,336	1	.08	587
Center for States Information and Referral Survey	48	16	1	.05	1
Center for States Intensive Projects Survey	1,320	440	2	.33	290
Center for States Constituency Groups Surveys	1,600	533	2	.33	352
Center for States Brief Tailored Services Survey	500	166	1	.33	55
Center for Tribes Contact Form	200	22	1	.05	1
Center for Tribes Demographic Survey	80	26	1	1.75	46
Center for Tribes Needs and Fit Exploration Tool Phase 1	120	40	1	1.5	60
Center for Tribes Needs and Fit Exploration Tool Phase 2	100	33	1	3.0	99
CIP Annual Meeting Survey	800	266	1	.13	35
Center for Courts CQI Workshops Survey	192	63	1	.17	11
Assessment and Capacity Building Work Plan Satisfaction Survey	1,800	600	1	.066	40
Leadership Interview—States and Territories	52	17	2	1	34
Leadership Interview—CIPs	52	17	2	1	34
Leadership Interview—Tribes	32	10	2	1.25	25
Leadership Interview Part II—Tribes	32	10	2	.67	13
Annual Collaboration Survey	920	306	1	.36	110
Total	.....	.....	.....	.....	2,275

[1] *For Learning Experiences that consist of a single event (e.g., on-line session or in-person training).*
[2] *For more intensive Learning Experiences that require administration of multiple surveys over a series of events, modules, or units.*

Estimated Total Annual Burden Hours: 2,275.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 5106.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–08247 Filed 4–23–19; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0232]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Interstate Shellfish Dealer's Certificate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 24, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0021. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Interstate Shellfish Dealer's Certificate OMB Control Number 0910–0021—Revision

Under section 243 of the Public Health Service Act (42 U.S.C. 243) FDA is required to cooperate with and aid State and local authorities in the enforcement of their health regulations, and is authorized to assist States in the prevention and suppression of communicable diseases. Under this authority, we participate with State regulatory agencies, some foreign nations, and the molluscan shellfish industry in the National Shellfish Sanitation Program (NSSP). NSSP is a voluntary, cooperative program to promote the safety of molluscan shellfish by providing for the classification and patrol of shellfish growing waters and for the inspection and certification of shellfish processors.

Each NSSP-participating State and foreign nation monitors its molluscan shellfish processors and for purposes of interstate or international commerce issues certificates for those that meet the State or foreign shellfish control authority's criteria. Each participating State and nation provides a certificate of its certified shellfish processors to FDA on Form FDA 3038, ''Interstate Shellfish Dealer's Certificate.'' We use this information to publish the ''Interstate Certified Shellfish Shippers List,'' a monthly comprehensive listing of all molluscan shellfish processors certified under the cooperative program. If we did not collect the information necessary to compile this list, participating States would not be able to identify and keep out shellfish processed by uncertified processors in other States and foreign nations. Consequently, NSSP would not be able to control the distribution of uncertified and possibly unsafe shellfish in interstate and international commerce, and its effectiveness would be nullified.

In the **Federal Register** of March 9, 2018 (83 FR 10487), we published a notice seeking comment on a proposed determination that the European Union's (EU's) system of food safety control measures for raw bivalve molluscan shellfish intended for export into the United States, as adopted and implemented in Spain and the Netherlands, provides at least the same level of sanitary protection as the United States equivalent. If finalized, such a determination would permit the importation of shellfish harvested from certain European production areas and processed by European establishments that have been listed by FDA on the Interstate Certified Shellfish Shippers List.

The March 9, 2018, notice also described the European Commission's (EC's) determination that the United States' system is equivalent to its own, and as a result of that determination, its stated intent to accept shellfish from certain growing areas in the United States. On November 6, 2018, the EC published Commission Implementing Decision (EU) 2018/1668 which added the United States (MA and WA only) to the list of Third Countries from which molluscan shellfish imports are permitted. Shellfish harvested from growing areas with an Approved classification in those states are eligible for export to the EU.

As part of the equivalence determination, the EC identified the need for FDA to provide documentation collected from NSSP-participating shellfish control authorities seeking recognition under the EC's equivalence determination. This documentation includes:

- A list of growing areas with an Approved classification,
- The most recent sanitary survey for each growing area with an Approved classification, and
- The most recent inspection report for each firm seeking to export shellfish to the EU.

For NSSP-Participants that do not produce live/raw shellfish required documentation is limited to the most recent Plant and Shipping Element Program Evaluation Report and the most recent inspection report for each shellfish processing firm to be listed for export to the EU.

In the **Federal Register** of June 8, 2018 (83 FR 26699), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of Interstate Shellfish Dealer's Certificate.	3038	40	57	2,280	0.10 (6 minutes)	228

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of NSSP Compliance Documentation.	N/A	13	1	13	0.25 (15 minutes)	3.25
Total	.....	.....	.....	.....	.....	231.25

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We estimate that 40 respondents will submit 2,280 Interstate Shellfish Dealer's Certificates (Form FDA 3038) annually, or an average of 57 responses per respondent. We estimate that it takes a respondent an average of 6 minutes or 0.1 hour to complete each form for a total burden of 228 hours (2,280 submissions × 0.10 hours). This estimate is based on our experience with this information collection and the number of certificates received in the past 3 years, which has remained constant.

In order to gain equivalence recognition by the EC, we estimate that respondents will make a one-time submission of documents demonstrating NSSP compliance. We estimate that 13 respondents will each submit 1 response, for a total of 13 responses. We estimate that each response will take 15 minutes, or 0.25 hour, for an annual total of 3.25 hours (13 responses × 0.25 hour).

Dated: April 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–08174 Filed 4–23–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3458]

Food Handler Antiseptic Drug Products for Over-the-Counter Human Use; Request for Data and Information; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for data and information; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the comment period provided in the notice entitled ''Food Handler Antiseptic Drug Products for Over-the-Counter Human Use; Request for Data and Information'' that appeared in the **Federal Register** of December 7, 2018. That notice announced the establishment of a docket to obtain data, information, and comments that will assist the Agency in assessing the safety and effectiveness of food handler antiseptic drug products (*i.e.,* antiseptic hand washes or rubs intended for use in food handling settings) for over-the-counter human use. The Agency is taking this action to allow interested persons additional time to submit comments, data, or information.

DATES: FDA is reopening the comment period on the notice published on December 7, 2018 (83 FR 63168). Submit either electronic or written comments by July 23, 2019.

ADDRESSES: You may submit comments, data, or information as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 23, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 23, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–N–3458 for ''Food Handler Antiseptic Drug Products for Over-the-Counter Human Use; Request for Data and Information; Reopening of Comment Period.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available

for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Pranvera Ikonomi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5418, Silver Spring, MD 20993–0002, 240–402–0272.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 7, 2018 (83 FR 63168), FDA published a notice entitled ''Food Handler Antiseptic Drug Products for Over-the-Counter Human Use; Request for Data and Information'' with a 60-day comment period to obtain data, information, and comments relating to the safety and effectiveness of food handler antiseptics. Following publication of the December 7, 2018, notice, FDA received a request to allow interested persons additional time to comment. FDA is reopening the comment period until July 23, 2019. The Agency believes that an additional 90 days will allow adequate time for interested persons to respond to FDA's specific requests for comments.

Dated: April 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–08251 Filed 4–23–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–1317]

Antimicrobial Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Antimicrobial Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on June 6, 2019, from 8:30 a.m. to 4:30 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2019–N–1317. The docket will close on June 5, 2019. Submit either electronic or written comments on this public meeting by June 5, 2019. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 5, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 5, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before May 22, 2019, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–1317 for ''Antimicrobial Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see the **ADDRESSES** section), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two

copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: LaToya Bonner, Center for Drug Evaluation and Research, HFD–21, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *AMDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The committee will discuss new drug application (NDA) 212862, pretomanid tablets for oral administration, submitted by The Global Alliance for TB Drug Development, Inc., proposed as part of a combination regimen with bedaquiline and linezolid in adults for the treatment of pulmonary extensively drug resistant and treatment-intolerant or non-responsive multidrug-resistant tuberculosis (TB).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see the **ADDRESSES** section) on or before May 22, 2019, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 14, 2019. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 15, 2019.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact LaToya Bonner (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–08175 Filed 4–23–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–1281]

General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on May 30, 2019, from 10 a.m. to 4 p.m. and on May 31, 2019, from 8 a.m. to 4 p.m.

ADDRESSES: The meeting will be held at the Gaithersburg Holiday Inn, Grand Ballroom, Two Montgomery Village Ave., Gaithersburg, MD 20879. The hotel's telephone number is 301–948–8900; additional information available online at: *https://www.reservations.com/hotel/holiday-inn-gaithersburg?rmcid=rcc4&msclkid=8cda4d308856180123cc11aeb932c40b&utm_source=bing&utm_medium=cpc&utm_campaign=Top%20Hotels&utm_term=Holiday%20Inn%20Gaithersburg&utm_content=Holiday%20Inn%20Gaithersburg_1736466.* Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/*

AdvisoryCommittees/AboutAdvisory Committees/ucm408555.htm.

FOR FURTHER INFORMATION CONTACT: Patricio Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G610, Silver Spring, MD 20993, *Patricio.garcia@fda.hhs.gov,* 301–796–6875, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On May 30, 2019, the committee will discuss and make recommendations regarding the reclassification of surgical stapler devices for internal use from Class I (general controls) to Class II (special controls). On May 31, 2019, the committee will discuss and make recommendations regarding the reclassification of certain absorbable hemostatic agents from Class III to Class II (special controls).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 20, 2019. Oral presentations from the public will be scheduled on May 30 and 31, 2019, between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**) and indicate which session they would like to present. The notification should include a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 10, 2019. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing sessions. The contact person will notify interested persons regarding their request to speak by May 13, 2019.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams at *annmarie.williams@fda.hhs.gov* or 301–796–5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–08261 Filed 4–23–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–1262]

Surgical Staplers and Staples for Internal Use—Labeling Recommendations; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Surgical Staplers and Staples for Internal Use—Labeling Recommendations.'' FDA is issuing this draft guidance to provide labeling recommendations for surgical staplers and staples for internal use. These labeling recommendations are being issued because malfunctions and misuse associated with these devices have resulted in serious adverse events, including deaths. This draft guidance is not final nor is it currently in effect.

DATES: Submit either electronic or written comments on the draft guidance by June 24, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–D–1262 for ''Surgical Staplers and Staples for Internal Use—Labeling Recommendations.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Surgical Staplers and Staples for Internal Use—Labeling Recommendations'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: R. Dale Rimmer, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G425, Silver Spring, MD 20993–0002, 240–402–4828.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled ''Surgical Staplers and Staples for Internal Use—Labeling Recommendations.'' Surgical staplers for internal use are specialized prescription devices used to deliver compatible staples to internal tissues during surgery for resection, transection, and creating anastomoses. Surgical staplers and staples for internal use may be indicated for use in a wide range of surgical applications, including but not limited to gastrointestinal, gynecologic, and thoracic surgery. FDA has become aware of a large number of adverse events associated with use of both surgical staplers and staples for internal use. Both device misuse and device malfunctions are root causes of these adverse events. FDA believes that these problems may be mitigated by providing specific information about the risks, limitations, and directions for use in the labeling for the surgical staplers and staples for internal use.

The draft guidance, when finalized, will provide recommendations for information that should be included in the product labeling for surgical staplers and staples for internal use, including contraindications, warnings, directions for use, and technical characteristics and performance parameters. Elsewhere in this issue of the **Federal Register**, FDA is announcing a proposed reclassification of surgical staplers for internal use from class I to class II with special controls. If the reclassification is finalized, some of the labeling recommendations in this guidance may be required as part of the special controls for surgical staplers for internal use. As such, FDA also intends to utilize this draft guidance, when finalized, to provide recommendations to help manufacturers comply with any labeling special controls identified in the final reclassification order.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Surgical Staplers and Staples for Internal Use—Labeling Recommendations.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Surgical Staplers and Staples for Internal Use—Labeling Recommendations'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 18013 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB control No.
807, subpart E	Premarket Notification	0910–0120

21 CFR part	Topic	OMB control No.
801	Medical Device Labeling Regulations	0910–0485

Dated: April 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–08259 Filed 4–23–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–1468]

Characterizing the Food and Drug Administration's Approach to Benefit-Risk Assessment Throughout the Medical Product Life Cycle; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled ''Characterizing FDA's Approach to Benefit-Risk Assessment Throughout the Medical Product Life Cycle'' and an opportunity for public comment. The meeting will be convened by Duke University's Robert J. Margolis, MD, Center for Health Policy (Duke-Margolis) and supported by a cooperative agreement with FDA. The meeting is intended to gather industry, patient, researcher, and other stakeholder input on applying FDA's Benefit-Risk Framework throughout the human drug lifecycle and best approaches to communicating FDA's benefit-risk assessment. Input from this meeting will support development of a draft guidance on benefit-risk assessment for new drugs and biologics and result in a publicly available summary report from Duke-Margolis. This meeting is intended to meet an FDA commitment included in the sixth authorization of the Prescription Drug User Fee Amendments of 2017 (PDUFA VI).

DATES: The public meeting will be held on May 16, 2019, from 9 a.m. to 5 p.m. Submit either electronic or written comments on this public meeting by June 17, 2019. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the Tommy Douglas Conference Center, 10000 New Hampshire Ave., Silver Spring, MD 20903. For information on the public meeting location please see *https://www.tommydouglascenter.com/.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 17, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 17, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–1468 for ''Characterizing FDA's Approach to Benefit-Risk Assessment Throughout the Medical Product Life Cycle; Public Meeting; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management

Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993–0002, 301–796–5003, Fax: 301–847–8443, *Graham.Thompson@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911, *Stephen.Ripley@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This public meeting is intended to satisfy a commitment included in PDUFA VI. This PDUFA reauthorization is part of the FDA Reauthorization Act of 2017 signed by the President on August 18, 2017. The complete set of performance goals and procedures documented in the PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022 (Goals Letter) is available at *https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf.* These goals were developed in consultation with patient and consumer advocates, healthcare professionals, and other public stakeholders as part of negotiations with industry. Section I.J.2 of the Goals Letter, ''Enhancing Benefit-Risk Assessment in Regulatory Decision-Making,'' outlines the commitment for FDA to convene and/or participate in a public meeting to gather stakeholder input on key topics relating to FDA's benefit-risk assessment.

II. Topics for Discussion at the Public Meeting

This meeting will provide FDA the opportunity to gather input from stakeholders on their experiences and perspectives regarding FDA's benefit-risk assessment. Input from this meeting will support development of the draft guidance on benefit-risk assessment for new drugs and biologics as outlined in Section I.J.2 of the Goals Letter, which FDA intends to issue by the end of June 2020. The meeting will allow participants (including industry, patients, researchers, and other stakeholders) to provide input on key topics, including the application of FDA's Benefit-Risk Framework throughout the human drug lifecycle and information that sponsors may develop or collect at the various stages of drug development that can inform the benefit-risk assessment and related regulatory decisions. This includes consideration of how relevant patient experience data and related information may inform the benefit-risk assessment. In addition, the meeting will consider appropriate approaches to communicate to the public FDA's thinking regarding a product's benefit-risk assessment.

For more information on meeting topics and discussion questions, visit *https://healthpolicy.duke.edu/events/benefit-risk-framework-public-workshop.* FDA will publish a background document outlining the topic areas that FDA plans to address in the draft guidance to this site approximately 2 weeks before the meeting date. FDA will also post the agenda and other meeting materials to this site approximately 5 business days before the meeting.

The format of the meeting will consist of a series of presentations, panel discussions, and audience Q&As. In addition to input generated through this public meeting, FDA is interested in receiving input on the planned draft guidance through written comments, which can be submitted to the public docket (see **ADDRESSES**).

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: *https://events.r20.constantcontact.com/register/eventReg?oeidk=a07eg01qxxd45281872&oseq=&c=&ch.* Please register by May 10, 2019. If you are unable to attend the meeting in person, you can register to view a live webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the webcast. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by May 10, 2019, 11:59 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation once they have been accepted. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public meeting.

If you need special accommodations due to a disability, please contact Graham Thompson no later than May 10, 2019, 11:59 p.m. Eastern Time.

Open Public Comment: There will be time allotted during the meeting for open public comment. Sign-up for this session will be on a first-come, first-served basis on the day of the meeting. Individuals and organizations with common interests are urged to consolidate or coordinate and request time for a joint presentation. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. Please register for the webcast by visiting *https://events.r20.constantcontact.com/register/eventReg?oeidk=a07eg01qxxd45281872&oseq=&c=&ch.*

FDA has verified the website addresses in this document as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It also may be viewed at the Dockets Management Staff (see **ADDRESSES**).

Dated: April 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–08219 Filed 4–23–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of a Supplemental Award to the Emergency Medical Services for Children Innovation and Improvement Center at the Baylor College of Medicine

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of a supplemental award to the Emergency Medical Services for Children Innovation and Improvement Center at the Baylor College of Medicine—Grant Number U07MC29829.

SUMMARY: HRSA announces the award of a supplement for $500,000 to the Emergency Medical Services for Children (EMSC) Innovation and Improvement Center. The supplement will permit the Baylor College of Medicine, the cooperative agreement recipient, to establish and lead a new

Quality Improvement Collaborative to support the EMSC State Partnership Program during the budget period of 07/1/2018–06/30/2019. EMSC plans to increase the proportion of EMS agencies that have a designated individual responsible for the coordination of pediatric emergency care by 2020 to 30 percent.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: Baylor College of Medicine.

Amount of Non-Competitive Award: $500,000.

Period of Supplemental Funding: 07/01/2018–06/30/2019.

CFDA Number: 93.127.

Authority: Public Health Service Act, Title XIX, Section 1910 (42 U.S.C. 300w–9); as amended by the Emergency Medical Services for Children Reauthorization Act of 2014, Public Law 113–180.

Justification: Baylor College of Medicine's EMSC Innovation and Improvement Center (EIIC) provides technical assistance to State Partnership grantees on effective methods to improve EMS for pediatric patients within state and local EMS systems. Participant states will be supported by the EIIC through targeted technical assistance, the provision of tools and resources to support local efforts, and sharing of best practices. The EIIC will support the awarded states in participation in the following activities:

—Convene up to 10 state project teams awarded by HRSA comprised of the state EMSC manager and their state and local partners for one face-to-face meeting and regular virtual meetings.

—Facilitate the development of a collective action plan representing the common methods and aims across the QI collaborative for outreach to EMS agencies.

—Provide a venue for participating states to share lessons learned and best practices in outreach design and implementation.

—Provide access to subject matter expertise to advise the QI collaborative on pediatric emergency care coordination in the pre-hospital EMS setting.

—Provide technical assistance to up to 10 participating states as they implement the action plan designed through the QI collaborative.

—Facilitate an assessment at the end of the project to determine the number of EMS agencies that newly report having an individual responsible for coordinating pediatric emergency care.

FOR FURTHER INFORMATION CONTACT: Theresa Morrison-Quinata, Division of Child, Adolescent and Family Health, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18N54, Rockville, MD 20852, Phone: 301–443–1527, Email: *TMorrison-Quinata@hrsa.gov*.

Grantee/organization name	Grant No.	State	FY 2018 authorized funding level	FY 2018 estimated supplemental funding
Baylor College of Medicine	U07MC29829	TX	$1,500,000	$500,000

Dated: April 18, 2019.

George Sigounas,

Administrator.

[FR Doc. 2019–08257 Filed 4–23–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS–0990-new]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before May 24, 2019.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 0990-New-30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Cross-site Study Data for Improving Implementation Evaluation among Office of Adolescent Health (OAH) TPP Grantees to inform National Implementations (IMAGIN).

Type of Collection: New.

OMB No.: 0990–NEW–Office of Adolescent Health—OASH—OS.

Abstract: The Office of Adolescent Health (OAH), U.S. Department of Health and Human Services (HHS) is requesting 3 years of approval by OMB on a new collection. The IMAGIN Cross-Site Study will examine the process that federal grantees follow to get their programs and staff ready for full implementation by exploring specific factors related to the program models' readiness for implementation and evaluation, the grantee organizations' capacity to operate and deliver the program as intended, and the local enabling context. The data from this study will be used to identify meaningful lessons, targeted resources, and timely guidance that could help both current and future federal grantees get their programs ready to implement, and add to the evidence on the successes and challenges of implementing a program. The cross-site study will be conducted with leadership, key program staff and community stakeholders from Fiscal Year 2018 and, if awarded Fiscal Year 2019, grantees of the OAH Teen Pregnancy Prevention Program. It will include semi-structured interviews with grantee leadership, site visits that will include in-person discussions with key program staff and community stakeholders, and a front-line staff web survey with up to 8 front line staff per grantee.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Grantee Leadership Staff Interview Topic Guide: Initial.	Grantee leadership staff	15	1	90/60	23
Grantee Leadership Staff Interview Topic Guide: Follow-up.	Grantee leadership staff	15	1	1	15
Key Program Staff Interview topic guide	Front line staff and supervisors.	47	1	1	47
Community Stakeholder Interview Topic Guide	Key community stakeholders.	9	1	45/60	7
Frontline Staff Survey	Frontline staff	117	1	30/60	59
Total			5		151

Terry Clark,

Office of the Secretary, Asst. Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 2019–08192 Filed 4–23–19; 8:45 am]

BILLING CODE 4150–30–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Planning Grant (R34).

Date: May 13, 2019.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Julio C. Aliberti, Ph.D., Scientific Review Officer, Immunology Review Branch, DEA/SRP RM 3G53A, National Institutes of Health, NIAID 5601 Fishers Lane, MSC 9823, Rockville, MD 20892–9823, 301–761–7322, *julio.aliberti@nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Application (P01).

Date: May 14, 2019.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Ln., Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Julio C. Aliberti, Ph.D., Scientific Review Officer, Immunology Review Branch, DEA/SRP RM 3G53A, National Institutes of Health, NIAID 5601 Fishers Lane, MSC 9823, Rockville, MD 20892–9823, 301–761–7322, *julio.aliberti@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: April 18, 2019.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–08186 Filed 4–23–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Examining Diversity in Aging Research ZAG1 ZIJ–9 O1.

Date: May 30, 2019.

Time: 10:30 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20814, (Telephone Conference Call).

Contact Person: Carmen, Moten, Ph.D., MPH, Scientific Review Officer, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7703, *cmoten@mail.nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel; NIA MSTEM ZAG1 ZIJ–9 O2.

Date: May 31, 2019.

Time: 10:30 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2W–200, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Carmen, Moten, Ph.D., MPH, Scientific Review Officer, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7703, *cmoten@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: April 18, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–08193 Filed 4–23–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Special Topic: Heal Initiative: Pain Management Effectiveness Research Network.

Date: May 22, 2019.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Joseph G. Rudolph, Ph.D., Chief and Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5186, MSC 7844, Bethesda, MD 20892, 301–408–9098, *josephru@csr.nih.gov*.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Neuroendocrinology, Neuroimmunology, Rhythms and Sleep Study Section.

Date: May 30–31, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Michael Selmanoff, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5164, MSC 7844, Bethesda, MD 20892, 301–435–1119, *mselmanoff@csr.nih.gov*.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Biobehavioral Regulation, Learning and Ethology Study Section.

Date: May 30–31, 2019.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Contact Person: Unja Hayes, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, md 20892, 301–827–6830, *unja.hayes@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Understanding and Modifying Temporal Dynamics of Coordinated Neural Activity.

Date: June 3, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Alexei Kondratyev, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5200, MSC 7846, Bethesda, MD 20892, 301–435–1785, *kondratyevad@csr.nih.gov*.

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Social Psychology, Personality and Interpersonal Processes Study Section.

Date: June 3–4, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Indigo, 24 West Franklin Street, Baltimore, MD 21201.

Contact Person: Marc Boulay, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3110, MSC 7808, Bethesda, MD 20892, (301) 300–6541, *boulaymg@csr.nih.gov*.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neurogenesis and Cell Fate Study Section.

Date: June 5, 2019.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Alexandrian, 480 King Street, Alexandria, VA 22314.

Contact Person: Joanne T. Fujii, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4184, MSC 7850, Bethesda, MD 20892, (301) 435–1178, *fujiij@csr.nih.gov*.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Cognition and Perception Study Section.

Date: June 6–7, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Alexandria Old Town, 1900 Diagonal Road, Alexandria, VA 22314.

Contact Person: Devon Rene Brost Oskvig, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3172, Bethesda, MD 20892, *brostd@csr.nih.gov*.

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Clinical Translational Imaging Science Study Section.

Date: June 6–7, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Canopy by Hilton, 940 Rose Avenue, North Bethesda, MD 20852.

Contact Person: Xiang-Ning Li, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5112, MSC 7854, Bethesda, MD 20892, 301–435–1744, *lixiang@csr.nih.gov*.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Arthritis, Connective Tissue and Skin Study Section.

Date: June 6–7, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel at Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.

Contact Person: Robert Gersch, BA, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817, 301–867–5309, *robert.gersch@nih.gov*.

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Pathogenic Eukaryotes Study Section.

Date: June 6–7, 2019.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Tera Bounds, DVM, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3198, MSC 7808, Bethesda, MD 20892, 301–435–2306, *boundst@csr.nih.gov*.

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Pathobiology of Kidney Disease Study Section.

Date: June 12–13, 2019.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Wyndham Grand Chicago Riverfront, 71 E Wacker Dr., Chicago, IL 60601.

Contact Person: Atul Sahai, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2188, MSC 7818, Bethesda, MD 20892, 301–435–1198, *sahaia@csr.nih.gov*.

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Molecular Genetics A Study Section.

Date: June 13, 2019.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Shinako Takada, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–402–9448, *shinako.takada@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Early Screening for Autism.

Date: June 13, 2019.
Time: 11:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Jane A. Doussard-Roosevelt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7848, Bethesda, MD 20892, (301) 435–4445, *doussarj@csr.nih.gov*.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Musculoskeletal Rehabilitation Sciences Study Section.
Date: June 17, 2019.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Westin BWI, 1110 Old Elkridge Landing Road, Linthicum, MD 21229.
Contact Person: Maria Nurminskaya, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, Bethesda, MD 20892, (301) 435–1222, *nurminskayam@csr.nih.gov*.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Auditory System Study Section.
Date: June 17–18, 2019.
Time: 8:00 a.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.
Contact Person: Janita N Turchi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, *turchij@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 18, 2019.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–08191 Filed 4–23–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, RFA–CA–19–009: US-China Program for Biomedical Collaborative Research (R01 Clinical Trial Optional).
Date: May 20, 2019.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Canopy Hotel Bethesda North, 940 Rose Ave., North Bethesda, MD 20852.
Contact Person: Nicholas J Donato, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040, Bethesda, MD 20892, 301–827–4810, *nick.donato@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 18, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–08196 Filed 4–23–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting of the Board of Scientific Counselors, NIDA.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute on Drug Abuse, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIDA.
Date: May 20–21, 2019.
Closed: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.
Place: Intramural Research Program, National Institute on Drug Abuse, NIH, Johns Hopkins Bayview Campus, Baltimore, MD 21223.
Contact Person: Joshua Kysiak, Program Specialist, Biomedical Research Center, Intramural Research Program, National Institute on Drug Abuse, NIH, DHHS, 251 Bayview Boulevard, Baltimore, MD 21224, 443–740–2465, *kysiakjo@nida.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: April 18, 2019.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–08189 Filed 4–23–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel; NEI Audacious Goals Initiative: Preliminary Studies for Translation-Enabling Models of the Visual System.
Date: May 23, 2019.
Time: 8:30 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.
Contact Person: Brian Hoshaw, Ph.D., Scientific Review Officer, National Eye Institute, National Institutes of Health, Division of Extramural Research, 6700 B Rockledge Dr., Ste 3400, Rockville, MD 20892, 301–451–2020, *hoshawb@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: April 18, 2019.

Natasha Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–08188 Filed 4–23–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, SEP–6: NCI Clinical and Translational R21, Omnibus R03, and Quantitative Imaging Tools.

Date: June 6–7, 2019.

Time: 4:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel and Conference Center, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Saejeong J. Kim, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W640, Bethesda, MD 20892–9750, 240–276–5179, *saejeong.kim@nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel, SEP–5: NCI Clinical and Translational R21 and Omnibus R03.

Date: June 18, 2019.

Time: 7:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Robert S. Coyne, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W236, Bethesda, MD 20892–9750, 240–276–7684, *coyners@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS

Dated: April 18, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–08195 Filed 4–23–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2019–0005; OMB No. 1660–0024]

Agency Information Collection Activities: Proposed Collection; Comment Request; Federal Assistance for Offsite Radiological Emergency Preparedness and Planning

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on an extension, without change, of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning extension of a currently approved information collection in use without change representing all information collections related to FEMA Radiological Emergency Preparedness Program requirements described in 44 CFR parts 350 and 352.

DATES: Comments must be submitted on or before June 24, 2019.

ADDRESSES: To avoid duplicate submissions to the docket, please use only one of the following means to submit comments:

(1) *Online.* Submit comments at *www.regulations.gov* under Docket ID FEMA–2019–0005. Follow the instructions for submitting comments.

(2) *Mail.* Submit written comments to Docket Manager, Office of Chief Counsel, DHS/FEMA, 500 C Street SW, 8NE, Washington, DC 20472–3100.

All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available via the link in the footer of *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Renae Connell, Emergency Management Specialist, FEMA/NPD/THD, *renae.connell@fema.dhs.gov* or Darrell Givens, Emergency Management Specialist, FEMA/NPD/THD, *Darrell.givens@fema.dhs.gov.* You may contact the Information Management Division for copies of the proposed collection of information at email address: *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: FEMA's Radiological Emergency Preparedness (REP) Program coordinates the national effort to provide State, Tribal and local governments with relevant and executable planning, training, and exercise guidance and policies necessary to ensure that adequate capabilities exist to prevent, protect against, mitigate the effects of, respond to, and recover from incidents involving commercial nuclear power plants (NPPs).

The REP Program assists State, Tribal and local governments in the development and conduct of off-site REP emergency planning and preparedness activities within the emergency planning zones (EPZs) of Nuclear Regulatory Commission (NRC)-licensed commercial nuclear power facilities. Sec. 109 of the NRC Authorization Act of 1980 (Public Law 96–295) directed the NRC to establish emergency preparedness as a criterion for licensing commercial NPPs. Specifically, section 109 of Public Law 96–295 directed the NRC to establish through rulemaking, (a) standards, developed with FEMA, for the evaluation of State and local government radiological emergency planning and preparedness; and (b) a requirement that the NRC will issue operating licenses. Before issuing a license the NRC must determine that there is (i) a State or local emergency response plan compliant with the standards developed with FEMA or (ii) in the absence of such a plan, a State, local, or utility emergency response plan that provides reasonable assurance that public health and safety is not endangered by the NPP's operation. See Public Law 96–295, 109(b)(1)(A)–(B)). The NRC revised its regulations in Part

50 of Title 10 of the CFR to incorporate additional emergency preparedness requirements, including 16 planning standards for onsite and offsite emergency plans as required by PL 96–295. FEMA mirrors these 16 planning standards in part 350, specifically at 44 CFR 350.5. In the communities surrounding commercial NPPs, 44 CFR 350.5(b) directs FEMA's REP Program to review offsite radiological emergency plans and preparedness. Approved plans and preparedness ''must be determined to adequately protect the public health and safety by providing reasonable assurance that appropriate protective measures can be taken offsite in the event of a radiological emergency.'' FEMA defines reasonable assurance as a determination that State, Tribal, local, and utility offsite plans and preparedness are adequate to protect public health and safety in the emergency planning areas of commercial NPPs. FEMA will consider plans, procedures, personnel, training, facilities, equipment, drills, and exercises, which in its professional judgment are important to the effective implementation of protective measures offsite in the event or any incident at a commercial NPP. FEMA will make its adequacy determination, supported by other Federal agencies, as necessary, by conducting inspections, providing Staff Assistance Visits (SAVs), organizing, conducting and reviewing training, participating in, observing and evaluating drills and exercises, and by being an engaged partner with Federal, State, Tribal, and local government officials and industry stakeholders. State, Tribal, or local government participation in offsite radiological emergency planning and preparedness is voluntary. However, participation in the REP planning and preparedness process necessitates adherence to the program requirements as set forth in 44 CFR part 350, the joint NRC/FEMA document NUREG–0645/FEMA–REP–1, Rev. 1, ''Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants'' (and supplements), and the REP Program Manual (RPM). If State, Tribal, or local governments choose not to participate in REP planning, 44 CFR part 352 outlines the licensee's obligation to develop offsite plans/procedures to protect the public health and safety in accordance with the requirements in Executive Order 12657, as amended.

Title: Federal Assistance for Offsite Radiological Emergency Preparedness and Planning.

Type of Information Collection: Extension, without change, of a currently approved information collection.

OMB Number: 1660–0024.

FEMA Forms: There are no forms for this collection; rather the regulatory text details the content in which information is transmitted to FEMA.

Abstract: The intent of this request is the collection of comments on an extension, without change, of a currently approved information collection an OMB control number representing all information collections related to FEMA REP Program requirements described in 44 CFR parts 350 and 352.

Affected Public: State, Local or Tribal Government; and business and other for profits.

Estimated Number of Respondents: 153.

Estimated Number of Responses: 153.

Estimated Total Annual Burden Hours: 5,360.

Estimated Total Annual Respondent Cost: $311,458.

Estimated Respondents' Operation and Maintenance Costs: $0.

Estimated Respondents' Capital and Start-Up Costs: $0.

Estimated Total Annual Cost to the Federal Government: $566,163.

Comments: Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) 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; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Tammi Hines,

Acting Records Management Branch Chief, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2019–08182 Filed 4–23–19; 8:45 am]

BILLING CODE 9111–46–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2019–0010; OMB No. 1660–0083]

Agency Information Collection Activities: Proposed Collection; Comment Request; Community Disaster Loan (CDL) Program

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency, 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 a revision, of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the Community Disaster Loan (CDL) Program. This revision will combine collections found under OMB Control Numbers 1660–0082 and 1660–0083. Upon approval of this revision, OMB Control Number 1660–0082, Application for Community Disaster Loan Cancellation will be discontinued.

DATES: Comments must be submitted on or before June 24, 2019.

ADDRESSES: To avoid duplicate submissions to the docket, please use only one of the following means to submit comments:

(1) *Online.* Submit comments at *www.regulations.gov* under Docket ID FEMA–2019–0010. Follow the instructions for submitting comments.

(2) *Mail.* Submit written comments to Docket Manager, Office of Chief Counsel, DHS/FEMA, 500 C Street SW, Room 8NE, Washington, DC 20472–3100.

All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available via the link in the footer of *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Martha Polanco, Program Manager,

Disaster Assistance Directorate, Public Assistance Division, (202) 212–5761. You may contact the Records Management Division for copies of the proposed collection of information at email address: *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: The Community Disaster Loan (CDL) Program is authorized by Section 417 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, Public Law 93–288, as amended, 42 U.S.C. 5184, and implementing regulations at 44 CFR subpart K. The Assistant Administrator may make a CDL to any local government which has suffered a substantial loss of tax or other revenues as a result of a major disaster or emergency and which demonstrates a need for Federal financial assistance in order to perform its governmental functions. FEMA shall cancel repayment of all or part of a CDL to the extent that the Assistant Administrator for the Disaster Assistance Directorate determines that revenues of the local government during the full three fiscal year period following the disaster are insufficient, as a result of the disaster, to meet the operating budget for the local government, including additional unreimbursed disaster-related expenses for a municipal operating character.

Collection of Information

Title: Community Disaster Loan Program.

Type of Information Collection: Revision of a currently approved information collection.

OMB Number: 1660–0083.

Form Titles and Numbers: FEMA Form 090–0–4, Letter of Application; FEMA Form 090–0–1, Certification of Eligibility for Community Disaster Loans; FEMA Form 116–0–1, Promissory Note; FEMA Form 085–0–1, Local Government Resolution—Collateral Security; FEMA Form 112–0–3c, Certification Regarding Lobbying; FEMA Form 009–0–15, Application for Loan Cancellation.

Abstract: The loan package for the CDL Program provides Local governments that have suffered substantial loss of tax or other revenues as a result of a major disaster or emergency, the opportunity to obtain financial assistance in order to perform their governmental functions. The loan must be justified on the basis of need and actual expenses.

Affected Public: State, local or Tribal Government.

Number of Respondents: 360.

Number of Responses: 360.

Estimated Total Annual Burden Hours: 1,006.67 hours.

Estimated Total Annual Respondent Cost: $53,937.11.

Estimated Respondents' Operation and Maintenance Costs: $0.

Estimated Respondents' Capital and Start-Up Costs: $0.

Estimated Total Annual Cost to the Federal Government: $1,022,264.28.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) 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; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

William H. Holzerland,

Sr. Director of Information Management Division, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2019–08185 Filed 4–23–19; 8:45 am]

BILLING CODE 9111–19–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

Determination Pursuant to Section 102 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, as Amended

AGENCY: Office of the Secretary, Department of Homeland Security.

ACTION: Notice of determination.

SUMMARY: The Secretary of Homeland Security has determined, pursuant to law, that it is necessary to waive certain laws, regulations, and other legal requirements in order to ensure the expeditious construction of barriers and roads in the vicinity of the international land border near San Luis, Arizona.

DATES: This determination takes effect on April 24, 2019.

SUPPLEMENTARY INFORMATION: Important mission requirements of the Department of Homeland Security (''DHS'') include border security and the detection and prevention of illegal entry into the United States. Border security is critical to the nation's national security. Recognizing the critical importance of border security, Congress has mandated DHS to achieve and maintain operational control of the international land border. Secure Fence Act of 2006, Public Law 109–367, section 2, 120 Stat. 2638 (Oct. 26, 2006) (8 U.S.C. 1701 note). Congress defined ''operational control'' as the prevention of all unlawful entries into the United States, including entries by terrorists, other unlawful aliens, instruments of terrorism, narcotics, and other contraband. *Id.* Consistent with that mandate from Congress, the President's Executive Order on Border Security and Immigration Enforcement Improvements directed executive departments and agencies to deploy all lawful means to secure the southern border. Executive Order 13767, section 1. In order to achieve that end, the President directed, among other things, that I take immediate steps to prevent all unlawful entries into the United States, including the immediate construction of physical infrastructure to prevent illegal entry. Executive Order 13767, section 4(a).

Congress has provided to the Secretary of Homeland Security a number of authorities necessary to carry out DHS's border security mission. One of those authorities is found at section 102 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, as amended (''IIRIRA''). Public Law 104–208, Div. C, 110 Stat. 3009–546, 3009–554 (Sept. 30, 1996) (8 U.S.C. 1103 note), as amended by the REAL ID Act of 2005, Public Law 109–13, Div. B, 119 Stat. 231, 302, 306 (May 11, 2005) (8 U.S.C. 1103 note), as amended by the Secure Fence Act of 2006, Public Law 109–367, section 3, 120 Stat. 2638 (Oct. 26, 2006) (8 U.S.C. 1103 note), as amended by the Department of Homeland Security Appropriations Act, 2008, Public Law 110–161, Div. E, Title V, § 564, 121 Stat. 2090 (Dec. 26, 2007). In section 102(a) of IIRIRA, Congress provided that the Secretary of Homeland Security shall take such actions as may be necessary to install additional physical barriers and roads (including the removal of obstacles to detection of illegal entrants) in the vicinity of the United States border to deter illegal crossings in areas of high illegal entry into the United States. In section 102(b) of IIRIRA, Congress mandated the installation of additional fencing, barriers, roads, lighting, cameras, and sensors on the southwest border. Finally, in section 102(c) of

IIRIRA, Congress granted to the Secretary of Homeland Security the authority to waive all legal requirements that I, in my sole discretion, determine necessary to ensure the expeditious construction of barriers and roads authorized by section 102 of IIRIRA.

Determination and Waiver:

Section 1

The United States Border Patrol's Yuma Sector is an area of high illegal entry. In fiscal year 2018 alone, the United States Border Patrol (''Border Patrol'') apprehended over 26,000 illegal aliens in the Yuma Sector. In that same year Border Patrol seized approximately 8,100 pounds of marijuana, over 78 pounds of cocaine, over 102 pounds of heroin, and over 1,700 pounds of methamphetamine in the Yuma Sector.

In order to satisfy the need for additional border infrastructure in the Yuma Sector, DHS will take action to replace existing barriers. The barrier replacement will occur within two segments of the border in the Yuma Sector. The two segments of the border within which such construction will occur are referred to herein as the ''project area'' and are more specifically described in Section 2 below. Congress provided funding for this project in the Fiscal Year 2018 DHS Appropriations Act, Public Law 115–141, Division F, Title II, section 230.

The replacement of primary fencing within the project area will further Border Patrol's ability to deter and prevent illegal crossings. The existing barriers were constructed between the early-to-mid 1990's and mid-to-late 2000's. The existing barriers will be replaced with an eighteen to thirty foot barrier that employs a more operationally effective design that is intended to meet Border Patrol's operational requirements. In addition, DHS will, where necessary make improvements to existing roads within the project area.

Section 2

I determine that the following areas in the vicinity of the United States border, located in the State of Arizona within the United States Border Patrol's Yuma Sector, are areas of high illegal entry (the ''project area''):

- Starting west of the intersection of County 21½ Street and West Main Canal Road extending south and generally following the Colorado River approximately one and six tenths (1.6) miles to the point where the Colorado River crosses the international border between the United States and Mexico.
- Starting approximately one mile west of the San Luis, Arizona Land Port of Entry and extending east to approximately two and one half (2.5) miles east of Border Monument 198.

There is presently an acute and immediate need to construct physical barriers and roads in the vicinity of the border of the United States in order to prevent unlawful entries into the United States in the project area, pursuant to sections 102(a) and 102(b) of IIRIRA. In order to ensure the expeditious construction of the barriers and roads in the project area, I have determined that it is necessary that I exercise the authority that is vested in me by section 102(c) of IIRIRA.

Accordingly, pursuant to section 102(c) of IIRIRA, I hereby waive in their entirety, with respect to the construction of roads and physical barriers (including, but not limited to, accessing the project area, creating and using staging areas, the conduct of earthwork, excavation, fill, and site preparation, and installation and upkeep of physical barriers, roads, supporting elements, drainage, erosion controls, safety features, lighting, cameras, and sensors) in the project area, all of the following statutes, including all federal, state, or other laws, regulations, and legal requirements of, deriving from, or related to the subject of, the following statutes, as amended:

The National Environmental Policy Act (Pub. L. 91–190, 83 Stat. 852 (Jan. 1, 1970) (42 U.S.C. 4321 *et seq.*)); the Endangered Species Act (Pub. L. 93–205, 87 Stat. 884 (Dec. 28, 1973) (16 U.S.C. 1531 *et seq.*)); the Federal Water Pollution Control Act (commonly referred to as the Clean Water Act (33 U.S.C. 1251 *et seq.*)); the National Historic Preservation Act (Pub. L. 89–665, 80 Stat. 915 (Oct. 15, 1966), as amended, repealed, or replaced by Pub. L. 113–287 (Dec. 19, 2014) (formerly codified at 16 U.S.C. 470 *et seq.,* now codified at 54 U.S.C. 100101 note and 54 U.S.C. 300101 *et seq.*)); the Migratory Bird Treaty Act (16 U.S.C. 703 *et seq.*); the Migratory Bird Conservation Act (16 U.S.C. 715 *et seq.*); the Clean Air Act (42 U.S.C. 7401 *et seq.*); the Archeological Resources Protection Act (Pub. L. 96–95 (16 U.S.C. 470aa *et seq.*)); the Paleontological Resources Preservation Act (16 U.S.C. 470aaa *et seq.*); the Federal Cave Resources Protection Act of 1988 (16 U.S.C. 4301 *et seq.*); the National Trails System Act (16 U.S.C. 1241 *et seq.*); the Safe Drinking Water Act (42 U.S.C. 300f *et seq.*); the Noise Control Act (42 U.S.C. 4901 *et seq.*); the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act (42 U.S.C. 6901 *et seq.*); the Comprehensive Environmental Response, Compensation, and Liability Act (42 U.S.C. 9601 *et seq.*); the Archaeological and Historic Preservation Act (Pub. L. 86–523, as amended, repealed, or replaced by Pub. L. 113–287 (Dec. 19, 2014) (formerly codified at 16 U.S.C. 469 *et seq.,* now codified at 54 U.S.C. 312502 *et seq.*)); the Antiquities Act (formerly codified at 16 U.S.C. 431 *et seq.,* now codified 54 U.S.C. 320301 *et seq.*); the Historic Sites, Buildings, and Antiquities Act (formerly codified at 16 U.S.C. 461 *et seq.,* now codified at 54 U.S.C. 3201–320303 and 320101–320106); the Wild and Scenic Rivers Act (Pub. L. 90–542 (16 U.S.C. 1281 *et seq.*)); the Farmland Protection Policy Act (7 U.S.C. 4201 *et seq.*); the Federal Land Policy and Management Act (Pub L. 94–579 (43 U.S.C. 1701 *et seq.*)); National Fish and Wildlife Act of 1956 (Pub. L. 84–1024 (16 U.S.C. 742a, *et seq.*)); the Fish and Wildlife Coordination Act (Pub. L. 73–121 (16 U.S.C. 661 *et seq.*)); the Wild Horse and Burro Act (16 U.S.C. 1331 *et seq.*); the Administrative Procedure Act (5 U.S.C. 551 *et seq.*); the Rivers and Harbors Act of 1899 (33 U.S.C. 403); the Eagle Protection Act (16 U.S.C. 668 *et seq.*); the Native American Graves Protection and Repatriation Act (25 U.S.C. 3001 *et seq.*); the American Indian Religious Freedom Act (42 U.S.C. 1996); the Military Lands Withdrawal Act of 1999 (Pub L. 106–65, 113 Stat. 885); the Sikes Act (16 U.S.C. 670, *et seq.*); and 43 U.S.C. § 387.

This waiver does not revoke or supersede previous waivers published in the **Federal Register** on January 19, 2007 (72 FR 2535) and April 8, 2008 (73 FR 19078) which shall remain in full force and effect in accordance with their terms. I reserve the authority to execute further waivers from time to time as I may determine to be necessary under section 102 of IIRIRA.

Dated: April 18, 2019.

Kevin K. McAleenan,

Acting Secretary of Homeland Security.

[FR Doc. 2019–08289 Filed 4–23–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

Determination Pursuant to Section 102 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, as Amended

AGENCY: Office of the Secretary, Department of Homeland Security.

ACTION: Notice of determination.

SUMMARY: The Secretary of Homeland Security has determined, pursuant to law, that it is necessary to waive certain laws, regulations, and other legal requirements in order to ensure the expeditious construction of barriers and roads in the vicinity of the international land border in Luna County, New Mexico and Doña Ana County, New Mexico.

DATES: This determination takes effect on April 24, 2019.

SUPPLEMENTARY INFORMATION: Important mission requirements of the Department of Homeland Security (''DHS'') include border security and the detection and prevention of illegal entry into the United States. Border security is critical to the nation's national security. Recognizing the critical importance of border security, Congress has mandated DHS to achieve and maintain operational control of the international land border. Secure Fence Act of 2006, Public Law 109–367, section 2, 120 Stat. 2638 (Oct. 26, 2006) (8 U.S.C. 1701 note). Congress defined ''operational control'' as the prevention of all unlawful entries into the United States, including entries by terrorists, other unlawful aliens, instruments of terrorism, narcotics, and other contraband. *Id.* Consistent with that mandate from Congress, the President's Executive Order on Border Security and Immigration Enforcement Improvements directed executive departments and agencies to deploy all lawful means to secure the southern border. Executive Order 13767, section 1. In order to achieve that end, the President directed, among other things, that I take immediate steps to prevent all unlawful entries into the United States, including the immediate construction of physical infrastructure to prevent illegal entry. Executive Order 13767, section 4(a).

Congress has provided to the Secretary of Homeland Security a number of authorities necessary to carry out DHS's border security mission. One of those authorities is found at section 102 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, as amended (''IIRIRA''). Public Law 104–208, Div. C, 110 Stat. 3009–546, 3009–554 (Sept. 30, 1996) (8 U.S.C. 1103 note), as amended by the REAL ID Act of 2005, Public Law 109–13, Div. B, 119 Stat. 231, 302, 306 (May 11, 2005) (8 U.S.C. 1103 note), as amended by the Secure Fence Act of 2006, Public Law 109–367, section 3, 120 Stat. 2638 (Oct. 26, 2006) (8 U.S.C. 1103 note), as amended by the Department of Homeland Security Appropriations Act, 2008, Public Law 110–161, Div. E, Title V, section 564, 121 Stat. 2090 (Dec. 26, 2007). In section 102(a) of IIRIRA, Congress provided that the Secretary of Homeland Security shall take such actions as may be necessary to install additional physical barriers and roads (including the removal of obstacles to detection of illegal entrants) in the vicinity of the United States border to deter illegal crossings in areas of high illegal entry into the United States. In section 102(b) of IIRIRA, Congress mandated the installation of additional fencing, barriers, roads, lighting, cameras, and sensors on the southwest border. Finally, in section 102(c) of IIRIRA, Congress granted to the Secretary of Homeland Security the authority to waive all legal requirements that I, in my sole discretion, determine necessary to ensure the expeditious construction of barriers and roads authorized by section 102 of IIRIRA.

Determination and Waiver:

Section 1

The United States Border Patrol's El Paso Sector is an area of high illegal entry. In fiscal year 2018, the United States Border Patrol (''Border Patrol'') apprehended over 31,000 illegal aliens attempting to enter the United States between border crossings in the El Paso Sector. Also in fiscal year 2018, the Border Patrol had over 700 separate drug-related events between border crossings in the El Paso Sector, through which it seized over 15,000 pounds of marijuana, over 342 pounds of cocaine, over 40 pounds of heroin, and over 200 pounds of methamphetamine. Additionally, Luna County, New Mexico, and Doña Ana County, New Mexico, which are located in the El Paso Sector, have been identified as High Intensity Drug Trafficking Areas by the Office of National Drug Control Policy.

Due to the high levels of illegal entry of people and drugs within the El Paso Sector, I must use my authority under Section 102 of IIRIRA to install additional physical barriers and roads in the El Paso Sector. Therefore, DHS will take immediate action to replace existing vehicle barriers in the El Paso Sector. The project will occur within two segments of the border in the El Paso Sector. One segment is west of the Columbus, New Mexico Land Port of Entry, and the other segment is located to the east of the Columbus New Mexico Land Port of Entry. The segments within which such construction will occur are referred to herein as the ''project area'' and are more specifically described in Section 2 below.

The existing vehicle barriers within the project area no longer meet the United States Border Patrol's operational needs. The construction of vehicle barriers in the project area initially curtailed illegal vehicular crossings. However, transnational criminal organizations have adapted their tactics by smuggling illicit cargo by foot, cutting the barrier, or driving over it, which has prompted the need for the construction of a more effective barrier. The existing vehicle barriers will be replaced with an eighteen to thirty foot barrier that employs a more operationally effective design. In addition, roads will be constructed or improved and lighting will be installed.

To support DHS's action under Section 102 of IIRIRA, DHS requested that the Department of Defense, pursuant to 10 U.S.C. 284(b)(7), assist by constructing fence, roads, and lighting within the El Paso Sector in order to block drug smuggling corridors across the international boundary between the United States and Mexico. The Acting Secretary of Defense has concluded that the support requested satisfies the statutory requirements of 10 U.S.C. 284(b)(7) and that the Department of Defense will provide such support in the project area described in Section 2 below.

Section 2

I determine that the following areas in the vicinity of the United States border, located in the State of New Mexico within the United States Border Patrol's El Paso Sector, are areas of high illegal entry (the ''project area''):

- Starting at Border Monument 31 and extending east to Border Monument 23.
- Starting at approximately one (1) mile west of Border Monument 20 and extending east to Border Monument 9.

There is presently an acute and immediate need to construct physical barriers and roads in the vicinity of the border of the United States in order to prevent unlawful entries into the United States in the project area pursuant to sections 102(a) and 102(b) of IIRIRA. In order to ensure the expeditious construction of the barriers and roads in the project area, I have determined that it is necessary that I exercise the authority that is vested in me by section 102(c) of IIRIRA.

Accordingly, pursuant to section 102(c) of IIRIRA, I hereby waive in their entirety, with respect to the construction of physical barriers and roads (including, but not limited to, accessing the project area, creating and using staging areas, the conduct of earthwork, excavation, fill, and site preparation, and installation and upkeep of physical barriers, roads, supporting elements, drainage, erosion

controls, safety features, lighting, cameras, and sensors) in the project area, all of the following statutes, including all federal, state, or other laws, regulations, and legal requirements of, deriving from, or related to the subject of, the following statutes, as amended: The National Environmental Policy Act (Pub. L. 91–190, 83 Stat. 852 (Jan. 1, 1970) (42 U.S.C. 4321 *et seq.*)); the Endangered Species Act (Pub. L. 93–205, 87 Stat. 884 (Dec. 28, 1973) (16 U.S.C. 1531 *et seq.*)); the Federal Water Pollution Control Act (commonly referred to as the Clean Water Act (33 U.S.C. 1251 *et seq.*)); the National Historic Preservation Act (Pub. L. 89–665, 80 Stat. 915 (Oct. 15, 1966), as amended, repealed, or replaced by Public Law 113–287 (Dec. 19, 2014) (formerly codified at 16 U.S.C. 470 *et seq.,* now codified at 54 U.S.C. 100101 note and 54 U.S.C. 300101 *et seq.*)); the Migratory Bird Treaty Act (16 U.S.C. 703 *et seq.*); the Migratory Bird Conservation Act (16 U.S.C. 715 *et seq.*); the Clean Air Act (42 U.S.C. 7401 *et seq.*); the Archeological Resources Protection Act (Pub. L. 96–95 (16 U.S.C. 470aa *et seq.*)); the Paleontological Resources Preservation Act (16 U.S.C. 470aaa *et seq.*); the National Trails System Act (16 U.S.C. 1241 *et seq.*); the Federal Cave Resources Protection Act of 1988 (16 U.S.C. 4301 *et seq.*); the Safe Drinking Water Act (42 U.S.C. 300f *et seq.*); the Noise Control Act (42 U.S.C. 4901 *et seq.*); the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act (42 U.S.C. 6901 *et seq.*); the Comprehensive Environmental Response, Compensation, and Liability Act (42 U.S.C. 9601 *et seq.*); the Archaeological and Historic Preservation Act (Pub. L. 86–523, as amended, repealed, or replaced by Pub. L. 113–287 (Dec. 19, 2014) (formerly codified at 16 U.S.C. 469 *et seq.,* now codified at 54 U.S.C. 312502 *et seq.*)); the Antiquities Act (formerly codified at 16 U.S.C. 431 *et seq.,* now codified 54 U.S.C. 320301 *et seq.*); the Historic Sites, Buildings, and Antiquities Act (formerly codified at 16 U.S.C. 461 *et seq.,* now codified at 54 U.S.C. 3201–320303 and 320101–320106); the Farmland Protection Policy Act (7 U.S.C. 4201 *et seq.*); the Federal Land Policy and Management Act (Pub L. 94–579 (43 U.S.C. 1701 *et seq.*)); National Fish and Wildlife Act of 1956 (Pub. L. 84–1024 (16 U.S.C. 742a *et seq.*)); the Fish and Wildlife Coordination Act (Pub. L. 73–121 (16 U.S.C. 661 *et seq.*)); the Wild Horse and Burro Act (16 U.S.C. 1331 *et seq.*); the Administrative Procedure Act (5 U.S.C. 551 *et seq.*); the Eagle Protection Act (16 U.S.C. 668 *et seq.*); the Native American Graves Protection and Repatriation Act (25 U.S.C. 3001 *et seq.*); and the American Indian Religious Freedom Act (42 U.S.C. 1996).

This waiver does not revoke or supersede the previous waiver published in the **Federal Register** on April 8, 2008 (73 FR 19078), which shall remain in full force and effect in accordance with its terms. I reserve the authority to execute further waivers from time to time as I may determine to be necessary under section 102 of IIRIRA.

Dated: April 18, 2019.

Kevin K. McAleenan,

Acting Secretary of Homeland Security.

[FR Doc. 2019–08290 Filed 4–23–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

Determination Pursuant to Section 102 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, as Amended

AGENCY: Office of the Secretary, Department of Homeland Security.

ACTION: Notice of determination.

SUMMARY: The Secretary of Homeland Security has determined, pursuant to law, that it is necessary to waive certain laws, regulations, and other legal requirements in order to ensure the expeditious construction of barriers and roads in the vicinity of the international land border in Yuma County, Arizona.

DATES: This determination takes effect on April 24, 2019.

SUPPLEMENTARY INFORMATION: Important mission requirements of the Department of Homeland Security (''DHS'') include border security and the detection and prevention of illegal entry into the United States. Border security is critical to the nation's national security. Recognizing the critical importance of border security, Congress has mandated DHS to achieve and maintain operational control of the international land border. Secure Fence Act of 2006, Public Law 109–367, section 2, 120 Stat. 2638 (Oct. 26, 2006) (8 U.S.C. 1701 note). Congress defined ''operational control'' as the prevention of all unlawful entries into the United States, including entries by terrorists, other unlawful aliens, instruments of terrorism, narcotics, and other contraband. *Id.* Consistent with that mandate from Congress, the President's Executive Order on Border Security and Immigration Enforcement Improvements directed executive departments and agencies to deploy all lawful means to secure the southern border. Executive Order 13767, section 1. In order to achieve that end, the President directed, among other things, that I take immediate steps to prevent all unlawful entries into the United States, including the immediate construction of physical infrastructure to prevent illegal entry. Executive Order 13767, section 4(a).

Congress has provided to the Secretary of Homeland Security a number of authorities necessary to carry out DHS's border security mission. One of those authorities is found at section 102 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, as amended (''IIRIRA''). Public Law 104–208, Div. C, 110 Stat. 3009–546, 3009–554 (Sept. 30, 1996) (8 U.S.C. 1103 note), as amended by the REAL ID Act of 2005, Public Law 109–13, Div. B, 119 Stat. 231, 302, 306 (May 11, 2005) (8 U.S.C. 1103 note), as amended by the Secure Fence Act of 2006, Public Law 109–367, section 3, 120 Stat. 2638 (Oct. 26, 2006) (8 U.S.C. 1103 note), as amended by the Department of Homeland Security Appropriations Act, 2008, Public Law 110–161, Div. E, Title V, section 564, 121 Stat. 2090 (Dec. 26, 2007). In section 102(a) of IIRIRA, Congress provided that the Secretary of Homeland Security shall take such actions as may be necessary to install additional physical barriers and roads (including the removal of obstacles to detection of illegal entrants) in the vicinity of the United States border to deter illegal crossings in areas of high illegal entry into the United States. In section 102(b) of IIRIRA, Congress mandated the installation of additional fencing, barriers, roads, lighting, cameras, and sensors on the southwest border. Finally, in section 102(c) of IIRIRA, Congress granted to the Secretary of Homeland Security the authority to waive all legal requirements that I, in my sole discretion, determine necessary to ensure the expeditious construction of barriers and roads authorized by section 102 of IIRIRA.

Determination and Waiver

Section 1

United States Border Patrol's Yuma Sector is an area of high illegal entry. In fiscal year 2018, the United States Border Patrol (''Border Patrol'') apprehended over 26,000 illegal aliens attempting to enter the United States between border crossings in the Yuma Sector. Also in fiscal year 2018, the Border Patrol had over 1,400 separate drug-related events between border

crossings in the Yuma Sector, through which it seized over 8,000 pounds of marijuana, over 78 pounds of cocaine, over 102 pounds of heroin, and over 1,700 pounds of methamphetamine. Additionally, Yuma County, Arizona, which is located in the Yuma Sector, has been identified as a High Intensity Drug Trafficking Area by the Office of National Drug Control Policy.

Due to the high levels of illegal entry of people and drugs within the Yuma Sector, I must use my authority under Section 102 of IIRIRA to install additional physical barriers and roads in the Yuma Sector. Therefore, DHS will take immediate action to replace existing barriers in the Yuma Sector. The project will occur within two segments of the border in the Yuma Sector. The first is southeast of the Andrade Port of Entry and runs south along the international border adjacent to the Colorado River. The second is situated on the eastern edge of the Barry M. Goldwater Range. The segments within which such construction will occur are referred to herein as the ''project area'' and are more specifically described in Section 2 below.

The existing barriers within the project area include both vehicle fencing and outmoded pedestrian fencing that no longer meet the United States Border Patrol's operational needs. The construction of vehicle barriers in the project area initially curtailed illegal vehicular crossings. However, transnational criminal organizations have adapted their tactics by smuggling illicit cargo by foot, cutting the barrier, or driving over it, which has prompted the need for the construction of a more effective barrier. The design of the existing pedestrian barrier makes it susceptible to being breached and repeated damage to the existing fencing has made it less effective. The existing vehicle barriers and outmoded pedestrian fencing will be replaced with an eighteen to thirty foot barrier that employs a more operationally effective design. In addition, roads will be constructed or improved and lighting will be installed.

To support DHS's action under Section 102 of IIRIRA, DHS requested that the Department of Defense, pursuant to 10 U.S.C. 284(b)(7), assist by constructing fence, roads, and lighting within the Yuma Sector in order to block drug smuggling corridors across the international boundary between the United States and Mexico. The Acting Secretary of Defense has concluded that the support requested satisfies the statutory requirements of 10 U.S.C. 284(b)(7), and that the Department of Defense will provide such support in the project area described in Section 2 below.

Section 2

I determine that the following areas in the vicinity of the United States border, located in the State of Arizona within the United States Border Patrol's Yuma Sector, are areas of high illegal entry (the ''project area''):

- Starting at the Morelos Dam and extending south and generally following the Colorado River for approximately five and one-half (5.5) miles.
- Starting two and one-half (2.5) miles east of Border Monument 198 and extending east to Border Monument 197.

There is presently an acute and immediate need to construct physical barriers and roads in the vicinity of the border of the United States in order to prevent unlawful entries into the United States in the project area pursuant to sections 102(a) and 102(b) of IIRIRA. In order to ensure the expeditious construction of the barriers and roads in the project area, I have determined that it is necessary that I exercise the authority that is vested in me by section 102(c) of IIRIRA.

Accordingly, pursuant to section 102(c) of IIRIRA, I hereby waive in their entirety, with respect to the construction of physical barriers and roads (including, but not limited to, accessing the project area, creating and using staging areas, the conduct of earthwork, excavation, fill, and site preparation, and installation and upkeep of physical barriers, roads, supporting elements, drainage, erosion controls, safety features, lighting, cameras, and sensors) in the project area, all of the following statutes, including all federal, state, or other laws, regulations, and legal requirements of, deriving from, or related to the subject of, the following statutes, as amended:

The National Environmental Policy Act (Pub. L. 91–190, 83 Stat. 852 (Jan. 1, 1970) (42 U.S.C. 4321 *et seq.*)); the Endangered Species Act (Pub. L. 93–205, 87 Stat. 884 (Dec. 28, 1973) (16 U.S.C. 1531 *et seq.*)); the Federal Water Pollution Control Act (commonly referred to as the Clean Water Act (33 U.S.C. 1251 *et seq.*)); the National Historic Preservation Act (Pub. L. 89–665, 80 Stat. 915 (Oct. 15, 1966), as amended, repealed, or replaced by Pub. L. 113–287 (Dec. 19, 2014) (formerly codified at 16 U.S.C. 470 *et seq.,* now codified at 54 U.S.C. 100101 note and 54 U.S.C. 300101 *et seq.*)); the Migratory Bird Treaty Act (16 U.S.C. 703 *et seq.*); the Migratory Bird Conservation Act (16 U.S.C. 715 *et seq.*); the Clean Air Act (42 U.S.C. 7401 *et seq.*); the Archeological Resources Protection Act (Pub. L. 96–95 (16 U.S.C. 470aa *et seq.*)); the Paleontological Resources Preservation Act (16 U.S.C. 470aaa *et seq.*); the Federal Cave Resources Protection Act of 1988 (16 U.S.C. 4301 *et seq.*); the National Trails System Act (16 U.S.C. 1241 *et seq.*); the Safe Drinking Water Act (42 U.S.C. 300f *et seq.*); the Noise Control Act (42 U.S.C. 4901 *et seq.*); the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act (42 U.S.C. 6901 *et seq.*); the Comprehensive Environmental Response, Compensation, and Liability Act (42 U.S.C. 9601 *et seq.*); the Archaeological and Historic Preservation Act (Pub. L. 86–523, as amended, repealed, or replaced by Pub. L. 113–287 (Dec. 19, 2014) (formerly codified at 16 U.S.C. 469 *et seq.,* now codified at 54 U.S.C. 312502 *et seq.*)); the Antiquities Act (formerly codified at 16 U.S.C. 431 *et seq.,* now codified 54 U.S.C. 320301 *et seq.*); the Historic Sites, Buildings, and Antiquities Act (formerly codified at 16 U.S.C. 461 *et seq.,* now codified at 54 U.S.C. 3201–320303 and 320101–320106); the Wild and Scenic Rivers Act (Pub. L. 90–542 (16 U.S.C. 1281 *et seq.*)); the Farmland Protection Policy Act (7 U.S.C. 4201 *et seq.*); the Federal Land Policy and Management Act (Pub L. 94–579 (43 U.S.C. 1701 *et seq.*)); National Fish and Wildlife Act of 1956 (Pub. L. 84–1024 (16 U.S.C. 742a *et seq.*)); the Fish and Wildlife Coordination Act (Pub. L. 73–121 (16 U.S.C. 661 *et seq.*)); the Wild Horse and Burro Act (16 U.S.C. 1331 *et seq.*); the Administrative Procedure Act (5 U.S.C. 551 *et seq.*); the Rivers and Harbors Act of 1899 (33 U.S.C. 403); the Eagle Protection Act (16 U.S.C. 668 *et seq.*); the Native American Graves Protection and Repatriation Act (25 U.S.C. 3001 *et seq.*); the American Indian Religious Freedom Act (42 U.S.C. 1996); the Military Lands Withdrawal Act of 1999 (Pub L. 106–65, 113 Stat. 885); the Sikes Act (16 U.S.C. 670, *et seq.*); and 43 U.S.C. 387.

This waiver does not revoke or supersede previous waivers published in the **Federal Register** on January 19, 2007 (72 FR 2535) and April 8, 2008 (73 FR 19078), which shall remain in full force and effect in accordance with their terms. I reserve the authority to execute further waivers from time to time as I may determine to be necessary under section 102 of IIRIRA.

Dated: April 18, 2019.

Kevin K. McAleenan,

Acting Secretary of Homeland Security.

[FR Doc. 2019–08291 Filed 4–23–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[190A2100DD/AAKC001030/A0A501010.999900 253G; OMB Control Number 1076–0181]

Agency Information Collection Activities; Rights-of-Way on Indian Land

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of Information Collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Bureau of Indian Affairs (BIA), are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before June 24, 2019.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to Ms. Sharlene Round Face, Bureau of Indian Affairs, Division of Real Estate Services, 1001 Indian School Road Northwest, Mailbox #44, Albuquerque, NM 87104; or by email to *Sharlene.RoundFace@bia.gov.* Please reference OMB Control Number 1076–0181 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Ms. Sharlene Round Face by email at *Sharlene.RoundFace@bia.gov* or by telephone at (505) 563–5258.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the BIA; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the BIA enhance the quality, utility, and clarity of the information to be collected; and (5) how might the BIA minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: This information collection is necessary for the BIA to authorize rights-of-way to cross land held in trust or restricted status on behalf of individual Indians and Tribes, for a specific purpose, including but not limited to building and operating a line or road. The statutory authority for this program is at 25 U.S.C. 323–328. The regulations at 25 CFR 169 implement the statutory authority. The BIA uses the information it collects to determine whether or not to grant a right-of-way, the value of the right-of-way, the appropriate compensation due to landowners, the amount of administrative fees that must be levied, and the penalties, if any, that should be assessed for violations of the right-of-way provisions.

Title of Collection: Rights-of-Way on Indian Land.

OMB Control Number: 1076–0181.

Form Number: Right-of-Way Application.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Tribes, Indian landowners, and the public.

Total Estimated Number of Annual Respondents: 473.

Total Estimated Number of Annual Responses: 473.

Estimated Completion Time per Response: Varies from 1 hour to 80 hours, with

an average of 40 hours.

Total Estimated Number of Annual Burden Hours: 18,920.

Respondent's Obligation: Required to Obtain a Benefit.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: $2,200,000.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Elizabeth K. Appel,

Director, Office of Regulatory Affairs and Collaborative Action—Indian Affairs.

[FR Doc. 2019–08278 Filed 4–23–19; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0027541; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Oregon Parks and Recreation Department, Salem, OR, and Oregon State University, Department of Anthropology, Corvallis, OR

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Oregon State University, Department of Anthropology and the Oregon Parks and Recreation Department (OPRD) have completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and have determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the OPRD. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the OPRD at the address in this notice by May 24, 2019.

ADDRESSES: Nancy Nelson, Oregon Parks and Recreation Department Archaeologist, 725 Summer Street NE, Suite C, Salem, OR 97301 telephone (503) 986–0578.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the

Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the Oregon Parks and Recreation Department, Salem, OR, and in the custody of the Oregon State University, Department of Anthropology, Corvallis, OR. The human remains and associated funerary objects were removed from Site 35CS3, Bullard's Beach State Park, Coos County, OR.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Oregon Parks and Recreation Department and Oregon State University, Department of Anthropology professional staff in consultation with representatives of the Confederated Tribes of Siletz Reservation of Oregon (previously listed as the Confederated Tribes of the Siletz Reservation); Confederated Tribes of the Coos, Lower Umpqua and Siuslaw Indians; and the Coquille Indian Tribe (previously listed as the Coquille Tribe of Oregon). The Burns Paiute Tribe (previously listed as the Burns Paiute Tribe of the Burns Paiute Indian Colony of Oregon); Confederated Tribes of the Grand Ronde Community of Oregon; Confederated Tribes of the Warm Springs Reservation of Oregon; Cow Creek Band of Umpqua Tribe of Indians (previously listed as the Cow Creek Band of Umpqua Indians of Oregon); and the Klamath Tribes were invited to consult but did not participate. Hereafter, all the Indian Tribes listed in this section are referred to as ''The Consulted and Notified Tribes.''

History and Description of the Remains

In 1974, human remains representing, at minimum, two individuals were removed from Site 35CS3, Bullard's Beach State Park, Bandon, Coos County, OR. The excavation, undertaken by the Department of Anthropology at Oregon State University (OSU) at the request of the OPRD was for the purpose of salvaging burials eroding out of the river near the boat landing in Bullards Beach State Park. No known individuals were identified.

Most of the human remains belonging to these two individuals were returned to the Coquille Indian Tribe for reburial in 1987. The human remains in this notice were not returned at that time. The 27 associated funerary objects are one lot of unknown metal fragments; one lot of wood and shell fragments; two lithics; three lots of shell fragments; one lot of seed and bone fragments; one lot of flakes; one lithic; one lot of unidentified bone fragments and lithics; three lots of lithic fragments; one lot of shell and bone fragments; one lot of fire cracked rock; one lot of unidentified shell fragments; two lots of mussel shell fragments; one metal spike; and seven lots of lithic material.

The Hanis and Miluk Coos were known as the Coos Bay Indians in 1935 when the Coos Indians asserted in the United States Court of Claims that their aboriginal land extended two miles south of the Coquille River. The Hanis Coos, who inhabited the Coos Bay area and points south as far as Tarheel or Pigeon Point, are the ancestors of the modern day Coos section of the Confederated Tribes of Coos, Lower Umpqua and Siuslaw Indians. The Coquille Indian Tribe and the Confederated Tribes of Coos, Lower Umpqua and Siuslaw Indians include descendants of the Miluk Coos. Beginning around Pigeon Point, including South Slough, and going south to the mouth of the Coquille River, the language spoken in the lower Coos Bay area was Miluk. The Upper Coquille shared the Coquille River watershed with the Miluk Coos. The Confederated Tribes of the Siletz Reservation, Oregon, are a confederation of 30 bands whose ancestral territory ranged along the entire Oregon coast and Coast Range, inland to the main divide of the Cascade Range and southward to the Rogue River watershed. The principal tribes include the Clatsop, Chinook, Klickitat, Molala, Kalapuya, Tillamook, Alsea, Siuslaw/Lower Umpqua, Coos, Coquille, Upper Umpqua, Tututni, Chetco, Tolowa, Takelma or Upper Rogue River, Galice/Applegate and Shasta. The ancestors of the Confederated Tribes of the Siletz Reservation spoke at least 10 different base languages. In general, five linguistic stocks—Salish, Yakonan, Kusan, Takelman, and Athapascan—are represented by the tribes. The tribes were forcibly removed from their homelands in 1855 and placed on the Siletz and Grand Ronde reservations. Federal recognition of the tribes was terminated in 1954, but in 1977 the Confederated Tribes of the Siletz Reservation, Oregon, were officially restored to recognized status. Historical, geographic, and linguistic evidence indicates the Confederated Tribes of the Siletz Indians of Oregon and the Coquille Indian Tribe are the most closely associated descendants of site 35CS3.

Determinations Made by the Oregon Parks and Recreation Department

Officials of the Oregon Parks and Recreation Department have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of two individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 27 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and the Confederated Tribes of Siletz Indians of Oregon (previously listed as the Confederated Tribes of the Siletz Reservation) and the Coquille Indian Tribe (previously listed as the Coquille Tribe of Oregon).

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Nancy Nelson, Oregon Parks and Recreation Department Archaeologist, 725 Summer Street NE, Suite C, Salem, OR 97301, telephone (503) 986–0578, by May 24, 2019. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Confederated Tribes of Siletz Indians of Oregon (previously listed as the Confederated Tribes of the Siletz Reservation) and the Coquille Indian Tribe (previously listed as the Coquille Tribe of Oregon) may proceed.

The Oregon Parks and Recreation Department is responsible for notifying The Consulted and Notified Tribes that this notice has been published.

Dated: March 25, 2019.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2019–08228 Filed 4–23–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA- NPS0027603; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: University of Georgia, Laboratory of Archaeology, Athens, GA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The University of Georgia, Laboratory of Archaeology in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of unassociated funerary objects. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to the University of Georgia, Laboratory of Archaeology. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to the University of Georgia, Laboratory of Archaeology at the address in this notice by May 24, 2019.

ADDRESSES: Amanda Roberts Thompson, University of Georgia, Laboratory of Archaeology, 1125 Whitehall Road, Athens, GA 30605, telephone (706) 542–8737, email *arobthom@uga.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of the University of Georgia, Laboratory of Archaeology, Athens, GA, that meet the definition of unassociated funerary objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Item(s)

In 2014, two Lamar incised rims were recovered from the bottom of excavations at a rock pile at site 9GE2085, at Reynolds Plantation in Greene County, GA. Brockington and Associates, Inc. also conducted phosphate testing on soil samples from the rock pile, as well as from areas around the site. The phosphate analysis revealed higher levels of phosphate in the rock pile, suggesting that the rock pile was utilized as a place of burial. No human remains were recovered from 9GE2085 but 2 Lamar incised rims (401–E.4:2–401–E.4:3) were recovered from an area known to have been utilized as a place of burial. The two unassociated funerary objects are two Lamar incised rims.

The geographical location of the burial within the historically documented territory of The Muscogee (Creek) Nation supports a cultural affiliation with The Muscogee (Creek) Nation.

Determinations Made by the University of Georgia, Laboratory of Archaeology

Officials of the University of Georgia, Laboratory of Archaeology have determined that:

- Pursuant to 25 U.S.C. 3001(3)(B), the two cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary objects and The Muscogee (Creek) Nation.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Amanda Roberts Thompson, University of Georgia, Laboratory of Archaeology, 1125 Whitehall Road, Athens, GA 30605, telephone (706) 542–8737, email *arobthom@uga.edu,* by May 24, 2019. After that date, if no additional claimants have come forward, transfer of control of the unassociated funerary objects to The Muscogee (Creek) Nation may proceed.

The University of Georgia, Laboratory of Archaeology is responsible for notifying The Muscogee (Creek) Nation that this notice has been published.

Dated: April 2, 2019.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2019–08231 Filed 4–23–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0027459; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: University of California Berkeley, Berkeley, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The University of California, Berkeley, has completed an inventory of human remains and an associated funerary object, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary object and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary object should submit a written request to the Phoebe A. Hearst Museum of Anthropology. If no additional requestors come forward, transfer of control of the human remains and associated funerary object to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary object should submit a written request with information in support of the request to the Phoebe A. Hearst Museum of Anthropology at the address in this notice by May 24, 2019.

ADDRESSES: Jordan Jacobs, Phoebe A. Hearst Museum of Anthropology, University of California Berkeley, 103 Kroeber Hall, Berkeley, CA 94720–3712, telephone (510) 643–8230, email *pahma-repatriation@berkeley.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary object under the control of the Phoebe A. Hearst Museum of Anthropology, University of California, Berkeley, CA. The human remains and associated funerary object were removed from San Nicolas Island, Ventura County, CA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary object. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by Phoebe A. Hearst Museum of Anthropology, University of California, Berkeley professional staff in consultation with representatives of the Pala Band of Mission Indians (previously listed as the Pala Band of Luiseno Mission Indians of the Pala Reservation, California); Pauma Band of Luiseno Mission Indians of the Pauma & Yuima Reservation, California; Pechanga Band of Luiseno Mission Indians of the Pechanga Reservation, California; Rincon Band of Luiseno Mission Indians of the Rincon Reservation, California; Santa Ynez Band of Chumash Mission Indians of the Santa Ynez Reservation, California; and the Soboba Band of Luiseno Indians, California; hereafter referred to as ''The Tribes.''

History and Description of the Remains

In 1901, two sets of human remains were removed from an unknown location on San Nicolas Island, Ventura County, CA, by Philip Mills Jones, who was under contract by Phoebe Apperson Hearst to collect archeological material from southern California. The human remains were subsequently donated to the University of California by Phoebe Apperson Hearst in 1901. No known individuals were identified. No associated funerary objects are present.

Between 1897 and 1902, 24 sets of human remains were removed from San Nicolas Island, Ventura County, CA, by Mrs. Blanche Trask and subsequently donated to the museum in 1902. No known individuals were identified. The one associated funerary object is an abalone shell.

An examination of the human remains by officials of the Phoebe A. Hearst Museum of Anthropology have determined the individuals to be of Native American origin. Archeological data, oral history, material culture, and religious cultural practices indicate that the Santa Ynez Band of Chumash Mission Indians of the Santa Ynez Reservation, California, can trace their ancestry back to the people who previously occupied the Channel Islands. Linguistic and religious evidence together with evidence from the oral traditions indicate that the Pechanga Band of Luiseño Mission Indians of the Pechanga Reservation, California, can trace their ancestry back to the people who previously occupied the Channel Islands.

Determinations Made by the University of California, Berkeley

Officials of the University of California, Berkeley have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent 26 sets of human remains of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the one object described in this notice is reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary object and the Santa Ynez Band of Chumash Mission Indians of the Santa Ynez Reservation, California, and the Pechanga Band of Luiseño Mission Indians of the Pechanga Reservation, California.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary object should submit a written request with information in support of the request to Jordan Jacobs, Phoebe A. Hearst Museum of Anthropology, University of California Berkeley, 103 Kroeber Hall, Berkeley, CA 94720–3712, telephone (510) 643–8230, email *pahma-repatriation@berkeley.edu,* by May 24, 2019. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary object to the Santa Ynez Band of Chumash Mission Indians of the Santa Ynez Reservation, California, and the Pechanga Band of Luiseño Mission Indians of the Pechanga Reservation, California, may proceed.

The Phoebe A. Hearst Museum of Anthropology is responsible for notifying The Tribes that this notice has been published.

Dated: March 11, 2019.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2019–08232 Filed 4–23–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS002746; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Robert S. Peabody Institute of Archaeology, Andover, MA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Robert S. Peabody Institute of Archaeology has completed an inventory of associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the associated funerary objects and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these associated funerary objects should submit a written request to the Robert S. Peabody Institute of Archaeology. If no additional requestors come forward, transfer of control of the associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these associated funerary objects should submit a written request with information in support of the request to the Robert S. Peabody Institute of Archaeology at the address in this notice by May 24, 2019.

ADDRESSES: Ryan Wheeler, Robert S. Peabody Institute of Archaeology, Phillips Academy, 180 Main Street, Andover, MA 01810, telephone (978) 749–4490, email *rwheeler@andover.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of associated funerary objects under the control of the Robert S. Peabody Institute of Archaeology, Andover, MA. The associated funerary objects were removed from Betheia Farm-Touisett Point #2, Warren, Bristol County, RI.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the associated funerary objects was made by the Robert S. Peabody Institute of Archaeology professional staff in consultation with representatives of the Wampanoag Repatriation Confederacy, representing the Mashpee Wampanoag Tribe (previously listed as the Mashpee Wampanoag Indian Tribal Council, Inc.), the Wampanoag Tribe of Gay Head (Aquinnah), and the Assonet Band of the Wampanoag Nation, a non-federally recognized Indian group.

History and Description of the Remains

In 1983, Maurice Robbins removed human remains representing, at minimum, one individual from the Betheia Farm-Touisett Point #2 site in Warren, Bristol County, RI, which were transferred to the Phillips Academy Department of Archaeology (now the Robert S. Peabody Institute of Archaeology). The human remains were reported in a notice of inventory completion published in the **Federal Register** (80 FR 10500–10501, February 26, 2015) and repatriated on August 24, 2018. The 25 associated funerary objects are 12 projectile points, eight broken projectile point bases, three hammerstones, one ceramic rim sherd, and one rim fragment from a soapstone bowl.

Information about the Betheia Farm-Touisett Point #2 site is found in the files of the Robert S. Peabody Institute of Archaeology and the files of the Rhode Island Historical Preservation & Heritage Commission (site numbers 1349 and 1350). Records at the former institution indicate that human remains washed out of the site during a storm and were collected by Robbins. The storm event may have been the ''Great Hurricane'' of September 1938, though a sketch map on file indicates erosion was already occurring in 1937. The site is described as a high sandy bluff facing Mount Hope Bay sitting on a very abrupt slope approximately 25 feet back from the beach. Projectile point styles suggest a Middle/Late Archaic to Early Woodland age for the human remains and associated funerary objects (8000—2000 B.P.). Robbins noted other artifacts from the site including points, hammerstones, fragmentary pestle, steatite bowl, and pottery fragments, matching the description of the associated funerary objects described above, and which were located in the Robert S. Peabody Institute's collections at the time the human remains were repatriated. Archeology, ethnohistory, linguistics, and oral history provide multiple lines of evidence that demonstrate longstanding ties between the Wampanoag and the area around Touisett Point and affirm affiliation with the burial at the Betheia Farm-Touisett Point #2 site.

Determinations Made by the Robert S. Peabody Institute of Archaeology

Officials of the Robert S. Peabody Institute of Archaeology have determined that:

- Pursuant to 25 U.S.C. 3001(3)(A), the 25 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American associated funerary objects and the Mashpee Wampanoag Tribe (previously listed as the Mashpee Wampanoag Indian Tribal Council, Inc.), the Wampanoag Tribe of Gay Head (Aquinnah), and, if joined, the Assonet Band of the Wampanoag Nation, a non-federally recognized Indian group.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribes or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these associated funerary objects should submit a written request with information in support of the request to Ryan Wheeler, Robert S. Peabody Institute of Archaeology, Phillips Academy, 180 Main Street, Andover, MA 01810, telephone (978) 749–4490, email *rwheeler@andover.edu,* by May 24, 2019. After that date, if no additional requestors have come forward, transfer of control of the associated funerary objects to the Wampanoag Repatriation Confederacy, representing the Mashpee Wampanoag Tribe (previously listed as the Mashpee Wampanoag Indian Tribal Council, Inc.); the Wampanoag Tribe of Gay Head (Aquinnah); and, if joined to a request from one or both of these Indian Tribes, the Assonet Band of the Wampanoag Nation, a non-federally recognized Indian group, may proceed.

The Robert S. Peabody Institute of Archaeology is responsible for notifying the Mashpee Wampanoag Tribe (previously listed as the Mashpee Wampanoag Indian Tribal Council, Inc.); the Wampanoag Tribe of Gay Head (Aquinnah); and the Assonet Band of the Wampanoag Nation, a non-federally recognized Indian group, that this notice has been published.

Dated: March 11, 2019.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2019–08226 Filed 4–23–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0027461; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: U.S. Army Corps of Engineers, Omaha District, Omaha, NE, and State Archaeological Research Center, Rapid City, SD; Correction

AGENCY: National Park Service, Interior.

ACTION: Notice; correction.

SUMMARY: The U.S. Army Corps of Engineers, Omaha District (Omaha District) has corrected an inventory of human remains and associated funerary objects, published in a Notice of Inventory Completion in the **Federal Register** on April 13, 2018. This notice corrects the number of associated funerary objects for site 39WW0003. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these associated funerary objects should submit a written request to the Omaha District. If no additional requestors come forward, transfer of control of the associated funerary objects to the lineal descendants, Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these

associated funerary objects should submit a written request with information in support of the request to the Omaha District at the address in this notice by May 24, 2019.

ADDRESSES: Ms. Sandra Barnum, U.S. Army Engineer District, Omaha, ATTN: CENWO–PM–AB, 1616 Capital Avenue, Omaha, NE 68102, telephone, (402) 995–2674, email *sandra.v.barnum@usace.army.mil.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the correction of an inventory of human remains and associated funerary objects under the control of the U.S. Army Corps of Engineers, Omaha District, Omaha, NE and in the physical custody of the South Dakota State Archaeological Research Center (SARC). The human remains and associated funerary objects were removed from sites 39WW0003 and 39CA0006, Walworth and Campbell Counties, SD.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

This notice corrects the number of associated funerary objects for site 39WW0003 published in a Notice of Inventory Completion in the **Federal Register** (83 FR 16124–16125, April 13, 2018). The correction is being made due to additional catalogues being found. Transfer of control of the items in this correction notice has not occurred.

Correction

In the **Federal Register** (83 FR 16125, April 13, 2018), column 2, paragraph 1, sentence 6 is corrected by substituting the following sentence:

The 846 associated funerary objects include 140 ceramic rim sherds, 629 ceramic body sherds, two ceramic handle sherds, three bone awls (faunal), two bone hoes (faunal), six modified bones (faunal), 12 unidentified bone fragments (faunal), two burnt corn cobs, one wood fragment, 12 glass beads, two abraders, one biface fragment, one biface knife, nine chipped stone flakes, one chipped stone tool, one groundstone, one modified flake, three projectile points, three uniface flakes, one catlinite fragment, one yellow mineral pigment vial, and 13 scrapers.

In the **Federal Register** (83 FR 16125, April 13, 2018), column 3, paragraph 1, sentence 2 is corrected by substituting the following sentence:

Pursuant to 25 U.S.C. 3001(3)(A), the 2,014 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these associated funerary objects should submit a written request with information in support of the request to Ms. Sandra Barnum, U.S. Army Engineer District, Omaha, ATTN: CENWO–PM–AB, 1616 Capital Avenue, Omaha, NE 68102, telephone, (402) 995–2674, email *sandra.v.barnum@usace.army.mil.* After that date, if no additional requestors have come forward, transfer of control of the associated funerary objects to the Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota, may proceed.

The U.S. Army Corps of Engineers, Omaha District is responsible for notifying the Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota, that this notice has been published.

Dated: March 11, 2019.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2019–08225 Filed 4–23–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA- NPS0027602; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: University of Georgia, Laboratory of Archaeology, Athens, GA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The University of Georgia, Laboratory of Archaeology has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the University of Georgia, Laboratory of Archaeology. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the University of Georgia, Laboratory of Archaeology, at the address in this notice by May 24, 2019.

ADDRESSES: Amanda Thompson, University of Georgia, Laboratory of Archaeology, 1125 Whitehall Road, Athens, GA 30605, telephone (706) 542–8737, email *arobthom@uga.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the University of Georgia, Laboratory of Archaeology, Athens, GA. The human remains and associated funerary objects were removed from Greene County, GA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by University of Georgia, Laboratory of Archaeology professional staff in consultation with representatives of The Muscogee (Creek) Nation.

History and Description of the Remains

In 2003–2004, human remains representing, at minimum, one individual were removed from site 9GE2084 in Greene County, GA. During an intensive survey, conducted by Southeastern Archeological Services from 2003–2004, a series of rock piles (9GE2084) was identified, and minimal excavations were conducted. One rock pile (Rock Pile C) was identified as prehistoric. As looting disturbance was

also noted, the rock pile was cleared of debris and loose rocks, revealing human remains at the bottom of the pothole. Work was halted and Southeastern Archeological Services contacted the U.S. Army Corps of Engineers, Georgia Department of Natural Resources—Historic Preservation Division, and the Georgia Indian Council. After consultation, excavation with a 1x1 meter unit was conducted to further delineate the burial. The human remains and the associated funerary objects were transferred from Southeastern Archeological Services to the University of Georgia, Laboratory of Archaeology on December 20, 2016. The human remains, which consist of 80 bone fragments, include four teeth of a young adult, 16–22 years of age. No known individuals were identified. The 44 associated funerary objects are 16 sherds (less than ½ inch), two quartz tertiary flakes, two quartz flake fragments, and 24 sherds of a mended Lamar pottery vessel (9GE2084).

The geographical location of the burial within the historically documented territory of The Muscogee (Creek) Nation supports a cultural affiliation with The Muscogee (Creek) Nation.

Determinations Made by the University of Georgia, Laboratory of Archaeology

Officials of the University of Georgia, Laboratory of Archaeology have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 44 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and The Muscogee (Creek) Nation.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Amanda Thompson, University of Georgia, Laboratory of Archaeology, 1125 Whitehall Road, Athens, GA 30605, telephone (706) 542–8737, email *arobthom@uga.edu,* by May 24, 2019. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to The Muscogee (Creek) Nation may proceed.

The University of Georgia, Laboratory of Archaeology is responsible for notifying The Muscogee (Creek) Nation that this notice has been published.

Dated: April 2, 2019.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2019–08230 Filed 4–23–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0027463; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Nebraska State Historical Society, DBA History Nebraska, Lincoln, NE

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: History Nebraska, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of a sacred object. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim this cultural item should submit a written request to History Nebraska. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to History Nebraska at the address in this notice by May 24, 2019.

ADDRESSES: Trisha Nelson, History Nebraska, 1500 R Street, Lincoln, NE 68508–1651, telephone (402) 471–4760, email *trisha.nelson@nebraska.gov.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of History Nebraska, Lincoln, NE, that meet the definition of sacred objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Item

On July 17, 1962, Charles A. Walker, a member of the Omaha Tribe of Nebraska, donated a trunk containing medicinal bundles to History Nebraska (then known as the Nebraska State Historical Society). In a letter dated July 9, 1962, Mr. Walker asked then-director Marvin Kivett if the Nebraska State Historical Society could preserve the ''Indian relic known as bundle.'' Mr. Kivett drove to the Omaha reservation in Thurston County, NE, and picked up the trunk on July 17, 1962. The trunk and its contents had been owned by Charles Walker's grandfather, Alan Walker (mistakenly noted as ELLEN Walker in History Nebraska's records), who reportedly died in 1907, at the age of 69. The collection was reported to have been previously owned by Alan Walker's father.

On June 21, 2018, Marisa Cummings, a lineal descendant of Charles Walker and Alan Walker, requested the repatriation of the trunk collection as a sacred object. History Nebraska first initiated consultation on this collection by sending a NAGPRA summary to the Omaha Tribe of Nebraska in November of 1993. History Nebraska reinitiated consultation with the Omaha Tribe of Nebraska in June of 2018. On September 26, 2018, the Omaha Tribe of Nebraska requested the repatriation of the trunk collection as an object of cultural patrimony.

Determinations Made by History Nebraska

Officials of History Nebraska have determined that:

- Pursuant to 25 U.S.C. 3001(3)(C), the one cultural item described above contains specific ceremonial objects needed by traditional Native American religious leaders for the practice of traditional Native American religions by their present-day adherents;
- Pursuant to 25 U.S.C. 3005(a)(5)(A) and 43 CFR 10.2(b)(1), Marissa Cummings is the direct lineal descendant of the individual who owned the sacred object;

• Pursuant to 25 U.S.C. 3005(b), the sacred object is not indispensable for any specific scientific study;

• Pursuant to 25 U.S.C. 3005(c), History Nebraska does not have right of possession to the sacred object; and

• Pursuant to 25 U.S.C. 3005(e), Marissa Cummings is the most appropriate claimant.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Trisha Nelson, History Nebraska, 1500 R Street, Lincoln, NE 68508–1651, telephone (402) 471–4760, email *trisha.nelson@nebraska.gov,* by May 24, 2019. After that date, if no additional claimants have come forward, transfer of control of the sacred objects to Marissa Cummings may proceed.

History Nebraska is responsible for notifying Marissa Cummings and the Omaha Tribe of Nebraska that this notice has been published.

Dated: March 11, 2019.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2019–08234 Filed 4–23–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0027466; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: The State Center Community College District—Fresno City College, Fresno, CA; Correction

AGENCY: National Park Service, Interior.

ACTION: Notice; correction.

SUMMARY: The State Center Community College District—Fresno City College has corrected an inventory of human remains and associated funerary objects, published in a Notice of Inventory Completion in the **Federal Register** on August 23, 2018. This notice corrects the number of associated funerary objects. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the State Center Community College District—Fresno City College. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the State Center Community College District—Fresno City College at the address in this notice by May 24, 2019.

ADDRESSES: Mary Beth Miller, Interim Dean of Social Sciences, in care of Jill Minar, Ph.D., Fresno City College of The State Center Community College District, 1101 E. University Avenue, Fresno, CA 93741, telephone (559) 442–8210, email *jill.minar@fresnocitycollege.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the correction of an inventory of human remains and associated funerary objects under the control of the State Center Community College District—Fresno City College, Fresno, CA. The human remains and associated funerary objects were removed from site CA–MAD–1785, Madera County, CA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

This notice corrects the number of associated funerary objects published in a Notice of Inventory Completion in the **Federal Register** (83 FR 42681–42682, August 23, 2018). A re-inventory identified fewer associated funerary objects than previously reported. Transfer of control of the items in this correction notice has not occurred.

Correction

In the **Federal Register** (83 FR 42682, August 23, 2018), column 1, paragraph 2, sentence 4 is corrected by substituting the following sentence:

The 10 associated funerary objects are one steatite sherd, five steatite beads, three shell beads, and one shell fragment.

In the **Federal Register** (83 FR 42682, August 23, 2018), column 1, paragraph 5, sentence 2 is corrected by substituting the following sentence:

Pursuant to 25 U.S.C. 3001(3)(A), the 15 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Mary Beth Miller, Interim Dean of Social Sciences, in care of Jill Minar, Ph.D., Fresno City College of The State Center Community College District, 1101 E. University Avenue, Fresno, CA 93741, telephone (559) 442–8210, email *jill.minar@fresnocitycollege.edu,* by May 24, 2019. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Northfork Rancheria of Mono Indians of California and the Picayune Rancheria of Chukchansi Indians of California may proceed.

The State Center Community College District—Fresno City College is responsible for notifying The Consulted and Notified Tribes that this notice has been published.

Dated: March 11, 2019.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2019–08229 Filed 4–23–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0027460; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Phoebe A. Hearst Museum of Anthropology, University of California Berkeley, Berkeley, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Phoebe A. Hearst Museum of Anthropology has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is no cultural affiliation between the human remains and any present-day Indian Tribes or Native Hawaiian organizations.

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Phoebe A. Hearst Museum of Anthropology. If no additional requestors come forward, transfer of control of the human remains to the Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the Phoebe A. Hearst Museum of Anthropology at the address in this notice by May 24, 2019.

ADDRESSES: Jordan Jacobs, Head of Cultural Policy & Repatriation, Phoebe A. Hearst Museum of Anthropology, University of California Berkeley, 103 Kroeber Hall, Berkeley, CA 94720, telephone (510) 643–8230, email *j.jacobs@berkeley.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the Phoebe A. Hearst Museum of Anthropology, University of California, Berkeley, CA. The human remains were removed from Kings County, CA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Phoebe A. Hearst Museum of Anthropology professional staff in consultation with representatives of the Agua Caliente Band of Cahuilla Indians of the Agua Caliente Indian Reservation, California; Buena Vista Rancheria of Me-Wuk Indians of California; Cahuilla Band Indians (previously listed as the Cahuilla Band of Mission Indians of the Cahuilla Reservation, California); California Valley Miwok Tribe, California; Chicken Ranch Rancheria of Me-Wuk Indians of California; Ione Band of Miwok Indians of California; Jackson Band of Miwuk Indians (previously listed as the Jackson Rancheria of Me-Wuk Indians of California); Los Coyotes Band of Cahuilla and Cupeno Indians, California (previously listed as the Los Coyotes Band of Cahuilla & Cupeno Indians of the Los Coyotes Reservation); Middletown Rancheria of Pomo Indians of California; Morongo Band of Mission Indians, California (previously listed as the Morongo Band of Cahuilla Mission Indians of the Morongo Reservation); Picayune Rancheria of Chukchansi Indians of California; Quechan Tribe of the Fort Yuma Indian Reservation, California & Arizona; Ramona Band of Cahuilla, California (previously listed as the Ramona Band or Village of Cahuilla Mission Indians of California); Santa Rosa Indian Community of the Santa Rosa Rancheria, California; Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California; Table Mountain Rancheria (previously listed as the Table Mountain Rancheria of California); Tejon Indian Tribe; Torres Martinez Desert Cahuilla Indians, California (previously listed as the Torres-Martinez Band of Cahuilla Mission Indians of California); Tule River Indian Tribe of the Tule River Reservation, California; and the Wilton Rancheria, California; hereafter referred to as ''The Tribes.''

History and Description of the Remains

In 1939, one set of human remains was removed from the ground surface of CA-Kin-1 in Kings County, CA, by Gordon W. Hewes and W. C. Massey of the Department of Anthropology at the University of California, Berkeley, and donated to the University the same year. The collecting archeologists noted an adjacent habitation and burial mound and the ongoing Works Progress Administration road construction activities that had disturbed it. No known individuals were identified. No associated funerary objects are present.

In 1939, one set of human remains was removed from the ground surface of CA-Kin-4 in Kings County, CA, by Gordon W. Hewes and W. C. Massey of the Department of Anthropology at the University of California, Berkeley, and donated to the University the same year. The presence of a habitation and burial mound and the burned remains of a modern house has been noted at this site. No known individuals were identified. No associated funerary objects are present.

In 1939, one set of human remains was removed from the ground surface of CA-Kin-7 in Kings County, CA, by Gordon W. Hewes and W. C. Massey of the Department of Anthropology at the University of California, Berkeley, and donated to the University the same year. The presence of a burial mound has been noted at this site. No known individuals were identified. No associated funerary objects are present.

In 1939, one set of human remains was removed from the ground surface of CA-Kin-8 in Kings County, CA, by Gordon W. Hewes and W. C. Massey of the Department of Anthropology at the University of California, Berkeley, and donated to the University the same year. The presence of a burial and occupational mound has been noted at this site. No known individuals were identified. No associated funerary objects are present.

In 1939, one set of human remains was removed from the ground surface of CA-Kin-9 in Kings County, CA, by Gordon W. Hewes and W. C. Massey of the Department of Anthropology at the University of California, Berkeley, and donated to the University the same year. The presence of a burial mound has been noted at this site. No known individuals were identified. No associated funerary objects are present.

In 1939, one set of human remains was removed from the ground surface of CA-Kin-10 in Kings County, CA, by Gordon W. Hewes and W. C. Massey of the Department of Anthropology at the University of California, Berkeley, and donated to the University the same year. The presence of a burial mound and the burned remains of a modern house have been noted at this site. No known individuals were identified. No associated funerary objects are present.

In 1939, one set of human remains was removed from the ground surface of CA-Kin-12 in Kings County, CA, by Gordon W. Hewes and W. C. Massey of the Department of Anthropology at the University of California, Berkeley, and donated to the University the same year. The presence of a burial and occupational mound have been noted at this site. No known individuals were identified. No associated funerary objects are present.

In 1939, one set of human remains was removed from the ground surface of CA-Kin-19 in Kings County, CA, by Gordon W. Hewes and W. C. Massey of the Department of Anthropology at the University of California, Berkeley, and donated to the University the same year. The presence of a burial and occupational mound have been noted at this site. No known individuals were identified. No associated funerary objects are present.

At the time of the removal, the land from which the remains were removed was not the tribal land of any Indian Tribe or Native Hawaiian organization. On August 29, 2013, the University of

California, Berkeley initiated consultation with all Indian tribes, The Tribes, who are recognized as aboriginal to the area from which these Native American human remains were removed. By October 2016, the University of California, Berkeley had conducted in-person consultation or received written acknowledgment indicating a lack of desired continued consultation from all of the aforementioned tribes.

In 2000, the University of California, Berkeley, determined that these human remains are Native American under statute, and in 2018, confirmed this determination in light of subsequent clarification in *Bonnichsen* v. *United States,* 367 F.3d 864 (9th Cir. Or. 2004). The University of California, Berkeley agreed to transfer control of the human remains to The Tribes. Consultation with all The Tribes indicates their unanimous support for the disposition of the human remains to Santa Rosa Indian Community of the Santa Rosa Rancheria, California.

Determinations Made by the University of California, Berkeley

Officials of the University of California, Berkeley have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based on the preponderance of evidence available, particularly the field notes about the collection sites prepared by the researcher who originally gathered the human remains and through consultation with Native American tribes relevant to the geography of these sites.
- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent eight sets of human remains of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and any present-day Indian Tribe.
- Treaties, Acts of Congress, Executive Orders, or other information indicate that the land from which the Native American human remains were removed is the aboriginal land of The Tribes.
- Pursuant to 43 CFR 10.11(c)(2)(i), the disposition of the human remains may be to The Tribes.

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Jordan Jacobs, Head of Cultural Policy & Repatriation, Phoebe A. Hearst Museum of Anthropology, University of California, Berkeley, 103 Kroeber Hall, Berkeley CA 94720, telephone (510) 643–8230, email *j.jacobs@berkeley.edu,* by May 24, 2019. After that date, if no additional requestors have come forward, transfer of control of the human remains to The Tribes may proceed.

The Phoebe A. Hearst Museum of Anthropology is responsible for notifying The Tribes that this notice has been published.

Dated: March 11, 2019.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2019–08233 Filed 4–23–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0027464; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: U.S. Army Garrison, Fort Campbell, Fort Campbell, KY

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Army Garrison, Fort Campbell has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is no cultural affiliation between the human remains and associated funerary objects and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the U.S. Army Garrison, Fort Campbell. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the U.S. Army Garrison, Fort Campbell at the address in this notice by May 24, 2019.

ADDRESSES: Ronald Grayson, U.S. Army Garrison, Fort Campbell, Directorate of Public Works, Building 865, 16th Street, Fort Campbell, KY 42223, telephone (270) 412–8174, email *ronald.i.grayson.civ@mail.mil.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the U.S. Army Garrison, Fort Campbell, Fort Campbell, KY. The human remains and associated funerary objects were removed from site 15TR0004 in Trigg County, KY, and sites 40MT0004, 40MT0018, 40MT0021, 40MT0022, and an unidentified site (40MT?) in Montgomery County, TN.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the U.S. Army Corps of Engineers, St. Louis District's Mandatory Center of Expertise for the Curation and Management of Archaeological Collections (MCX CMAC) and U.S. Army Garrison, Fort Campbell professional staff in consultation with representatives of the Absentee-Shawnee Tribe of Indians of Oklahoma; Cherokee Nation; Coushatta Tribe of Louisiana; Eastern Band of Cherokee Indians; Eastern Shawnee Tribe of Oklahoma; Kialegee Tribal Town; Poarch Band of Creeks (previously listed as the Poarch Band of Creek Indians of Alabama); Shawnee Tribe; The Chickasaw Nation of Oklahoma; The Muscogee (Creek) Nation; Thlopthlocco Tribal Town; and the United Keetoowah Band of Cherokee Indians in Oklahoma, hereafter referred to as ''The Consulted Tribes.''

History and Description of the Remains

In 1930, human remains representing, at minimum, 31 individuals were removed from 15TR0004, the Duncan Site, in Trigg County, KY. Excavations at the cemetery site were conducted by University of Kentucky archeologists William S. Webb and William D. Funkhouser. All the human remains, as well as the associated funerary objects

were stored at the University of Kentucky until August 2017, when they were transferred to the Cultural Resource Office of the U.S. Army Garrison, Fort Campbell, the current land owners. In October 2017, the human remains and associated funerary objects were transferred to the MCX CMAC Lab in St. Louis, MO, to be inventoried. The collection was returned to the U.S. Army Garrison, Fort Campbell Cultural Resource Office in June 2018. Individuals from the site include 30 adults of undetermined sex and one child of undetermined sex. No known individuals were identified. The three associated funerary objects are one mortuary pot, one mortuary vessel with handles, and one faunal bone needle.

Between 1965 and 1966, human remains representing, at minimum, three individuals were removed from site 40MT0004 in Montgomery County, TN. Excavations at the site were conducted by E.L. Sheppard, avocational archeologists, and Fort Campbell Pratt Museum curator Glen Koons. All the human remains, as well as the associated funerary objects, were stored at the U.S. Army Garrison, Fort Campbell Pratt Museum. In October 2017, the human remains and associated funerary objects were transferred to the MCX CMAC Lab in St. Louis, MO, to be inventoried. The collection was returned to the U.S. Army Garrison, Fort Campbell Cultural Resource Office in June 2018. Individuals from the site include one adult of undetermined sex and two infants of undetermined sex. No known individuals were identified. The two associated funerary objects are one shell fragment and one faunal bone fragment.

In 1973, human remains representing, at minimum, one individual was removed from site 40MT0018 in Montgomery County, TN. Excavations at the site were conducted by Joe Benthall, Tennessee Division of Archaeology. All the human remains, as well as the associated funerary objects, were stored at the Tennessee Division of Archaeology Collection Facility at Pinson Mounds until 2017, when they were transferred to the U.S. Army Garrison, Fort Campbell Cultural Resource Office. In October 2017, the human remains and associated funerary objects were transferred to the MCX CMAC Lab in St. Louis, MO, to be inventoried. The collection was returned to the U.S. Army Garrison, Fort Campbell Cultural Resource Office in June 2018. Individuals from the site include one adult of undetermined sex. No known individuals were identified. The two associated funerary objects are one ceramic rim sherd and one ceramic body sherd.

In 1963, human remains representing, at minimum, eight individuals were removed from site 40MT0021 in Montgomery County, TN. Excavations at the site were conducted by Fort Campbell Pratt Museum curator Glen Koons. All the human remains, as well as the associated funerary objects, have been stored at the U.S. Army Garrison, Fort Campbell since the excavation, first at the Pratt Museum, and later at the Cultural Resource Office. In October 2017, the human remains and associated funerary objects were transferred to the MCX CMAC Lab in St. Louis, MO, to be inventoried. The collection was returned to the U.S. Army Garrison, Fort Campbell Cultural Resource Office in June 2018. Individuals from the site include four adults of undetermined sex, one subadult of undetermined sex, two children of undetermined sex, and one infant of undetermined sex. No known individuals were identified. The 78 associated funerary objects are two charcoal fragments, 31 effigy bottle fragments, five ceramic body sherds, four faunal bone fragments, 16 lithic flakes, eight shell beads, 10 shells, and two debris bags.

In 1963, human remains representing, at minimum, five individuals were removed from site 40MT0022 in Montgomery County, TN. Excavations at the site were conducted by Fort Campbell Pratt Museum curator Glen Koons. All the human remains, as well as the associated funerary objects, have been stored at the U.S. Army Garrison, Fort Campbell since the excavation, first at the Pratt Museum, and later at the Cultural Resource Office. In October 2017 the human remains and associated funerary objects were transferred to the MCX CMAC Lab in St. Louis, MO, to be inventoried. The collection was returned to the U.S. Army Garrison, Fort Campbell Cultural Resource Office in June 2018. Individuals from the site include two adults of undetermined sex, one child of undetermined sex, and two infants of undetermined sex. No known individuals were identified. The 391 associated funerary objects are one ceramic effigy head, 191 ceramic body sherds, five ceramic rim sherds, one horn-shaped ceramic object, one ceramic effigy bottle fragment, one ceramic owl pendant, three bone (non-human) hair pin fragments, 22 faunal bone fragments, two fossils, one bead, one stone pipe, 155 shell beads, six shell fragments, and one unidentified white object.

In the 1960s, human remains representing, at minimum, five individuals were removed from an unidentified site in Montgomery County, TN. The human remains were reportedly excavated by Fort Campbell Pratt Museum curator Glen Koons. All the human remains, as well as the associated funerary objects, have been stored at the U.S. Army Garrison, Fort Campbell since the excavation, first at the Pratt Museum, and later at the Cultural Resource Office. In October 2017, the human remains and associated funerary objects were transferred to the MCX CMAC Lab in St. Louis, MO, to be inventoried. The collection was returned to the U.S. Army Garrison, Fort Campbell Cultural Resource Office in June 2018. Individuals from the site include three adults of undetermined sex, one child of undetermined sex, and one infant of undetermined sex. No known individuals were identified. The 22 associated funerary objects are one chipped stone, five ceramic body sherds, six shell fragments, and 10 lithic flakes.

Determinations Made by the U.S. Army Garrison, Fort Campbell

Officials of the U.S. Army Garrison, Fort Campbell have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based on morphological characteristics, archeological context, and associated funerary objects.
- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 53 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 498 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and associated funerary objects and any present-day Indian Tribe.
- According to final judgments of the Indian Claims Commission, the land from which the Native American human remains and associated funerary objects from site 40MT0018 were removed is the aboriginal land of the Cherokee Nation; Eastern Band of Cherokee Indians; and the United Keetoowah Band of Cherokee Indians in Oklahoma.
- Treaties indicate that the land from which the Native American human remains and associated funerary objects from sites 15TR0004, 40MT0004, 40MT0021, 40MT0022, and 40MT? were removed is the aboriginal land of the Cherokee Nation; Eastern Band of

Cherokee Indians; and the United Keetoowah Band of Cherokee Indians in Oklahoma.

• Pursuant to 43 CFR 10.11(c)(1), the disposition of the human remains and associated funerary objects may be to the Cherokee Nation; Eastern Band of Cherokee Indians; and the United Keetoowah Band of Cherokee Indians in Oklahoma (hereafter referred to as ''The Tribes'').

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Ronald Grayson, U.S. Army Garrison, Fort Campbell, Directorate of Public Works, Building 865, 16th Street, Fort Campbell, KY 42223, telephone (270) 412–8174, email *ronald.i.grayson.civ@mail.mil,* by May 24, 2019. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to The Tribes may proceed.

The U.S. Army Garrison, Fort Campbell is responsible for notifying The Consulted Tribes that this notice has been published.

Dated: March 11, 2019.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2019–08227 Filed 4–23–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NRSS–GRD–FR00000043; PPWONRADG0, PPMRSNR1Y.NG0000 (199); OMB Control Number 1024–0064]

Agency Information Collection Activities; Mining and Mining Claims and Non-Federal Oil and Gas Rights

AGENCY: National Park Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the National Park Service (NPS) are proposing to renew an information collection with revisions.

DATES: Interested persons are invited to submit comments on or before June 24, 2019.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to Phadrea Ponds, Acting, NPS Information Collection Clearance Officer, 1201 Oakridge Drive, Fort Collins, CO 80525; or by email at *phadrea_ponds@nps.gov;* or by telephone at 970–267–7231. Please reference OMB Control Number 1024–0064 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Edward O. Kassman, Jr., Regulatory Specialist, Energy and Minerals Branch, Geologic Resources Division, National Park Service, by mail at P.O. Box 25287, Lakewood, Colorado 80225; or by email at *Edward_Kassman@nps.gov;* or by fax at 303–987–6792.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed Information Collection Request (ICR) described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the NPS; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the NPS enhance the quality, utility, and clarity of the information to be collected; and (5) how might the NPS minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to the Office of Management and Budget (OMB) to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The Organic Act of 1916 (NPS Organic Act) (54 U.S.C. 100101) authorizes the Secretary of the Interior to develop regulations for units of the national park system (System units) under the Department's jurisdiction. The Mining in the Parks Act (54 U.S.C. 100731 *et seq.*) directs the Secretary of the Interior to regulate all operations in System units in connection with the exercise of mineral rights on patented and unpatented mining claims.

The regulations at 36 CFR part 9, subparts A and B, ensure that mining and non-Federal oil and gas activities in System units are conducted in a manner consistent with conserving each System unit for the benefit of present and future generations. The information required by Subpart A identifies the claim, claimant, and operator (the claimant and operator are often the same) and details how the operator intends to access and develop the minerals associated with the claim. It also identifies the steps the operator intends to take to minimize any adverse impacts of the mining operations on park resource and values. No information, except claim ownership information, is submitted unless the claimant wishes to conduct mining operations. The information required by subpart B identifies the owner and operator (the owner and operator are often the same) and details how the operator intends to access and develop the oil and gas rights. It also identifies the steps the operator intends to take to minimize any adverse impacts on park resources and values. No information is submitted unless the owner wishes to conduct oil and gas operations.

With this submission, we plan to request OMB approval to consolidate the information collection requirements currently approved under OMB Control No. 1024–0274, ''Non-Federal Oil and Gas Rights, 36 CFR part 9, subpart B'' into this collection. We identified the information collection requirements associated with 1024–0274 in the burden table below. If OMB approves this revision, we will discontinue OMB Control Number 1024–0274.

Title of Collection: Mining and Mining Claims and Non-Federal Oil and Gas Rights, 36 CFR part 9, subparts A and B.

OMB Control Number: 1024–0064.

Form Number: None.

Type of Review: Revision of a currently approved collection.

Respondents/Affected Public: Businesses.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: None.

Activity/requirement	Estimated number of annual responses	Completion time per response (hours)	Estimated total annual burden hours
ICs Currently Approved Under 1024–0064			
Mining and Mining Claims	1	176	176
Non-Federal Oil and Gas Rights	20	176	3,520
ICs Previously Approved Under 1024–0274 Proposed To Be Merged Into 1024–0064			
Previously Exempt Operations (§§ 9.50–9.53)	106	10	1,060
Application for Temporary Access Permit (§§ 9.60–9.63)	5	15	75
Extension of Temporary Access Permit	1	1	1
Accessing Oil and Gas Rights From a Surface Location Outside the Park Boundary—Application for Exemption (§§ 9.70–9.73)	3	80	240
Accessing Oil and Gas Rights From a Surface Location Outside the Park Boundary—Notice of change (§§ 9.70–9.73)	1	2	2
Operations Permit (New Operations)			
Application—(§§ 9.80–9.90)	5	140	700
Operating Standards—Simulation Operations (§ 9.118(b))			
Demonstrate mechanical integrity	5	4	20
Record treating pressures and all annular pressures	5	4	20
Notify Superintendent if mechanical integrity is lost	1	1	1
Report of accident	2	1	2
Operating Standards—Production (§ 9.118(c))			
Document maintenance of mechanical integrity	534	2	1,068
Signage to identify wells	5	4	20
General Terms and Conditions (§§ 9.120–9.122)			
Affidavit that proposed operations are in compliance with all laws and that information submitted to NPS is accurate	111	1	111
Third-Party Monitor Report	60	17	1,020
Notification—Accidents involving Serious Personal Injuries/Death and Fires/Spills	2	1	2
Written Report—Accidents Involving Serious Injuries/Deaths and Fires/Spills	2	16	32
Notification—Discovery of any cultural or scientific resources	1	1	1
Report—Verify Compliance with Permits	534	4	2,136
Reporting for Hydraulic Fracturing	1	2	2
Financial Assurance (§§ 9.140–9.144)	5	1	5
Modification to an Operation (§ 9.150)	1	16	16
Change of Operator (§§ 9.160–9.161)	5	8	40
Well Plugging (§§ 9.170–9.171)	33	14	462
Reconsideration and Appeals (§§ 9.190–9.194)	1	16	16
Public Participation (§ 9.200)	1	4	4
Total	1,451	.....	10,752

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: April 18, 2019.

Kevin Schmitt,

Deputy Associate Director Information Resources, National Park Service.

[FR Doc. 2019–08250 Filed 4–23–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under The Clean Air Act

On April 18, 2019, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the District of Minnesota in the lawsuit entitled *United States* v. *United Taconite LLC,* Civil Action No. 19–1043.

The United States filed a Complaint in this lawsuit under the Clean Air Act (CAA), naming United Taconite LLC as the defendant. The Complaint seeks injunctive relief and civil penalties for violations of the environmental regulations that govern taconite mines and processing plants and the emission of particulate matter from certain sources at defendant's taconite processing plant in Forbes, St. Louis County, Minnesota. Under the proposed Consent Decree, United Taconite agrees to implement procedures to improve future compliance with the CAA and State regulations, and pay $50,000 in civil penalties. Under the proposed Consent Decree, United Taconite also agrees to replace an existing wet scrubber at its processing plant with a more efficient dry fabric filter particulate matter control system at an estimated cost of over $480,000. In

return, the United States agrees not to sue the defendant under section 113 of the CAA for additional relief related to its past violations.

The publication of this notice opens a period for public comment on the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *United Taconite LLC,* D.J. Ref. No. 90–5–2–1–11178. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	Send them to:
By e-mail	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the proposed Consent Decree may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.*

We will provide a paper copy of the proposed Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $7.50 (25 cents per page reproduction cost) payable to the United States Treasury.

Randall M. Stone,

Acting Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2019–08190 Filed 4–23–19; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OMB Number 1121–0219]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension Without Change, of a Previously Approved Collection Juvenile Residential Facility Census (JRFC)

AGENCY: Office of Justice Programs, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until June 24, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Benjamin Adams, Social Science Analyst, National Institute of Justice, 810 Seventh Street NW, Washington, DC 20531 (email: *benjamin.adams@usdoj.gov;* telephone: 202–616–3687).

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;

—Evaluate whether the accuracy of the agency's estimate of the burden on the proposed collection of information, including the validity of the methodology and assumptions that were used;

—Evaluate whether and if so how the quality, utility, and clarity of the information collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this information collection:

1. *Type of Information Collection:* Extension, without change, of a currently approved collection.

2. *The Title of the Form/Collection:* Juvenile Residential Facility Census.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form number is CJ–15, Office of Justice Programs, United States Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Federal Government, State, Local or Tribal. *Other:* Not-for-profit institutions; Business or other for-profit. *Abstract:* The Juvenile Residential Facility Census (JRFC), which is administered biennially, collects information from all secure and nonsecure residential placement facilities that house juvenile offenders about how juvenile facilities operate and the services they provide. The information gathered in the national collection will be used in published reports and statistics. The reports will be made available to the U.S. Congress, Executive Office of the President, practitioners, researchers, students, the media, others interested in juvenile facilities, and the general public via the OJP agency websites.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The number of respondents in the facility universe is currently 2,208. It is estimated that 1,988 respondents will complete the entire questionnaire in an average of 2 hours per respondent (2 hours × 1,988 facilities = 3,976 hours). It is anticipated that approximately 10 percent or 220 facilities will provide critical item data by phone during nonresponse follow-up calls taking an average of 10 minutes (10 minutes × 220 facilities = 36.7 hours). It is also anticipated that approximately 10 percent or 220 facilities will provide updated contact information on calls taking an average of 5 minutes (5 minutes × 220 facilities = 18.3 hours).

6. *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 4,031 total burden hours associated with the collection.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: April 19, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–08258 Filed 4–23–19; 8:45 am]

BILLING CODE 4410–18–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Biological Sciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended),

the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: Advisory Committee for Biological Sciences (#1110).

Date and Time: May 24, 2019; 10:00 a.m.–4:00 p.m.

Place: National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; Room E 3410.

Please contact Melody Jenkins at *MJenkins@nsf.gov* to obtain a visitor badge. All visitors to the NSF will be required to show photo ID to obtain a badge.

Type of Meeting: Open.

Contact Person: Nancy Sung, National Science Foundation, 2415 Eisenhower Avenue, Room C 12031, Alexandria, VA 22314; Telephone: (703) 292–8400.

Purpose of Meeting: The Advisory Committee for the Directorate for Biological Sciences (BIO) provides advice, recommendations, and oversight concerning major program emphases, directions, and goals for the research-related activities of the divisions that make up BIO.

Agenda: This meeting will be held telephonically among the Advisory Committee members; public visitors will be able to attend the meeting in person at NSF headquarters. Agenda items will include welcoming new Advisory Committee (AC) members, Directorate updates; Committee on Equal Opportunities in Science and Engineering updates; Subcommittee updates; National Ecological Observatory Network (NEON) updates, discussion of programmatic activities within BIO and other matters relevant to the Directorate for Biological Sciences.

Dated: April 18, 2019.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2019–08212 Filed 4–23–19; 8:45 am]

BILLING CODE 7555–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2018–262; MC2019–125 and CP2019–134; MC2019–126 and CP2019–135; MC2019–127 and CP2019–136]

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 negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* April 26, 2019.

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 3007.301.[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 3010, and 39 CFR part 3020, 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 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* CP2018–262; *Filing Title:* USPS Notice of Amendment to Priority Mail Express & Priority Mail Contract 69, Filed Under Seal; *Filing Acceptance Date:* April 18, 2019; *Filing Authority:* 39 CFR 3015.5; *Public Representative:* Lyudmila Y. Bzhilyanskaya; *Comments Due:* April 26, 2019.

2. *Docket No(s).:* MC2019–125 and CP2019–134; *Filing Title:* USPS Request to Add Priority Mail Contract 522 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* April 18, 2019; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5; *Public Representative:* Lyudmila Y. Bzhilyanskaya; *Comments Due:* April 26, 2019.

3. *Docket No(s).:* MC2019–126 and CP2019–135; *Filing Title:* USPS Request to Add Priority Mail & First-Class Package Service Contract 99 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* April 18, 2019; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5; *Public Representative:* Lyudmila Y. Bzhilyanskaya; *Comments Due:* April 26, 2019.

4. *Docket No(s).:* MC2019–127 and CP2019–136; *Filing Title:* USPS Request to Add Priority Mail Express & Priority Mail Contract 92 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* April 18, 2019; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5; *Public Representative:* Lyudmila Y. Bzhilyanskaya; *Comments Due:* April 26, 2019.

This Notice will be published in the **Federal Register**.

Stacy L. Ruble,

Secretary.

[FR Doc. 2019–08242 Filed 4–23–19; 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 SERVICE

Product Change—Priority Mail Express and Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* April 24, 2019.

FOR FURTHER INFORMATION CONTACT: Elizabeth Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on April 18, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express & Priority Mail Contract 92 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2019–127, CP2019–136.

Elizabeth Reed,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2019–08200 Filed 4–23–19; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* April 24, 2019.

FOR FURTHER INFORMATION CONTACT: Elizabeth Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on April 18, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & First-Class Package Service Contract 99 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2019–126, CP2019–135.

Elizabeth Reed,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2019–08202 Filed 4–23–19; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* April 24, 2019.

FOR FURTHER INFORMATION CONTACT: Elizabeth Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on April 18, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Contract 522 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2019–125, CP2019–134.

Elizabeth Reed,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2019–08201 Filed 4–23–19; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85690; File No. SR–NYSEArca–2019–06]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Amend Commentary .01 to NYSE Arca Rule 8.600–E Relating to Generic Listing Standards for Managed Fund Shares Applicable to Holdings in Fixed Income Securities

April 18, 2019.

On February 14, 2019, NYSE Arca, Inc. (''NYSE Arca'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend Commentary .01 to NYSE Arca Rule 8.600–E relating to generic listing standards for Managed Fund Shares applicable to holdings in fixed income securities. The proposed rule change was published for comment in the **Federal Register** on March 6, 2019.[3] The Commission has received no comments on the proposed rule change.

Section 19(b)(2) of the Act [4] provides that, within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is April 20, 2019. The Commission is extending this 45-day time period.

The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates June 4, 2019, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File Number SR–NYSEArca–2019–06).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–08208 Filed 4–23–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85686; File No. SR–FICC–2019–002]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Include References to Uniform Mortgage-Backed Securities

April 18, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 9,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 85220 (February 28, 2019), 84 FR 8138.

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

2019, Fixed Income Clearing Corporation (''FICC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the clearing agency. FICC filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act [3] and Rule 19b–4(f)(4)(i) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of modifications to the FICC Government Securities Division (''GSD'') Rulebook, the Methodology Document—GSD Initial Market Risk Margin Model (the ''GSD Methodology Document,'' together with the GSD Rulebook, the ''GSD Rules''), the FICC Mortgage-Backed Securities Division (''MBSD'') Clearing Rules, and the Methodology and Model Operations Document—MBSD Quantitative Risk Model (the ''MBSD Methodology Document,'' together with the MBSD Clearing Rules, the ''MBSD Rules'') to include references, as described below, to a new type of mortgage-backed securities, referred to as uniform mortgage-backed securities (''UMBS''), issued by the Federal National Mortgage Association (''Fannie Mae'') and the Federal Home Loan Mortgage Corporation (''Freddie Mac'').[5] The proposed changes would not require any changes to FICC's systems nor would the changes impact the rights and obligations of GSD Netting Members and MBSD Clearing Members (collectively, ''Members''). FICC would treat UMBS in the same manner that it currently treats Fannie Mae securities and Freddie Mac securities from an operational and risk management perspective.

Specifically, FICC is proposing to (1) amend the GSD Rulebook and the MBSD Clearing Rules to apply the current haircut for Fannie Mae securities and Freddie Mac securities to the proposed UMBS for purposes of satisfying Required Fund Deposit amounts, (2) amend the GSD Rulebook to apply the current Pricing Rate for CCIT Transactions backed by Fannie Mae securities and Freddie Mac securities to CCIT Transactions backed by UMBS, and (3) amend the GSD Methodology Document and MBSD Methodology Document to include references to UMBS. FICC is requesting confidential treatment of the GSD Methodology Document and the MBSD Methodology Document, and has filed these documents separately with the Commission.[6] The proposed changes are described below.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

FICC is proposing to (1) amend the GSD Rulebook and the MBSD Clearing Rules to apply the current haircut for Fannie Mae securities and Freddie Mac securities to the proposed UMBS for purposes of satisfying Required Fund Deposit amounts, (2) amend the GSD Rulebook to apply the Pricing Rate for CCIT Transactions backed by Fannie Mae securities and Freddie Mac securities to CCIT Transactions backed by UMBS, and (3) amend the GSD Methodology Document and MBSD Methodology Document to include references to UMBS because UMBS will be included in MBSD's TBA [7] product line and will be eligible collateral for GSD's GCF Repo Transactions [8] backed by mortgage-backed securities. The proposed changes would not require any changes to FICC's systems nor would the changes impact the rights and obligations of Members. FICC would treat UMBS in the same manner that it currently treats Fannie Mae securities and Freddie Mac securities from an operational and risk management perspective.

(i) Background

Under the direction of the Federal Housing Finance Agency (''FHFA''), Fannie Mae and Freddie Mac will create a new mortgage-backed security pursuant to an initiative referred to as the single security initiative (''Single Security Initiative'').[9]

Pursuant to the FHFA's proposed rule and final rule, respectively, and the information that has been publicly made available on the FHFA, Fannie Mae and Freddie Mac websites, the stated goals of the Single Security Initiative are to (i) bring additional liquidity and fungibility to the TBA market; and (ii) to reduce or eliminate the trading disparities that exist today between Fannie Mae's and Freddie Mac's TBA securities.[10] In connection with the Single Security Initiative, FICC understands the following:

- The new mortgage-backed securities, referred to as UMBS, will be issued and guaranteed by either Fannie Mae or Freddie Mac, and backed by fixed rate 30-year, 20-year, 15-year, or 10-year single family mortgage loans.[11]
- UMBS will be single-class securities backed by mortgage loans purchased by either Freddie Mac or Fannie Mae.[12]
- the key features of UMBS will be the same as those of Fannie Mae securities, and as a result, the existing Fannie Mae securities will be interchangeable with UMBS.[13]
- Freddie Mac will give market participants the opportunity to exchange 45-day Freddie Mac Participation Certificates and Freddie

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(4).

[5] Terms not defined herein are defined in the GSD Rulebook, *available at http://dtcc.com/~/media/Files/Downloads/legal/rules/ficc_gov_rules.pdf,* or the MBSD Clearing Rules, *available at http://dtcc.com/~/media/Files/Downloads/legal/rules/ficc_mbsd_rules.pdf,* as applicable.

[6] *See* 17 CFR 240–24b–2.

[7] Pursuant to the MBSD Clearing Rules, the term ''TBA'' means a contract for the purchase or sale of a mortgage-backed security to be delivered at an agreed-upon future date because as of the transaction date, the seller has not yet identified certain terms of the contract, such as the pool number and number of pools, to the buyer. *See* MBSD Rule 1, *supra* note 5.

[8] Pursuant to the GSD Rulebook, the term ''GCF Repo Transaction'' means a Repo Transaction involving Generic CUSIP Numbers the data on which are submitted to FICC on a Locked-In-Trade basis pursuant to the provisions of GSD Rule 6C, for netting and settlement by FICC pursuant to the provisions of GSD Rule 20. *See* GSD Rule 1, *supra* note 5.

[9] *See* ''Uniform Mortgage-Backed Security,'' 84 FR 7793 (March 5, 2019) (to be codified at 12 CFR 1248); ''Single Security Initiative and Common Securitization Platform,'' FHFA, *available at https://www.fhfa.gov/PolicyProgramsResearch/Policy/Pages/Securitization-Infrastructure.aspx;* ''Single Security Initiative and Common Securitization Platform,'' Fannie Mae, *available at http://fanniemae.com/portal/funding-the-market/single-security/index.html* (''Fannie Mae website''); and ''Single Security Initiative and the Common Securitization Platform,'' Freddie Mac, *available at http://www.freddiemac.com/mbs/html/single_security_csp.html* (''Freddie Mac website'').

[10] *Id. See also* ''Uniform Mortgage-Backed Security,'' 83 FR 46889 (proposed September 17, 2018).

[11] *See* Freddie Mac website, *supra* note 9.

[12] *See* 84 FR at 7800; Fannie Mae website, *supra* note 9.

[13] *See* 84 FR at 7800.

Mac Giant Participation Certificates[14] for comparable UMBS backed by the same mortgage loans.[15]

Based on the information noted above, FICC will include UMBS in MBSD's existing TBA product line (which currently includes Fannie Mae securities and Freddie Mac securities) and amend the GSD Rules and the MBSD Rules to treat the proposed UMBS in the same manner that it treats existing TBA securities. As a result, MBSD Clearing Members will be allowed to submit TBA transactions backed by UMBS[16] and GSD Netting Members will be allowed to submit GCF Repo Transactions collateralized with UMBS. FICC will implement these changes to give Members the ability to clear and settle UMBS as an Eligible Security.

(ii) Proposed Changes

In order to facilitate the submission of TBA transactions backed by UMBS and GCF Repo Transactions collateralized by UMBS, FICC is proposing to (1) amend the GSD Rulebook and the MBSD Clearing Rules to apply the current haircut for Fannie Mae securities and Freddie Mac securities, respectively, to the proposed UMBS used to satisfy Required Fund Deposit amounts, (2) amend the GSD Rulebook to apply the current Pricing Rate for Fannie Mae securities and Freddie Mac securities to CCIT Transactions backed by UMBS, and (3) amend the GSD Methodology Document and the MBSD Methodology Document to include references to UMBS. The proposed changes are set forth below:

A. Proposed Changes to the GSD Rulebook

FICC is proposing to amend GSD Rule 1 to include the definition for UMBS. This term would be defined as a single-class mortgage-backed security backed by fixed-rate mortgage loans on one to four unit (single-family) properties issued by either Fannie Mae or Freddie Mac which has the same characteristics (such as payment delay, pooling prefixes and minimum pool submission amounts) regardless of whether Fannie Mae or Freddie Mac is the issuer. FICC is proposing this change because this term would be referenced in GSD Rule 3B Section 14(a)(xii) and GSD's Schedule of Haircuts for Eligible Clearing Fund Securities.

FICC is also proposing to amend GSD Rule 3B Section 14(a)(xii) to include a reference to UMBS. This section defines the Pricing Rate for CCIT MRA transactions backed by U.S. Treasury securities, Non-Mortgage-Backed U.S. Agency Securities, and Fannie Mae and Freddie Mac mortgage-backed securities. FICC is proposing to amend this section to add UMBS to the references to Fannie Mae and Freddie Mac mortgage-backed securities. Due to this change, the calculated Pricing Rate for UMBS would be the same as the Pricing Rate for Fannie Mae and Freddie Mac mortgage-backed securities.

FICC is also proposing to amend item 3 entitled ''MBS Pass-Throughs'' in GSD's Schedule of Haircuts for Eligible Clearing Fund Securities to apply the current haircut for Fannie Mae securities and Freddie Mac securities to the proposed UMBS.

B. Proposed Changes to the MBSD Clearing Rules

FICC is proposing to amend MBSD Rule 1 to include the definition for UMBS. This term would be defined as a single-class mortgage-backed security backed by fixed-rate mortgage loans on one to four unit (single-family) properties issued by either Fannie Mae or Freddie Mac which has the same characteristics (such as payment delay, pooling prefixes and minimum pool submission amounts) regardless of whether Fannie Mae or Freddie Mac is the issuer. FICC is proposing this change because this term would be referenced in MBSD's Schedule of Haircuts for Eligible Clearing Fund Securities.

FICC is proposing to amend item 3 entitled ''MBS Pass-Throughs'' in MBSD's Schedule of Haircuts for Eligible Clearing Fund Securities to apply the current haircut for Fannie Mae securities and Freddie Mac securities to the proposed UMBS.

C. Proposed Changes to the GSD Methodology Document

FICC is proposing to amend the GSD Methodology Document to include references to UMBS. Given that the FHFA's proposed rule and final rule state that the key features of the proposed UMBS would be the same as the current Fannie Mae securities,[17] FICC would treat UMBS in the same manner that it treats Fannie Mae securities from a risk management perspective—meaning, FICC would calculate a GSD Netting Member's Required Fund Deposit amount for GCF Repo Transactions backed by UMBS consistent with FICC's current calculation of GCF Repo Transactions backed by Fannie Mae securities.

D. Proposed Changes to the MBSD Methodology Document

FICC is proposing to amend the MSBD Methodology Document to include references to UMBS. Given that the FHFA's proposed rule and final rule state that the key features of the proposed UMBS would be the same as the current Fannie Mae securities.[18] FICC would treat UMBS in the same manner that it treats Fannie Mae securities from a risk management perspective—meaning, FICC would calculate a MBSD Clearing Member's Required Fund Deposit amount for portfolios that are comprised of UMBS in a manner that is consistent with FICC's current calculation for portfolios that are comprised of Fannie Mae securities.

2. Statutory Basis

Section 17A(b)(3)(F) of the Act requires, in part, that the GSD Rules and MBSD Rules be designed to promote the prompt and accurate clearance and settlement of securities transactions.[19] As described above, FICC is proposing to (1) amend the GSD Rulebook and the MBSD Clearing Rules to apply the current haircut for Fannie Mae securities and Freddie Mac securities to the proposed UMBS, (2) amend the GSD Rulebook to apply the current Pricing Rate for CCIT Transactions backed by Fannie Mae securities and Freddie Mac securities to CCIT Transactions backed by UMBS, and (3) amend the GSD Methodology Document and MBSD Methodology Document to include references to UMBS.

FICC believes the proposed rule change would promote the prompt and accurate clearance and settlement of securities transactions because the

[14] Freddie Mac refers to its pass-through mortgage-backed securities as ''Participation Certificates.'' Freddie Mac Giant Participation Certificates are single-class pass-through securities that enable investors to manage their portfolios more efficiently by consolidating smaller participation certificates into larger giant participation certificates. *See* ''Giant PCs,'' *available at http://www.freddiemac.com/mbs/products/giants.html.* Introduced in 1988, Freddie Mac Giant Participation Certificates are popular with dealers and investors because they are an efficient and profitable way to aggregate production and investment portfolios. *Id.*

[15] *See* 83 FR at 46890; Fannie Mae website, *supra* note 9. The opportunity to exchange 45-day Freddie Mac Participation Certificates and Freddie Mac Giant Participation Certificates for comparable UMBS backed by the same mortgage loans occurs outside of FICC. FICC is not involved in any aspect of this exchange process. Information on this exchange is *available at http://www.freddiemac.com/mbs/exchange/.*

[16] *See* GSD Rule 1, Definitions—''Eligible Security,'' and MBSD Rule 1, Definitions—''Eligible Security,'' *supra* note 5.

[17] 83 FR at 46890; 84 FR at 7793.

[18] *Id.*

[19] 15 U.S.C. 78q–1(b)(3)(F).

proposed UMBS would present the same risks to FICC that the existing Fannie Mae securities and Freddie Mac securities currently present to FICC given that the FHFA, Fannie Mae and Freddie Mac have indicated that the key characteristics of UMBS will be the same as Fannie Mae securities as described in Item II(A)1 above. As a result, FICC would treat UMBS in the same manner that it treats Fannie Mae securities and Freddie Mac securities. Specifically, the changes would promote the prompt and accurate clearance and settlement of securities because (1) the proposed haircut, which would be the same as the haircuts for Fannie Mae securities and Freddie Mac securities, would protect FICC from the potential decline in the value of UMBS in normal and in stressed market conditions, (2) the proposed Pricing Rate for CCIT Transactions backed by UMBS would help to ensure that such rate is calculated in the same manner as Fannie Mae securities and Freddie Mac securities for purposes of a CCIT MRA transaction, and (3) the proposed inclusion of UMBS in the GSD Methodology Document and MBSD Methodology Document would help to ensure that UMBS is treated in the same manner as Fannie Mae securities for risk management purposes. For these reasons, FICC believes that the proposed changes are consistent with the requirements of the Act, in particular Section 17A(b)(3)(F), cited above.

(B) Clearing Agency's Statement on Burden on Competition

FICC does not believe that the proposed rule changes would have any impact, or impose any burden, on competition because, as described in Item II(A)1 above, FICC would treat UMBS in the same manner that it treats Fannie Mae securities and Freddie Mac securities (*i.e.,* the same haircut that is currently applied to Fannie Mae securities and Freddie Mac securities would be applied to UMBS; the same CCIT Pricing Rate that is currently applied to CCIT Transactions backed by Fannie Mae securities and Freddie Mac securities would be applied to CCIT Transactions backed by UMBS; and the same risk management that is applied to Fannie Mae securities and Freddie Mac securities would be applied to UMBS). Given this, FICC's proposed treatment of UMBS would not give Members an advantage or a disadvantage if such Members use UMBS rather than Fannie Mae securities or Freddie Mac securities (1) for purposes of satisfying Required Fund Deposits amounts or (2) to back CCIT Transactions. Therefore, FICC does not believe that the proposed rule changes would have any impact or impose any burden on competition.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

FICC has not received or solicited any written comments relating to this proposal. FICC will notify the Commission of any written comments received by FICC.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [20] and paragraph (f) of Rule 19b–4 thereunder.[21] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–FICC–2019–002 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–FICC–2019–002. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of FICC and on DTCC's website (*http://dtcc.com/legal/sec-rule-filings.aspx*). All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FICC–2019–002 and should be submitted on or before May 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–08204 Filed 4–23–19; 8:45 am]

BILLING CODE 8011–01–P

[20] 15 U.S.C. 78s(b)(3)(A).

[21] 17 CFR 240.19b–4(f).

[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85693; File No. SR–MIAX–2019–20]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule

April 18, 2019.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 11, 2019, Miami International Securities Exchange LLC (''MIAX Options'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend the MIAX Options Fee Schedule (the ''Fee Schedule'') to adjust and adopt certain SPIKES transaction fees. The Exchange initially filed the proposal on March 29, 2019 (SR–MIAX–2019–18). That filing has been withdrawn and replaced with the current filing (SR–MIAX–2019–20).

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings,* at MIAX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange adopted its initial SPIKES transaction fees on February 15, 2019.[3] The Exchange now proposes to amend the Fee Schedule to adjust and adopt certain SPIKES transaction fees. Specifically, the Exchange proposes to (i) adopt new fees for SPIKES Combinations; [4] (ii) change the complex fees so that complex orders are charged the same fees as simple orders of the same Origin (and combined in the same fee table), using the simple maker and taker fee structure already in place; (iii) adjust the number of contracts in the Simple Large Trade Discount Threshold, adjust the number of contracts in the Complex Large Trade Discount Threshold, and create a new, stand-alone column in the table for the Complex Large Trade Discount; (iv) establish a new PRIME Large Trade Discount and a new cPRIME Large Trade Discount; and (v) make a non-substantive, technical change to the Fee Schedule.

SPIKES Combinations

The Exchange is proposing to adopt new transaction fees for SPIKES Combinations. A SPIKES Combination is a specific type of complex order, which will have separate pricing from all other SPIKES complex orders. The Exchange is proposing to insert the definition of a SPIKES Combination beneath the SPIKES Simple and Complex Fees table on its Fee Schedule. Generally, a SPIKES Combination is a type of complex strategy that is designed to replicate the exposure provided by a futures contract. Accordingly, the Exchange is proposing to have separate transaction fees for SPIKES Combinations, which will be significantly lower than the transaction fees for all other types of SPIKES complex orders, with the exception of complex orders for Priority Customers [5] (which are assessed at the same rate—$0.00 per contract). For all Origins other than Priority Customer, the Exchange is proposing a transaction fee of $0.01 per contract, per leg for SPIKES Combinations. Additionally, the Exchange is proposing to add a note beneath the SPIKES Simple and Complex Fees table clarifying that, if a complex strategy contains both a Combination component as well as a non-Combination component, the portion (*i.e.,* legs) of the complex strategy that comprises the SPIKES Combination will be charged at the Combination rate, and the portion of the complex strategy that comprises the non-Combination component will be charged at the applicable complex rates.

Complex Fees

The Exchange is proposing to change the complex fees so that complex orders (other than SPIKES Combinations) are charged the same fees as simple orders or quotes of the same Origin (and combined in the same fee table), using the simple maker and taker fee structure already in place. Currently, the Exchange charges a single fee for complex orders based on Origin, regardless of whether such order was a maker or a taker. As proposed, the Exchange will now charge complex orders, depending on whether such order is a maker or a taker, and based on the Origin. Except for Priority Customer Origin (which will be assessed a charge of $0.00 per contract, whether maker or taker), all Origins will be charged the same maker or taker rate for complex orders as the Origin is currently charged for simple orders or quotes. For MIAX Market Maker and Firm Proprietary Origins, the maker rate is $0.00 and the taker rate is $0.20 per contract. Additionally, for MIAX Market Maker and Firm Proprietary Origins, taker fees for options with a premium price of $0.10 or less will be charged $0.05 per contract for Complex orders. For non-MIAX Market Maker, Broker-Dealer, and Public Customer that is not a Priority Customer Origins, the maker rate is $0.10 and the taker rate is $0.25 per contract. The Exchange also proposes to clarify the rates that apply to all Origins in a Complex Auction.[6] In a Complex Auction, Priority Customer Origin will be charged the complex maker rate. Origins that are not a Priority Customer will be charged the applicable complex taker rate. The Exchange proposes to add a note beneath the Simple and Complex Fees table clarifying such fee applicability for quotes/orders executed in a Complex Auction.

Simple and Complex Large Trade Discount Thresholds

The Exchange currently has in place a Simple/Complex Large Trade Discount. Pursuant to such discount program, for any single order/quote, no fee applies to the number of contracts executed above the threshold amount. The threshold amount is currently set at 175,000 contracts, and applies to both simple and complex orders of all Origins (except for Priority Customer Origin, which has a threshold amount of 0, because Priority Customer orders are assessed a fee of $0.00 for simple and complex volume). The Exchange now proposes to create a separate Large Trade Discount Threshold for both simple and complex orders, and to lower the threshold amounts for each. As proposed, a simple order that reaches the proposed size threshold of 10,000 contracts, tied to a single order, will have the relevant fees apply to the contracts at and below the size threshold for simple volume; no fees shall apply to the number of contracts executed above the threshold, with certain exceptions. As proposed, a

[3] *See* Securities Exchange Release No. 85283 (March 11, 2019), 84 FR 9567 (March 15, 2019) (SR–MIAX–2019–11). (The Exchange initially filed the proposal on February 15, 2019 (SR–MIAX–2019–04). That filing was withdrawn and replaced with (SR–MIAX–2019–11)).

[4] A ''Combination'' is a purchase (sale) of a SPIKES call option and the sale (purchase) of a SPIKES put option having the same expiration date and strike price.

[5] The term ''Priority Customer: Means a person or entity that (i) is not a broker or dealer in securities, and (ii) does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). *See* Exchange Rule 100.

[6] A ''Complex Auction'' is an auction of a complex order as set forth in Exchange Rule 518(d). *See* Exchange Rule 518(a)(3).

complex order that reaches the proposed size threshold of 25,000 contracts, tied to a single order, will have the relevant fees apply to the contracts at and below the size threshold for complex volume; no fees shall apply to the number of contracts executed above the threshold, with certain exceptions. In the case of each discount program, the exceptions are the same and are not proposed to be changed: The Large Trade Discount does not apply to volume from Priority Customer orders, Maker orders, SPIKES Opening orders, and the Surcharge.

Accordingly, for any simple order/quote, no fee shall apply to the number of contracts executed above the first 10,000 contracts for simple orders and the first 25,000 contracts for complex orders for Market Makers, Non-MIAX Market Makers, Broker-Dealers, Firm Proprietary orders, and Public Customers that are not Priority Customers. The Exchange is not proposing to change that such discount program does not apply to Priority Customer orders because, as discussed, the Exchange is currently charging Priority Customers a $0.00 fee for these volume segments.

As proposed, the SPIKES Simple and Complex Fees table will be as follows:

SIMPLE AND COMPLEX FEES #

Origin	Simple/complex ¥ maker ($)	Simple/complex ¥ taker ($)	Simple opening ($)	Combination ~! ($)	Simple large trade discount threshold +	Complex large trade discount threshold +
Priority Customer	$0.00	$0.00	$0.00	$0.00	0	0
Market Maker	0.00	*0.20	0.15	0.01	First 10,000 contracts	First 25,000 contracts.
Non-MIAX Market Maker	0.10	0.25	0.15	0.01	First 10,000 contracts	First 25,000 contracts.
Broker-Dealer	0.10	0.25	0.15	0.01	First 10,000 contracts	First 25,000 contracts.
Firm Proprietary	0.00	*0.20	0.15	0.01	First 10,000 contracts	First 25,000 contracts.
Public Customer that is Not a Priority Customer	0.10	0.25	0.15	0.01	First 10,000 contracts	First 25,000 contracts.

*Taker fees for options with a premium price of $0.10 or less will be charged $0.05 per contract.
~A "SPIKES Combination" is a purchase (sale) of a SPIKES call option and sale (purchase) of a SPIKES put option having the same expiration date and strike price.
!The SPIKES Combination portion of a SPIKES Combination Order will be charged at the Combination rate and other legs will be charged at the Complex rate. All fees are per contract per leg.
+ Tied to Single Order/Quote ID. For any single order/quote, no fee shall apply to the number of contracts executed above the Simple or Complex Large Trade Discount Threshold. This discount does not apply to Priority Customer orders, Maker orders, SPIKES Opening orders, and the Surcharge.
¥For quotes/orders in a Complex Auction, Priority Customer Complex Orders will receive the Complex Maker rate. Origins that are not a Priority Customer will be charged the applicable Complex Taker rate.

PRIME and cPRIME Large Trade Discounts

The Exchange further proposes to establish a Large Trade Discount program for both PRIME [7] and cPRIME [8] orders in SPIKES. These discount programs will operate in the same manner as the discount programs for simple and complex orders, and will have the same threshold amounts, with one exception described below relating to Priority Customer Origin. Specifically, the Exchange proposes to establish a Large Trade Discount Threshold for PRIME orders in the amount of 10,000 contracts. A PRIME order that reaches the proposed size threshold of 10,000 contracts, tied to a single order, will have the relevant fees apply to the contracts at and below the size threshold for PRIME volume; no fees shall apply to the number of contracts executed above the threshold, with certain exceptions described below. Since a PRIME order is a paired order, the transaction fee will be capped at 10,000 contracts from a single order, for the Agency Side and Contra Side, independently. Contracts greater than the threshold will not be charged the transaction fee but will continue to be charged the Surcharge. Responder fees and Break-up Credits will not be capped. The Exchange notes that, unlike the Simple and Complex Large Trade Discount programs, there is a non-zero threshold amount for Priority Customer Origin, which is the same amount as all other Origins. The purpose for having a cap for Priority Customer Origin in the PRIME Large Trade Discount program is because Priority Customer Origin is currently assessed a fee of $0.20 per contract if it is a Contra in the execution. Therefore, the Exchange believes it is appropriate to apply the cap to Priority Customer Origin in this circumstance.

Similarly, the Exchange proposes to establish a Large Trade Threshold for cPRIME orders in the amount of 25,000 contracts. A cPRIME order that reaches the proposed size threshold of 25,000 contracts, tied to a single order, will have the relevant fees apply to the contracts at and below the size threshold for cPRIME volume; no fees shall apply to the number of contracts executed above the threshold, with certain exceptions described below. Since a cPRIME order is a paired order, the transaction fee will be capped at 25,000 contracts that are traded per strategy from a single order, for the Agency Side and for the Contra Side independently. Contracts greater than the threshold will not be charged the transaction fee but will continue to be charged the Surcharge. Responder fees and Break-up Credits will not be capped. The Exchange notes that, unlike the Simple and Complex Large Trade Discount programs, there is a non-zero threshold amount for Priority Customer Origin, which is the same amount as all other Origins. The purpose for having a cap for Priority Customer Origin in the cPRIME Large Trade Discount program is because Priority Customer Origin is currently assessed a fee of $0.20 per contract if it is a Contra in the execution. Therefore, the Exchange believes it is appropriate to apply the cap to Priority Customer Origin in this circumstance.

As proposed, the SPIKES PRIME and cPRIME Fees table will be as follows:

[7] PRIME is a process by which a Member may electronically submit for execution (''Auction'') an order it represents as agent (''Agency Order'') against principal interest, and/or an Agency Order against solicited interest. *See* Exchange Rule 515A(a).

[8] cPRIME is the process by which a Member may electronically submit a ''cPRIME Order'' (as defined in Exchange Rule 518(b)(7)) it represents as agent (a ''cPRIME Agency Order'') against principal or solicited interest for execution (a ''cPRIME Auction''). *See* Interpretation and Policy .12 of Exchange Rule 515A.

PRIME AND cPRIME FEES #

Origin	Initiating ($)	Contra ($)	Responder ($)	Break-up ($)	PRIME large trade discount threshold ^	cPRIME large trade discount threshold ◊
Priority Customer	$0.00	$0.20	$0.25	($0.15)	First 10,000 contracts.	First 25,000 contracts
Market Maker	0.10	0.20	0.25	(0.15)	First 10,000 contracts.	First 25,000 contracts
Non-MIAX Market Maker	0.10	0.20	0.25	(0.15)	First 10,000 contracts.	First 25,000 contracts
Broker-Dealer	0.10	0.20	0.25	(0.15)	First 10,000 contracts.	First 25,000 contracts
Firm Proprietary	0.10	0.20	0.25	(0.15)	First 10,000 contracts.	First 25,000 contracts
Public Customer that is Not a Priority Customer.	0.10	0.20	0.25	(0.15)	First 10,000 contracts.	First 25,000 contracts

An Index License Surcharge (''Surcharge'') of $0.075 will apply to any contract that is executed by an Origin except Priority Customer. The Surcharge applies per contract side per leg. The Surcharge will be waived for the ''Waiver Period'' which, for purposes of this Section 1)a)xi) of the Fee Schedule, means the period of time from the launch of trading of SPIKES options until such time that the Exchange submits a filing to terminate the Waiver Period. The Exchange will issue a Regulatory Circular announcing the end of the Waiver Period at least fifteen (15) days prior to the termination of the Waiver Period and effective date of such Surcharge.

^ The transaction fee for SPIKES PRIME will be capped at 10,000 contracts from a single order, for the Agency Side and Contra Side independently. Contracts greater than the threshold will not be charged the transaction fee but will continue to be charged the Surcharge. Responder fees and Break-up Credits will not be capped.

◊ The transaction fee for SPIKES cPRIME will be capped at 25,000 contracts that are traded per strategy from a single order, for the Agency Side and for the Contra Side independently. Contracts greater than the threshold will not be charged the transaction fee but will continue to be charged the Surcharge. Responder fees and Break-up Credits will not be capped.

SPIKES Settlement Day SPY Opening Auction Fees

SPIKES SETTLEMENT DAY SPY OPENING AUCTION FEES

Origin	SPY opening quotes/ orders ¤
Priority Customer	$0.00
Market Maker	0.03
Non-MIAX Market Maker	0.06
Broker-Dealer	0.06
Firm Proprietary	0.03
Public Customer that is Not a Priority Customer	0.06

¤ These fees will be charged to each side of all trades occurring in the SPY opening in the expiration month used to determine SPIKES settlement on settlement day only; in lieu of any other fees in the Fee Schedule.

The Exchange proposes to make a minor non-substantive technical correction to the SPIKES Settlement Day SPY Opening Auction Fees table. The Exchange proposes to amend the column heading for SPY Opening Orders to include Quotes to clarify that the fees listed apply to both SPY Opening Quotes and Orders. These fees are only applicable on SPIKES settlement day. The purpose for lower, separate fees for these SPY transactions is to encourage Market Makers and other market participants that need to unwind a SPIKES hedge to participate in the Opening Auction, by making the pricing more attractive.

The Exchange believes that each of the proposed SPIKES transaction fee changes described herein are reasonable in that they are designed to encourage market participants to provide liquidity for SPIKES index options on the Exchange.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act [9] in general, and furthers the objectives of Section 6(b)(4) of the Act [10] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among Exchange Members [11] and issuers and other persons using its facilities. The Exchange also believes the proposal furthers the objectives of Section 6(b)(5) of the Act [12] in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest and is not designed to permit unfair discrimination between customer, issuers, brokers and dealers.

SPIKES Combinations and Complex Fees

The Exchange believes that the proposed fee changes for transactions in SPIKES Combinations and complex orders is consistent with Section 6(b)(4) of the Act in that they are reasonable, equitable, and not unfairly discriminatory. The proposed fee changes are reasonably designed because they are intended to incentivize market participants to transact in SPIKES index options on the Exchange, which enables the Exchange to improve its overall competitiveness and strengthen its market quality for all market participants in SPIKES index options.

The Exchange believes that it is reasonable to establish separate pricing for SPIKES Combinations, in order to encourage trading in SPIKES Combinations on the Exchange. Generally, a SPIKES Combination is a type of complex strategy that is designed to replicate the exposure provided by a futures contract. Accordingly, the Exchange believes it is appropriate to have separate transaction fees for SPIKES Combinations, which will be significantly lower than the transaction fees for all other types of complex orders, with the exception of complex orders for Priority Customers (which are assessed at the same rate—$0.00 per contract). A SPIKES Combination will be charged lower fees than a standard SPIKES complex order. The Exchange also believes combining complex maker and taker fees with the respective simple maker and taker fees simplifies the Exchange's fee structure, which benefits investors as it clarifies the Exchange's fees and reduces the risk of confusion.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4).

[11] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[12] 15 U.S.C. 78f(b)(5).

The Exchange believes that it is reasonable, equitable, and not unfairly discriminatory to apportion Complex Auction fees among participants by Origin. Priority Customer Complex orders will be assessed the Complex Maker rate of $0.00 per contract, and Origins that are not a Priority Customer will be charged the applicable Complex Taker rate. During a Complex Auction there is no Maker/Taker distinction, therefore the Exchange will assign a role, and applicable fee, based upon Origin. The Exchange notes that other exchanges employ this methodology in similar circumstances.[13] The Exchange believes this a fair and equitable way to apportion fees among participants in a Complex Auction.

The proposed SPIKES Combination fees and complex fees are reasonable, equitable, and not unfairly discriminatory because they will apply similarly to Priority Customer orders, Market Maker orders, Non-MIAX Market Maker orders, Broker Dealer orders, Firm Proprietary orders, and Public Customers that are not Priority Customers orders, in each respective category of SPIKES index option orders. All similarly situated categories of participants are subject to the same transaction fee and rebate schedule, and access to the Exchange is offered on terms that are not unfairly discriminatory.

The exchanges in general have historically aimed to improve markets for investors and develop various features within market structure for customer benefit. The Exchange assesses Priority Customers lower or no transaction fees because Priority Customer order flow enhances liquidity on the Exchange for the benefit of all market participants. Priority Customer liquidity benefits all market participants by providing more trading opportunities, which attracts Market Makers. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants.

Moreover, the Exchange believes that assessing all other market participants that are not Priority Customers a higher transaction fee than Priority Customers for SPIKES Combinations and complex orders is reasonable, equitable, and not unfairly discriminatory because these types of market participants are more sophisticated and have higher levels of order flow activity and system usage. This level of trading activity draws on a greater amount of system resources than that of Priority Customers. Further, the Exchange believes it is equitable and not unfairly discriminatory to assess all other market participants that are not Priority Customers, Market Makers, or Firm Proprietary orders a higher complex maker and taker fees for orders in SPIKES options because Priority Customers, Market Makers, and Firm Proprietary orders bring valuable liquidity to the market, which in turn benefits other market participants. Priority Customer and Firm Proprietary order flow enhances liquidity on the Exchange for the benefit of all market participants. Specifically, Priority Customer and Firm Proprietary order flow liquidity benefits all market participants (as Priority Customer and Firm Proprietary orders are generally providers of liquidity) by providing more robust trading opportunities, which attracts Market Makers. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants, which in turn benefits the market as a whole.

Simple and Complex Large Trade Discount Thresholds

The Exchange believes reducing the Large Trade Discount Threshold for simple orders or quotes from 175,000 to 10,000 is reasonable, equitable, and not unfairly discriminatory because it provides an incentive for Members to submit large sized simple orders or quotes to the Exchange, which will benefit all market participants. All similarly situated categories of participants are subject to the same threshold (except for Priority Customers which are not charged a transaction fee otherwise, so no discount is necessary), and access to the Exchange is offered on terms that are not unfairly discriminatory. Additionally, the Exchange believes that creating a separate Large Trade Discount for complex orders at 25,000 contracts is reasonable, equitable, and not unfairly discriminatory because it provides an incentive for Members to submit large sized complex orders to the Exchange, which will benefit all market participants. All similarly situated categories of participants are subject to the same threshold (except for Priority Customers which are not charged a transaction fee otherwise, so no discount is necessary), and access to the Exchange is offered on terms that are not unfairly discriminatory.

PRIME and cPRIME Large Trade Discounts

The Exchange believes that offering Members a Large Trade Discount for PRIME orders and cPRIME orders with identical thresholds as those proposed for simple and complex orders, respectively, is reasonable, equitable, and not unfairly discriminatory because it provides an incentive for Members to submit large sized PRIME and cPRIME liquidity to the Exchange, which will benefit all market participants. All similarly situated categories of participants are subject to the same discount, and access to the Exchange is offered on terms that are not unfairly discriminatory.

The Exchange believes that it is reasonable, equitable, and not unfairly discriminatory to not cap Responder fees as there is no cap on corresponding Break-up Credits. The Exchange believes it is necessary to provide Break-up Credits in order to incentivize Members to submit PRIME and cPRIME orders to the Exchange, which provides important price improvement opportunities for Agency orders. The Exchange notes that other exchanges exclude response fees from fee caps as well, including Nasdaq ISE, which excludes Crossing Orders from the firm fee cap.[14]

SPIKES Settlement Day SPY Opening Auction Fees

The non-substantive technical change proposed to the column heading for SPY Opening Orders to include Quotes promotes just and equitable principles of trade, removes impediments to and perfects the mechanism of a free and open market and a national market system, and, in general protects investors and the public interest by providing additional detail and clarity regarding fees charged by the Exchange. It is in the best interest of investors and the public for fees to be as clear and concise as possible so that investors and the public may make informed decisions regarding their orders.

The purpose for adopting lower, separate fees for these SPY transactions is to encourage Market Makers and other market participants that need to unwind a SPIKES hedge to participate in the Opening Auction, by making the pricing more attractive. Specifically, market participants holding short, hedged SPIKES options could liquidate that hedge by selling their SPY options series, while traders holding long, hedged SPIKES options could liquidate their hedge by buying SPY option series.

[13] *See* Nasdaq GEMX Options 7, Section 3, Footnote 4.

[14] *See* Nasdaq ISE, Options 7, Section 6(H).

These market participants may liquidate their hedges by submitting SPIKES strategy orders in the appropriate SPY option series during the SPIKES Special Settlement Auction[15] on the SPIKES expiration/final settlement date.

The Exchange believes that the fee and rebate structure for transactions involving SPY Opening orders for options that are used in the calculation of the SPIKES Index on final settlement day is reasonable, equitable, and not unfairly discriminatory because it will apply similarly to Priority Customer orders, Market Maker orders, Non-MIAX Market Maker orders, Broker Dealer orders, Firm Proprietary orders, and Public Customers that are not Priority Customers orders, in each respective category of such orders.

The Exchange currently applies fees to orders that participate in the SPIKES Settlement Day SPY Opening Auction.[16] The Exchange believes it would not be unfairly discriminatory to apply an identical fee structure to quotes that participate in the SPIKES Settlement Day SPY Opening Auction. The Exchange believes that the fee and rebate structure for transactions involving SPY Opening Quotes for options that are used in the calculation of the SPIKES Index on final settlement day is reasonable, equitable, and not unfairly discriminatory because it will apply similarly to all Market Makers. All similarly situated categories of participants are subject to the same transaction fee and rebate schedule, and access to the Exchange is offered on terms that are not unfairly discriminatory.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed change will enhance the competitiveness of the Exchange relative to other exchanges that offer their own singly-listed products. The Exchange believes that the proposed fees and rebates for transactions in SPIKES index options are not going to have an impact on intra-market competition based on the total cost for participants to transact in such order types versus the cost for participants to transact in other order types available for trading on the Exchange.

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues and competing products if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and to attract order flow to the Exchange. The Exchange believes that the proposed rule change reflects this competitive environment because it is adjusting its fees in a manner that encourages market participants to provide liquidity in SPIKES index options, and to attract additional transaction volume to the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[17] and Rule 19b–4(f)(2) [18] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MIAX–2019–20 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–MIAX–2019–20. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MIAX–2019–20 and should be submitted on or before May 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–08211 Filed 4–23–19; 8:45 am]

BILLING CODE 8011–01–P

[15] *See* Exchange Rule 503, Interpretations and Policies .03.

[16] *See* Securities Exchange Release No. 85283 (March 11, 2019), 84 FR 9567 (March 15, 2019) (SR–MIAX–2019–11) (Proposal to amend the MIAX Options Fee Schedule to adopt transaction fees and rebates for SPIKES index option orders and quotes).

[17] 15 U.S.C. 78s(b)(3)(A)(ii).

[18] 17 CFR 240.19b–(f)(2).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85692; File No. SR–Phlx–2019–16]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Pilot Period for the Listing of P.M.-Settled Nasdaq-100 Index Options Expiring on the Third Friday of the Month

April 18, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 12, 2019, Nasdaq PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend the pilot period for the listing of P.M.-settled Nasdaq-100 Index Options expiring on the third Friday of the month (''NDXPM'').

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqphlx.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

In August 2017, the Commission approved a proposed rule change for the listing on the Exchange of NDXPM options on a pilot basis, with the pilot to terminate on the earlier to occur of (i) 12 months following the date of the first listing of the NDXPM options, or (ii) December 29, 2018 pursuant to Phlx Rule 1101A Commentary .05.[3] Thereafter, the Exchange amended Commentary .05 to Phlx Rule 1101A to extend the pilot through May 6, 2019 because P.M.-settled options on the NASDAQ–100 Index (''NASDAQ–100'') had not yet been listed by Phlx.[4]

By way of background, the Pilot permits the listing and trading, on a pilot basis, of NASDAQ–100 options with third-Friday-of-the month expiration dates, whose exercise settlement value will be based on the closing index value, symbol XQC, of the NASDAQ–100 on the expiration day (''P.M.-settled''). In particular, NDXPM uses a $100 multiplier, and the minimum trading increment will be $0.05 for options trading below $3.00 and $0.10 for all other series. Strike price intervals are set at no less than $5.00. Consistent with existing rules for index options, the Exchange allows up to nine near term expiration months, as well as LEAPS. The product will have European-style exercise and will not be subject to position limits, though there would be enhanced reporting requirements.

The Exchange now proposes to amend Commentary .05 to Phlx Rule 1101A to extend the duration of the pilot program for these nonstandard expirations through November 4, 2019. The Exchange continues to experience technical programming delays related to P.M.-settled options on the NASDAQ–100 and as a result, these option series have not yet been listed by the Exchange. In order to allow sufficient time to realize the benefits of a pilot program for NDXPM options, the Exchange proposes the extension. By extending the outer limit of the pilot period, the Exchange believes it will have adequate time to resolve the programming issues, implement the listing of NDXPM options, and provide the pilot reports associated with the initial approval order over a meaningful period of time.[5] Without the amendment, the pilot period would end on May 6, 2019 and would not afford the Exchange or Commission a sufficient period of time within which NDXPM options may trade in order to be meaningfully evaluated by the Exchange as provided in the August 2017 approval order.[6] The Exchange will make public on its website any data and analysis it submits to the Commission under the pilot program.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Section 6(b)(5) of the Act,[8] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The Exchange believes the proposed rule change will protect investors and the public interest by extending the pilot period for listing NDXPM options until November 4, 2019, providing the Exchange, the Commission and investors the benefit of a pilot program of sufficient duration to yield meaningful information concerning the impact of NDXPM options on the market.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. NDXPM options would be available for trading to all market participants. The proposed rule change will facilitate the listing and trading of a novel option product that will enhance competition among market participants, to the benefit of investors and the marketplace. The listing of NDXPM will enhance competition by providing investors with an additional investment vehicle, in a fully-electronic trading environment, through which

[3] *See* Securities Exchange Act Release No. 81293 (August 2, 2017), 82 FR 37138 (August 8, 2017) (approving SR–Phlx–2017–04) (Order Granting Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2, To Permit the Listing and Trading of P.M.-Settled Nasdaq-100 Index Options on a Pilot Basis) (''Pilot'').

[4] *See* Securities Exchange Act Release No. 84685 (November 29, 2019 [sic]), 83 FR 62942 (December 6, 2018) (SR–Phlx–2018–76) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Pilot Period for the Listing of P.M.-Settled Nasdaq-100 Index Options Expiring on the Third Friday of the Month).

[5] The Exchange will issue an Options Trader Alert notifying Members when NDXPM options are listed.

[6] *See* note 4 above.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

investors can gain and hedge exposure to NASDAQ–100 stocks. Further, this product could offer a competitive alternative to other existing investment products that seek to allow investors to gain broad market exposure. Also, the Exchange notes that it is possible for other exchanges to develop or license the use of a new or different index to compete with the NASDAQ–100 and seek Commission approval to list and trade options on such an index.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [9] and Rule 19b–4(f)(6) thereunder.[10]

A proposed rule change filed under Rule 19b–4(f)(6) [11] normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii) [12] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become effective and operative immediately upon filing. The Exchange states that such waiver would allow the Exchange to extend the pilot period for listing NDXPM options prior to the Pilot's scheduled expiration, providing the Exchange, the Commission, and investors the benefit of a pilot program of sufficient duration to yield meaningful information concerning the impact of NDXPM options on the market. For this reason, the Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the 30-day operative delay requirement and designates the proposed rule change as operative upon filing.[13]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–Phlx–2019–16 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2019–16. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2019–16 and should be submitted on or before May 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Jill M. Peterson,

Assistant Secretary.

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[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6). As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

[11] 17 CFR 240.19b–4(f)(6).

[12] 17 CFR 240.19b–4(f)(6)(iii).

[13] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85688; File No. SR–CBOE–2019–023]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Extend the Operation of Its SPXPM Pilot Program

April 18, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 10, 2019, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to extend the operation of its SPXPM pilot program. The text of the proposed rule change is provided below.

(additions are *italicized;* deletions are [bracketed])

* * * * *

Rules of Cboe Exchange, Inc.

* * * * *

Rule 24.9. Terms of Index Option Contracts

(No change).

. . . Interpretations and Policies:

.01–.13 (No change).

.14 In addition to A.M.-settled Standard & Poor's 500 Stock Index options approved for trading on the Exchange pursuant to Rule 24.9, the Exchange may also list options on the S&P 500 Index whose exercise settlement value is derived from closing prices on the last trading day prior to expiration (P.M.-settled third Friday-of-the-month SPX options series). The Exchange may also list options on the Mini-SPX Index (''XSP'') whose exercise settlement value is derived from closing prices on the last trading day prior to expiration (''P.M.-settled''). P.M.-settled third Friday-of-the-month SPX options series and P.M.-settled XSP options will be listed for trading for a pilot period ending [May 6] *November 4,* 2019.

* * * * *

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On February 8, 2013, the Exchange received approval of a rule change that established a Pilot Program that allows the Exchange to list options on the S&P 500 Index whose exercise settlement value is derived from closing prices on the last trading day prior to expiration (''SPXPM'').[5] On July 31, 2013, the Exchange received approval of a rule change that amended the Pilot Program to allow the Exchange to list options on the Mini-SPX Index (''XSP'') whose exercise settlement value is derived from closing prices on the last trading day prior to expiration (''P.M.-settled'')[6] (together, SPXPM and P.M.-settled XSP to be referred to herein as the ''Pilot Products'').[7] The Exchange has extended the pilot period five [sic] times, which is currently set to expire on the earlier of May 6, 2019 or the date on which the pilot program is approved on a permanent basis.[8] The Exchange hereby proposes to further extend the end date of the pilot period to November 4, 2019.

During the course of the Pilot Program and in support of the extensions of the Pilot Program, the Exchange submits to the Securities and Exchange Commission (the ''Commission'') reports regarding the Pilot Program that detail the Exchange's experience with the Pilot Program, pursuant to the SPXPM Approval Order and the P.M.-settled XSP Approval Order. Specifically, the Exchange submits annual Pilot Program reports to the Commission that contain an analysis of volume, open interest, and trading patterns. The analysis examines trading in Pilot Products as well as trading in the securities that comprise the underlying index. Additionally, for series that exceed certain minimum open interest parameters, the annual reports provide analysis of index price volatility and share trading activity. The Exchange also submits periodic interim reports that contain some, but not all, of the information contained in the annual reports. In providing the annual and periodic interim reports (the ''pilot reports'') to the Commission, the Exchange has previously requested confidential treatment of the pilot reports under the Freedom of Information Act (''FOIA'').[9]

The pilot reports both contain the following volume and open interest data:

(1) Monthly volume aggregated for all trades;

(2) monthly volume aggregated by expiration date;

(3) monthly volume for each individual series;

(4) month-end open interest aggregated for all series;

(5) month-end open interest for all series aggregated by expiration date; and

(6) month-end open interest for each individual series.

The annual reports also contain the information noted in Items (1) through (6) above for Expiration Friday, A.M.-settled, S&P 500 index options traded on Cboe Options, as well as the following analysis of trading patterns in the Pilot Products options series in the Pilot Program:

(1) A time series analysis of open interest; and

(2) an analysis of the distribution of trade sizes.

Finally, for series that exceed certain minimum parameters, the annual reports contain the following analysis related to index price changes and underlying share trading volume at the close on Expiration Fridays:

(1) A comparison of index price changes at the close of trading on a given Expiration Friday with comparable price changes from a control sample. The data includes a calculation of percentage price changes for various time intervals and compare that information to the respective control sample. Raw percentage price change data as well as percentage price change data normalized for prevailing market

[5] *See* Securities Exchange Act Release No. 68888 (February 8, 2013), 78 FR 10668 (February 14, 2013) (SR–CBOE–2012–120) (the ''SPXPM Approval Order''). Pursuant to Securities Exchange Act Release No. 80060 (February 17, 2017), 82 FR 11673 (February 24, 2017) (SR–CBOE–2016–091), the Exchange moved third-Friday P.M.-settled options into the S&P 500 Index options class, and as a result, the trading symbol for P.M.-settled S&P 500 Index options that have standard third Friday-of-the-month expirations changed from ''SPXPM'' to ''SPXW.'' This change went into effect on May 1, 2017, pursuant to Cboe Options Regulatory Circular RG17–054.

[6] *See* Securities Exchange Act Release No. 70087 (July 31, 2013), 78 FR 47809 (August 6, 2013) (SR–CBOE–2013–055) (the ''P.M.-settled XSP Approval Order'').

[7] For more information on the Pilot Products or the Pilot Program, *see* the SPXPM Approval Order and the P.M.-settled XSP Approval Order.

[8] *See* Securities Exchange Act Release Nos. 71424 (January 28, 2014), 79 FR 6249 (February 3, 2014) (SR–CBOE–2014–004); 73338 (October 10, 2014), 79 FR 62502 (October 17, 2014) (SR–CBOE–2014–076); 77573 (April 8, 2016), 81 FR 22148 (April 14, 2016) (SR–CBOE–2016–036); 80386 (April 6, 2017), 82 FR 17704 (April 12, 2017) (SR–CBOE–2017–025); 83166 (May 3, 2018), 83 FR 21324 (May 9, 2018) (SR–CBOE–2018–036); and 84535 (November 5, 2018), 83 FR 56129 (November 9, 2018) (SR–CBOE–2018–069).

[9] 5 U.S.C. 552.

volatility, as measured by the Cboe Volatility Index (VIX), is provided; and

(2) a calculation of share volume for a sample set of the component securities representing an upper limit on share trading that could be attributable to expiring in-the-money series. The data includes a comparison of the calculated share volume for securities in the sample set to the average daily trading volumes of those securities over a sample period.

The minimum open interest parameters, control sample, time intervals, method for randomly selecting the component securities, and sample periods are determined by the Exchange and the Commission. In proposing to extend the Pilot Program, the Exchange will continue to abide by the reporting requirements described herein, as well as in the SPXPM Approval Order and the P.M.-settled XSP Approval Order.[10] Additionally, the Exchange will provide the Commission with any additional data or analyses the Commission requests because it deems such data or analyses necessary to determine whether the Pilot Program is consistent with the Exchange Act. The Exchange is in the process of making public on its website data and analyses previously submitted to the Commission under the Pilot Program, and will make public any data and analyses it submits to the Commission under the Pilot Program in the future.

The Exchange proposes the extension of the Pilot Program in order to continue to give the Commission more time to consider the impact of the Pilot Program. To this point, Cboe Options believes that the Pilot Program has been well-received by its Trading Permit Holders and the investing public, and the Exchange would like to continue to provide investors with the ability to trade SPXPM and P.M.-settled XSP options. All terms regarding the trading of the Pilot Products shall continue to operate as described in the SPXPM Approval Order and the P.M.-settled XSP Approval Order. The Exchange merely proposes herein to extend the term of the Pilot Program to November 4, 2019.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[11] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[12] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[13] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that the proposed extension of the Pilot Program will continue to provide greater opportunities for investors. Further, the Exchange believes that it has not experienced any adverse effects or meaningful regulatory concerns from the operation of the Pilot Program. As such, the Exchange believes that the extension of the Pilot Program does not raise any unique or prohibitive regulatory concerns. Also, the Exchange believes that such trading has not, and will not, adversely impact fair and orderly markets on Expiration Fridays for the underlying stocks comprising the S&P 500 index. The extension of the Pilot Program will continue to provide investors with the opportunity to trade the desirable products of SPXPM and P.M.-settled XSP, while also providing the Commission further opportunity to observe such trading of the Pilot Products.

B. Self-Regulatory Organization's Statement on Burden on Competition

Cboe Options does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe the continuation of the Pilot Program will impose any unnecessary or inappropriate burden on intramarket competition because it will continue to apply equally to all Cboe Options market participants, and the Pilot Products will be available to all Cboe Options market participants. The Exchange believes there is sufficient investor interest and demand in the Pilot Program to warrant its extension. The Exchange believes that, for the period that the Pilot Program has been in operation, it has provided investors with desirable products with which to trade. Furthermore, the Exchange believes that it has not experienced any adverse market effects or regulatory concerns with respect to the Pilot Program. The Exchange further does not believe that the proposed extension of the Pilot Program will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because it only applies to trading on Cboe Options. To the extent that the continued trading of the Pilot Products may make Cboe Options a more attractive marketplace to market participants at other exchanges, such market participants may elect to become Cboe Options market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[14] and Rule 19b–4(f)(6)(iii) thereunder.[15]

The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that waiver of the 30-day operative delay will allow

[10] Pursuant to Securities Exchange Act Release No. 75914 (September 14, 2015), 80 FR 56522 (September 18, 2015) (SR–CBOE–2015–079), the Exchange added SPXPM and P.M.-settled XSP options to the list of products approved for trading during Extended Trading Hours (''ETH''). The Exchange will also include the applicable information regarding SPXPM and P.M.-settled XSP options that trade during ETH in its annual and interim reports.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] *Id.*

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f)(6)(iii). As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

it to extend the Pilot Program prior to its expiration on May 6, 2019, and maintain the status quo, thereby reducing market disruption. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, as it will allow the Pilot Program to continue uninterrupted, thereby avoiding investor confusion that could result from a temporary interruption in the Pilot Program. For this reason, the Commission designates the proposed rule change to be operative upon filing.[16]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2019–023 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2019–023. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2019–023, and should be submitted on or before May 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Jill M. Peterson,

Assistant Secretary.

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[16] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85689; File No. SR–CboeBZX–2019–028]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Extend the Pilot Program Related to BZX Rule 11.18, Trading Halts Due to Extraordinary Market Volatility, to the Close of Business on October 18, 2019

April 18, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 12, 2019, Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (''BZX'' or the ''Exchange'') is filing with the Securities and Exchange Commission (the ''Commission'') a proposed rule change to extend the pilot program related to BZX Rule 11.18, Trading Halts Due to Extraordinary Market Volatility, to the close of business on October 18, 2019.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

BZX Rules 11.18(a) through (d), (f) and (g) describe the methodology for determining when to halt trading in all stocks due to extraordinary market volatility, *i.e.,* market-wide circuit breakers. The market-wide circuit breaker mechanism was approved by the Commission to operate on a pilot basis, the term of which is to coincide with the pilot period for the Plan to Address Extraordinary Market Volatility Pursuant to Rule 608 of Regulation NMS (the ''LULD Plan'' or ''Plan''),[5] including any extensions to the pilot period for the Plan. The Commission published an amendment to the LULD Plan for it to operate on a permanent, rather than

[5] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012) (the ''Limit Up-Limit Down Release'').

pilot, basis on December 18, 2018,[6] and the Commission approved that amendment on April 11, 2019.[7]

Market-wide circuit breakers provide an important, automatic mechanism that is invoked to promote stability and investor confidence during a period of significant stress when securities markets experience extreme broad-based declines. All U.S. equities exchanges have similar rules related to market-wide circuit breakers, which are designed to slow the effects of extreme price movement through coordinated trading halts across securities markets when severe price declines reach levels that may exhaust market liquidity. Market-wide circuit breakers provide for trading halts in all equities markets during a severe market decline as measured by a single-day decline in the S&P 500 Index.

Pursuant to BZX Rule 11.18, a market-wide trading halt will be triggered if the S&P 500 Index declines in price by specified percentages from the prior day's closing price of that index. Currently, the triggers are set at three circuit breaker thresholds: 7% (Level 1), 13% (Level 2) and 20% (Level 3). A market decline that triggers a Level 1 or Level 2 circuit breaker after 9:30 a.m. ET and before 3:25 p.m. ET would halt market-wide trading for 15 minutes, while a similar market decline at or after 3:25 p.m. ET would not halt market-wide trading. A market decline that triggers a Level 3 circuit breaker, at any time during the trading day, would halt market-wide trading for the remainder of the trading day. The Exchange proposes to amend BZX Rule 11.18 to untie the market-wide circuit breaker pilot program's effectiveness from that of the LULD Plan and to extend the pilot's effectiveness to the close of business on October 18, 2019.

In addition, the Exchange proposes to amend BZX Rule 11.18 such that the pilot only applies to the provisions of paragraphs (a) through (d), (f) and (g) of BZX Rule 11.18—*i.e.,* the provisions related to the market-wide circuit breaker mechanism, and not paragraph (e), which discusses provisions implementing the LULD Plan.[8] The Exchange is required by the LULD Plan to establish, maintain, and enforce written policies and procedures that are reasonably designed to comply with the limit up-limit down and trading pause requirements specified in the Plan. BZX Rule 11.18(e) states that the Exchange is a Participant in the LULD Plan, and requires that members comply with the provisions of the Plan. Furthermore, BZX Rule 11.18(e) describes order handling performed by the Exchange to maintain compliance with the LULD Plan. Specifically, the rule: (1) Provides that the System shall not display or execute buy (sell) interest above (below) the Upper (Lower) Price Bands, unless such interest is specifically exempted under the Plan; (2) describes how the System re-prices and/or cancels buy (sell) interest that is priced or could be executed above (below) the Upper (Lower) Price Band; (3) confirms that the Exchange may declare a Trading Pause during a Straddle State; and (4) addresses how the Exchange would re-open a security following a Trading Pause. With the approval of the LULD Plan to operate on a permanent basis, the Exchange believes that the provisions of BZX Rule 11.18(e) should similarly be permanent, thus ensuring continued compliance with the Plan.

The Exchange intends to file a separate proposed rule change with the Commission to operate the provisions of paragraphs (a) through (d), (f) and (g) of BZX Rule 11.18 on a permanent, rather than pilot, basis. Extending the effectiveness of such provisions to the close of business on October 18, 2019 should provide the Commission adequate time to consider whether to approve the Exchange's separate proposal to operate the market-wide circuit breaker mechanism on a permanent basis.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the requirements of Section 6(b) of the Act,[9] in general, and Section 6(b)(5) of the Act,[10] in particular, in that it is designed to remove impediments to and perfect the mechanism of a free and open market and a national market system, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest and not to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed rule change promotes just and equitable principles of trade in that it promotes transparency and uniformity across markets concerning when and how to halt trading in all stocks as a result of extraordinary market volatility. The Exchange believes that extending the market-wide circuit breaker pilot program for an additional six months would ensure the continued, uninterrupted operation of a consistent mechanism to halt trading across the U.S. markets while the Commission considers whether to approve the pilot program on a permanent basis. The proposed rule change would thus promote fair and orderly markets and the protection of investors and the public interest. Based on the foregoing, the Exchange believes the benefits to market participants from the market-wide circuit breaker mechanism should continue on a pilot basis while the Commission considers whether to permanently approve those rules.

The Exchange also believes that it is consistent with the public interest and the protection of investors to make permanent the order handling provisions of BZX Rule 11.18. Today, like the market-wide circuit breaker rules, those rules are operated under a pilot that coincides with the pilot period for the LULD Plan. Unlike the market-wide circuit breaker rules, however, these rules directly implement the requirements of the LULD Plan, including by implementing order handling that is consistent with the requirements of the Plan. As such, the Exchange believes that it is appropriate to make these rules permanent now that the Plan is no longer operating on a pilot basis. Making these rules permanent would ensure continued compliance by the Exchange and its members with the requirements of the LULD Plan as the Plan transitions to permanent status.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule change implicates any competitive issues because the proposal would ensure the continued, uninterrupted operation of a consistent mechanism to halt trading across the U.S. markets while the Commission considers whether to permanently approve the market-wide circuit breaker mechanism under BZX Rule 11.18. The Exchange believes that FINRA and other national securities exchange will also file similar proposals to extend their respective market-wide circuit breaker pilot programs with the Commission so that the market-wide circuit breaker mechanism may continue uninterrupted while the Commission considers whether to approve its operation on a

[6] *See* Securities Exchange Act Release No. 84843 (December 18, 2018), 83 FR 66464 (December 26, 2018) (Amendment No. 18 Proposing Release).

[7] *See* Securities Exchange Act Release No. 85623 (April 11, 2018) (**Federal Register** publication pending) (Amendment No. 18 Approval Order).

[8] Paragraph (e) of BZX Rule 11.18, which is being made permanent, is subject to a pilot coterminous with the LULD Plan today.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

permanent basis. Furthermore, the proposed rule change would ensure continued compliance with the requirements of the LULD Plan as it becomes permanent, which the Exchange believes would not have a significant impact on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No comments were solicited or received on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [11] and Rule 19b–4(f)(6) [12] thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) [13] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[14] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the Exchange may implement the proposed rule change immediately. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because the Commission approved making the Plan pilot permanent on April 11, 2019, and therefore the Exchange's proposed changes to its rules reflecting that the Plan is now permanent should go into effect immediately. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposed rule change to be operative upon filing with the Commission.[15]

[11] 15 U.S.C. 78s(b)(3)(A). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Commission has waived this requirement.

[12] 17 CFR 240.19b–4(f)(6).

[13] 17 CFR 240.19b–4(f)(6).

[14] 17 CFR 240.19b–4(f)(6)(iii).

[15] For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov. Please include File Number SR–CboeBZX–2019–028 on the subject line.*

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeBZX–2019–028. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeBZX–2019–028 and should be submitted on or before May 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–08207 Filed 4–23–19; 8:45 am]

BILLING CODE 8011–01–P

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85691; File No. SR–BX–2019–002]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing of Proposed Rule Change To Reassign Certain Investigation and Enforcement Functions Under the Exchange's Authority and Supervision

April 18, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 5, 2019, Nasdaq BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to assume operational responsibility for certain investigation and enforcement functions currently performed by the Financial Industry Regulatory Authority (''FINRA'') under the Exchange's authority and supervision. BX Rule 0150 requires Commission approval for this transfer of operational responsibility to BX. BX anticipates a phased transition, whereby BX would assume increasing responsibility throughout 2019 and into 2020 for investigation and enforcement activities

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

for certain conduct occurring on the BX market.

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqbx.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Section 6 of the Act requires that national securities exchanges enforce their members' compliance with federal securities laws and rules as well as the exchanges' own rules.[3] As a self-regulatory organization (''SRO''), BX must have a comprehensive regulatory program that includes investigation and prosecution of suspicious activity. Since its acquisition by The NASDAQ OMX Group, Inc., BX has contracted with FINRA through various regulatory services agreements (''RSAs'') to perform certain of these regulatory functions on its behalf. However, as the Commission has made clear with respect to BX's affiliate, The Nasdaq Stock Market LLC (''Nasdaq''), ''the Nasdaq Exchange bears the responsibility for self-regulatory conduct and primary liability for self-regulatory failures, not the SRO retained to perform regulatory functions on the Exchange's behalf.'' [4]

Notwithstanding its use of FINRA, the Exchange has also retained operational responsibility for a number of regulatory functions, including real-time surveillance, qualification of companies listed on Nasdaq and most surveillance related to its affiliated options markets. Historically, BX retained operational responsibility in areas where BX's expertise regarding its own markets, technology and listed companies enhanced regulation. In recognition of this, on September 30, 2013, the Commission approved BX's proposal to reallocate operational responsibility from FINRA to BX for certain equities surveillance patterns and related review functions, focused on: (1) Manipulation patterns that monitor solely BX activity; and (2) monitoring of compliance by member firms with elements of the Commission's Regulation M and Nasdaq Rule 4619 compliance.[5]

Building on BX's experience and expertise, this proposal reflects a natural evolution of BX's proven model to assume and retain operational responsibility in areas where its in-depth knowledge of its markets and members enhances market regulation. For the reasons outlined below, BX now seeks Commission approval to reallocate operational responsibility from FINRA to the Exchange's Regulation Department [6] for certain investigation and enforcement activity, namely:

- Investigation and enforcement responsibilities for conduct occurring on The BX Options Market,[7] and
- Investigation and enforcement responsibilities for conduct occurring on BX's equity market only, *i.e.,* not also on non-Nasdaq equities markets.[8]

Currently, under RSAs, FINRA is responsible for, among other things, the investigation of matters referred from Nasdaq MarketWatch and the Phlx Market Surveillance department.[9] FINRA is also responsible for providing services related to BX's formal disciplinary process, including the issuance of Wells Notices, Cautionary Action Letters, Complaints, and settlement documents.

BX now proposes to perform the functions described in the bullet points above and is seeking Commission approval to do so. BX believes that its expertise in its own market structure coupled with its expertise in surveillance activities will enable it to conduct investigation and enforcement responsibilities for the Exchange effectively, efficiently and with immediacy. In addition, this proposal represents an incremental reallocation of operational responsibility because Nasdaq Regulation Staff currently performs investigative and enforcement work on behalf of Phlx, ISE, GEMX, and MRX, providing it with relevant experience to perform these functions for the Exchange as well.[10] Most recently, Phlx filed for immediate effectiveness amendments to the Phlx's rules that set forth an investigatory and disciplinary process identical in all material respects to the investigatory and disciplinary processes of Nasdaq and BX.[11] The amendments also had the effect of granting Phlx's Regulation Department investigation and enforcement authority.[12] BX now seeks Commission approval to exercise this same authority for conduct on the Exchange that its Staff already exercises for Phlx, ISE, GEMX, and MRX.[13]

Notwithstanding this proposal, FINRA will continue to perform certain functions, including, among other things: (1) The investigation and enforcement of conduct occurring on the BX equity market that also relates to

[3] 15 U.S.C. 78(f).

[4] Securities Exchange Act Release No. 53128 (January 13, 2006), 71 FR 3550, 3556 (January 23, 2006).

[5] Securities Exchange Act Release No. 70568 (September 30, 2013), 78 FR 62884 (October 22, 2013) (SR–BX–2013–047).

[6] Under BX Rule 9120(t), the Exchange's Regulation Department includes the Exchange's Enforcement Department. The Exchange notes that the Staff that comprises the Exchange's Regulation Department is the same that comprises the Nasdaq Regulation Department.

[7] As appropriate, the Exchange's Regulation Department will coordinate with other SROs to the extent it is investigating activity occurring on Non-Nasdaq options markets to ensure no regulatory duplication occurs.

[8] With respect to the operational responsibilities described in both bullet points, Nasdaq Regulation Staff currently performs these functions for the Nasdaq PHLX LLC (''Phlx''), Nasdaq ISE, LLC (''ISE''), Nasdaq GEMX, LLC (''GEMX''), and Nasdaq MRX, LLC (''MRX'') because there is no comparable rule to Rule 0150 on those markets.

[9] The Phlx Market Surveillance department performs surveillance work for all of Nasdaq's options markets (*i.e.,* Nasdaq Options, BX Options, Phlx Options, ISE, GEMX, and MRX).

[10] As noted above, because BX is an affiliate of Nasdaq, the Staff that comprises the Exchange's Regulation Department is the same that comprises the Nasdaq Regulation Department.

[11] *See* Securities Exchange Act Release No. 82143 (November 22, 2017), 82 FR 56672 (November 29, 2017) (SR–Phlx–2017–92) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt Investigatory and Disciplinary Processes Substantially Similar to Nasdaq BX, Inc. and The Nasdaq Stock Market LLC for Phlx, which, among other things, similarly enabled Phlx's Regulation Department to perform these functions).

[12] *See* Securities Exchange Act Release No. 82143 (November 22, 2017), 82 FR 56672 (November 29, 2017) (SR-Phlx-2017–92) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt Investigatory and Disciplinary Processes Substantially Similar to Nasdaq BX, Inc. and The Nasdaq Stock Market LLC for Phlx, which, among other things, similarly enabled Phlx's Regulation Department to perform these functions).

[13] In a separate filing Nasdaq also proposed to reallocate operational responsibility from FINRA to Nasdaq Regulation for investigation and enforcement responsibilities for conduct occurring on The Nasdaq Options Market and investigation and enforcement responsibilities for conduct occurring on the Nasdaq equity market only, *i.e.,* not also on non-Nasdaq equities markets. *See* SR–Nasdaq–2019–007. The Commission approved that rule filing on April 3, 2019. *See* Securities and Exchange Act Release No. 34–85505 (Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 2, to Reassign Certain Investigation and Enforcement Functions Under the Exchange's Authority and Supervision.)

cross market activity on non-Nasdaq exchanges; (2) the handling of contested disciplinary proceedings arising out of BX Regulation-led investigation and enforcement activities; [14] and (3) matters covered by agreements to allocate regulatory responsibility under Rule 17d–2 of the Act. As with all investigation and enforcement work, all tasks delegated to FINRA are subject to BX's supervision and ultimate responsibility.

BX Regulation has instituted the requisite infrastructure to accommodate the internalization of investigative and enforcement work on behalf of the Exchange. Specifically, BX created a new investigation and enforcement group to perform the functions covered by this proposal, which included hiring additional staff. BX is also leveraging its existing staff of experienced analysts, lawyers, programmers, and market structure experts to assist, where necessary, with performing the new functions covered by this proposal. In addition, BX Regulation has developed comprehensive plans covering the transition and has met regularly for more than one year to ensure a smooth transition of the work and prevent any gaps in regulatory coverage. Finally, BX filed for immediate effectiveness amendments to its rules that aligned its existing investigatory and disciplinary processes with the investigatory and disciplinary processes of Phlx. The amendments also granted the Exchange's Enforcement Department with the investigative and enforcement authority that it now seeks approval to exercise.[15]

BX anticipates a phased transition of investigative and enforcement responsibility, whereby BX would assume increasing investigation and enforcement responsibility throughout 2019 and into 2020 for the conduct occurring on the Exchange.[16] BX also anticipates transitioning certain matters currently pending with FINRA to the Exchange's Enforcement Department if the Exchange's Regulation Department believes doing so is consistent with ensuring prompt resolution of regulatory matters.

BX Rule 0150 requires that BX obtain Commission approval if regulatory functions subject to RSAs in effect at the time BX executed the agreement in 2008 are no longer performed by FINRA or an affiliate thereof, or by another independent self-regulatory organization. For the reasons stated above, BX believes that the reassignment of the specified investigation and enforcement responsibility will further its regulatory program and benefit investors and the markets. Commission approval of the proposal would allow BX to better leverage its surveillance, investigation, and enforcement teams; to deliver increased efficiencies in the regulation of its market; and to act promptly and provide more effective regulation.

In addition, BX notes that its proposal is consistent with, but more limited than, investigation and enforcement work performed by other national securities exchanges. For example, in 2015, the SEC approved the New York Stock Exchange's (''NYSE'') application whereby NYSE amended certain of its disciplinary rules to facilitate the reintegration of certain market surveillance, investigation and enforcement functions performed on behalf of NYSE by FINRA.[17] Unlike NYSE, however, BX will also continue to rely on FINRA to prosecute contested matters before a Hearing Panel.[18]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[19] in general, and furthers the objectives of Section 6(b)(5) of the Act,[20] in particular in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. In addition, the Exchange believes that the proposal furthers the objectives of Section 6(b)(7) of the Act,[21] in particular, in that these changes will continue to provide for fair procedures for the disciplining of members and persons associated with members, the denial of membership to any person seeking membership therein, the barring of any person from becoming associated with a member thereof, and the prohibition or limitation by the Exchange of any person with respect to access to services offered by the Exchange or a member thereof.

The Exchange believes that this proposal is in keeping with those principles because it leverages BX's extensive operational experience and expertise in regulating its markets and marries BX's surveillance capabilities with its surveillance, investigation and enforcement staff, thereby increasing effectiveness and enabling prompt action. BX believes that it can achieve these important objectives because it is uniquely positioned to understand conduct on its own markets and take timely action when appropriate to investigate potential violations and enforce the rules to punish and deter misconduct, hold bad actors accountable, and protect investors and market integrity. In this regard, the Exchange's surveillance, investigative and enforcement teams work together to identify and review potentially violative conduct. This results in more effective regulation because it facilitates timely and more efficient action. Indeed, the underlying driving force for the current proposal is BX's belief that it can conduct this regulatory work more effectively and efficiently given its technology, structure and in-depth knowledge of its markets and members. For these reasons, BX believes it can conduct investigative and enforcement functions specified above in a thorough and timely manner, thereby promoting the fair and orderly operation of the markets and serving the interests of market participants and investors. In so doing, BX will fulfill the Commission's mandate that BX's affiliate, Nasdaq, bear responsibility for self-regulatory conduct.[22]

BX will continue to refer certain potentially violative conduct to FINRA

[14] For example, pursuant to Rule 9216, if at the conclusion of a BX Regulation-led investigation, BX Regulation has reason to believe that a violation occurred but the Respondent disputes the violation and therefore does not execute an Acceptance, Waiver, and Consent (''AWC'') letter, or if the Respondent executes the AWC letter but the Exchange Review Council, Review Subcommittee or FINRA's Office of Disciplinary Affairs does not accept the executed letter, the Exchange may decide to pursue formal disciplinary proceedings. In such a case, the Exchange would refer the matter to FINRA to handle the formal disciplinary proceedings on its behalf. FINRA's Office of Hearing Officers will continue to be responsible for the administration of the hearing process.

[15] Securities Exchange Act Release No. 84354 (October 3, 2018), 83 FR 50723 (October 9, 2018) (SR–BX–2018–042).

[16] The Exchange notes that the investigatory and disciplinary processes and related rules applicable to its Members that FINRA currently follows on the Exchange's behalf (*i.e.,* the Series 8000 and 9000 Rules) will remain the same.

[17] *See* Securities Exchange Act Release No. 75721 (August 18, 2015), 80 FR 51334 (August 24, 2015) and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1, 3 and 5, Amending Exchange Disciplinary Rules to Facilitate the Reintegration of Certain Regulatory Functions from Financial Industry Regulatory Authority, Inc., Securities Exchange Act Release No. 76436 (November 13, 2015), 80 FR 72460 (November 19, 2015) (SR–NYSE–2015–35).

[18] *See* BX Rule 9120(q) (''The term ''Hearing Panel'' means an Adjudicator that is constituted under Rule 9231 to conduct a disciplinary proceeding governed by the Rule 9200 Series, that is constituted under the Rule 9520 Series or the Rule 9550 Series to conduct a proceeding, or that is constituted under the Rule 9800 Series to conduct a temporary cease and desist proceeding.''). *See also supra* note 14.

[19] 15 U.S.C. 78f(b).

[20] 15 U.S.C. 78f(b)(5).

[21] 15 U.S.C. 78f(b)(7).

[22] *See supra* note 4.

for further review, including matters covered by agreements to allocate regulatory responsibility under Rule 17d–2 of the Act. Moreover, FINRA will continue to have responsibility for, among other things, the investigation and enforcement of conduct occurring on the BX equity market that also occurs on non-Nasdaq exchanges, as well as the handling of contested disciplinary proceedings arising out of BX Regulation-led investigation and enforcement activities.[23] All referrals to FINRA remain subject to BX's supervision and ultimate responsibility.

BX also believes that the proposal is consistent with the Act because, as the Commission has made clear, BX's affiliate, Nasdaq, bears the ultimate responsibility for self-regulatory conduct and primary liability for self-regulatory failures.[24] In addition, BX notes that its proposal is consistent with, but more limited than, investigation and enforcement work performed by NYSE. As noted above, the SEC approved NYSE's application to amend certain of its disciplinary rules to facilitate the reintegration of certain market surveillance, investigation and enforcement functions performed on behalf of NYSE by FINRA.[25] BX believes it would therefore be consistent with the Act for BX to perform more limited investigation and enforcement work than NYSE.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but rather to enable the Exchange to directly investigate and initiate disciplinary actions for the specified conduct discussed above following the integration of certain regulatory functions from FINRA.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2019–002 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2019–002. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2019–002 and should be submitted on or before May 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–08209 Filed 4–23–19; 8:45 am]

BILLING CODE 8011–01–P

[23] *See supra* note 14.

[24] *See supra* note 4.

[25] *See supra* note 17.

[26] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85685; File No. SR–FINRA–2019–013]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to the Regulation NMS Plan To Address Extraordinary Market Volatility

April 18, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 12, 2019, Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as constituting a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4 under the Act,[3] which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to make permanent FINRA Rules 6190 (Compliance with Regulation NMS Plan to Address Extraordinary Market Volatility) and 6121.01 (Resumption of Trading in Securities Subject to the Regulation NMS Plan to Address Extraordinary Market Volatility) in light of the permanent approval of the Regulation NMS Plan to Address

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

Extraordinary Market Volatility (''Plan'' or ''LULD Plan'').

The text of the proposed rule change is available on FINRA's website at *http://www.finra.org,* at the principal office of FINRA and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

FINRA proposes to amend FINRA Rules 6190 and 6121.01, which implement the provisions of the LULD Plan, to reflect that these provisions now operate on a permanent basis, consistent with the approval of the LULD Plan to operate on a permanent basis.[4] FINRA is not proposing any substantive changes to the text of these rules.

Rule 6190 requires members that are trading centers [5] in NMS Stocks to establish, maintain and enforce written policies and procedures that are reasonably designed to comply with the requirements of the Plan and specifically to prevent: (1) The execution of trades at prices that are below the lower price band or above the upper price band for an NMS Stock, except as permitted under the Plan; (2) the display of offers below the lower price band and bids above the upper price band for an NMS Stock; and (3) the execution of trades in an NMS Stock during a trading pause; however, bids and offers may be displayed during a Trading Pause, as permitted under the Plan.[6] FINRA Rule 6121.01 addresses the circumstances under which a member may resume trading otherwise than on an exchange following a Trading Pause or Regulatory Halt in an NMS Stock that is subject to the Plan.[7]

Rules 6190 and 6121.01 both currently contain provisions stating that these rules will be in effect for a pilot period to coincide with the pilot period for the LULD Plan (including any extensions to the pilot period for the Plan). Because the LULD Plan now operates on a permanent basis, the proposed rule change is necessary to delete the pilot period language from Rules 6190 and 6121.01 to make clear that these rules also now operate on a permanent basis, consistent with the Plan.

FINRA has filed the proposed rule change for immediate effectiveness and has requested that the SEC waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing, so that the operative date of the proposed rule change will be the same as the date of SEC approval of the Eighteenth Amendment to the Plan.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[8] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade and, in general, to protect investors and the public interest. The proposed rule change also is designed to support the principles of Section 11A(a)(1) of the Act [9] in that it seeks to assure fair competition among brokers and dealers and among exchange markets. FINRA believes that the proposed rule change meets these requirements in that it facilitates compliance with the Plan, which has been approved and found by the Commission to be reasonably designed to prevent potentially harmful price volatility in NMS Stocks. Accordingly, FINRA believes that the proposed rules will further the goals of investor protection and fair and orderly markets.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is necessary to reflect that the LULD Plan no longer operates as a pilot and has been approved to operate on a permanent basis by the Commission; likewise, Rules 6190 and 6121.01, which implement the requirements of the Plan, must be amended to operate on a permanent basis.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [10] and Rule 19b–4(f)(6) thereunder.[11]

A proposed rule change filed under Rule 19b–4(f)(6) [12] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[13] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that FINRA may implement the proposed rule change immediately. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because the Commission approved making the Plan pilot permanent on April 11, 2019, and therefore FINRA's proposed changes to its rules reflecting

[4] *See* Securities Exchange Act Release No. 83044 [sic] (April 11, 2019) (File No. 4–631) (Order Approving Eighteenth Amendment); *see also* Securities Exchange Act Release No. 84843 (December 18, 2018), 83 FR 66464 (December 26, 2018) (File No. 4–631) (Notice of Filing of Eighteenth Amendment).

[5] Unless otherwise specified, the terms used herein have the same meaning as set forth in the Plan.

[6] *See* Securities Exchange Act Release No. 68985 (February 25, 2013), 78 FR 13922 (March 1, 2013) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2013–016).

[7] *See* Securities Exchange Act Release No. 81824 (October 5, 2017), 82 FR 47586 (October 12, 2017) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2017–031).

[8] 15 U.S.C. 78*o*–3(b)(6).

[9] 15 U.S.C. 78k–1(a)(1).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Commission has waived the pre-filing requirement.

[12] 17 CFR 240.19b–4(f)(6).

[13] 17 CFR 240.19b–4(f)(6)(iii).

that the Plan is now permanent should go into effect immediately. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposed rule change to be operative upon filing with the Commission.[14]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2019–013 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2019–013. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2019–013 and should be submitted on or before May 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–08203 Filed 4–23–19; 8:45 am]

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[14] For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85687; File No. SR–NASDAQ–2019–017]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing of Proposed Rule Change To Adopt Additional Requirements for Listings in Connection With an Offering Under Regulation A of the Securities Act

April 18, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 5, 2019, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to adopt an additional listing requirement for companies listing in connection with an offering under Regulation A [3] under the Securities Act of 1933 (''Securities Act'').[4]

The text of the proposed rule change is set forth below. Proposed new language is in italics.

* * * * *

The Nasdaq Stock Market Rules

* * * * *

5210. Prerequisites for Applying to List on The Nasdaq Stock Market

All Companies applying to list on The Nasdaq Stock Market must meet the following prerequisites:

(a)–(i) No change.

(j) Regulation A Offerings

Any Company listing on Nasdaq in connection with an offering under Regulation A of the Securities Act of 1933 must, at the time of approval of its initial listing application, have a minimum operating history of two years.

* * * * *

The text of the proposed rule change is available on the Exchange's website at *http://nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to adopt a new initial listing requirement that would require a company applying to list on the Exchange in connection with an offering under Regulation A of the Securities Act to have a minimum operating history of two years at the time of approval of its initial listing application. Regulation A was amended in 2015 to implement provisions of the Jumpstart Our Business Startups Act [5] and to reflect the desire of Congress and

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 230.251–230.263.

[4] 15 U.S.C. 77a *et seq.*

[5] Securities Exchange Act Release No. 74578 (March 25, 2015), 80 FR 21805 (April 20, 2015).

the SEC to facilitate smaller companies' access to capital and provide investors with more investment choices.[6] As amended, Regulation A provides an exemption from registration under the Securities Act for offerings up to $50 million, for ''Tier 2'' offerings, and permits a company to sell securities to ''non-accredited'', or retail, investors.[7] A company offering securities under Tier 2 may register its securities under the Exchange Act concurrently with the qualification of its Regulation A offering statement and list those securities on a national securities exchange, such as Nasdaq, if it meets applicable listing standards.[8]

To rely on the exemption under Regulation A, a company must file a Form 1–A with the SEC along with an offering statement, financial statements and other exhibits. The offering statement is reviewed and qualified by the SEC but requires less burdensome accounting and disclosure standards than a traditional initial public offering on Form S–1. For example, a Regulation A company qualifying its offering statement nine months after its most recently completed fiscal year can include balance sheets for its last two fiscal years, with no interim financial statements.[9] In contrast, a company conducting its initial public offering on Form S–1 at that same time would be required to include balance sheets for its last two fiscal years, in the case of emerging growth and smaller reporting companies, or three fiscal years, in the case of all other companies, and interim financial statements dated no later than 134 days prior to effectiveness.[10] As a result, the financial information presented to investors in Regulation A offerings may not be as current as the financial information presented to investors traditional public offerings.

The Exchange has observed problems with certain Regulation A companies.[11] Most significantly, the Exchange believes that companies seeking to list in conjunction with a Regulation A offering are generally less mature companies with less developed business plans than other companies seeking to list. In addition, the Exchange believes that the Regulation A offering process may not adequately prepare companies for the rigors of operating a public company and satisfying the SEC and Exchange's reporting and corporate governance requirements. The Exchange also notes that the financial press,[12] Congress (prior to the adoption of Regulation A)[13] and others[14] have raised concerns about the potential for fraud by companies conducting offerings under Regulation A.

In response to these concerns, Nasdaq staff has adopted heightened review procedures for companies applying to list on the Exchange in connection with an offering under Regulation A. However, the Exchange also believes that additional requirements for listing such companies are appropriate to help ensure that adequate safeguards are in place to better protect investors. Accordingly, Nasdaq proposes to enhance its initial listing standards by adopting a new requirement at Listing Rule 5210(j) that a company listing in connection with an offering under Regulation A must, at the time of approval of its initial listing application, have a minimum operating history of two years. Nasdaq believes that this proposed requirement will help assure that companies have more established business plans and a history of operations upon which investors can rely. In addition, the proposed operating history requirement will help assure that the company has been able to fund the initial phase of its operations. Further, Nasdaq believes that these more seasoned companies are more likely to be ready for the rigors of being a public company, including satisfying the SEC and Exchange's reporting and corporate governance requirements. Nasdaq believes that these are important benefits given the lighter disclosure requirements otherwise associated with a Regulation A offering.[15]

Nasdaq proposes that this change be effective 30 days after approval by the SEC. Nasdaq notes that it had originally solicited comment on a similar proposal in October 2018,[16] which provided companies with notice that Nasdaq was considering adopting a minimum operating history requirement for companies listing in connection with a Regulation A offering. The proposed 30-day delay from approval until operation of the proposed rule will allow companies that have substantially completed the Nasdaq review process, or are near completion of their offering, a short opportunity to complete that offering and list before the new rules become effective.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Exchange Act,[17] in general, and furthers the objectives of Section 6(b)(5) of the Exchange Act,[18] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest; and is not designed to permit unfair discrimination between issuers, because it is reasonably designed to enhance investor protection by imposing an additional requirement on a category of companies that are able to sell securities to non-accredited investors with limited accounting and disclosure requirements.

Nasdaq believes that the addition of an operating history requirement will protect investors and the public interest by helping to assure that a company listing in conjunction with a Regulation

[6] *See, e.g.,* ''SEC Adopts Rules to Facilitate Smaller Companies Access to Capital'' (March 25, 2015), available at *https://www.sec.gov/news/pressrelease/2015-49.html.*

[7] 17 CFR 230.251–230.263.

[8] *See* General Instruction A(a)(2) of Form 8–A for Registration of Certain Classes of Securities pursuant to Section 12(b) or (g) of the Securities Exchange Act of 1934, available at *https://www.sec.gov/about/forms/form8-a.pdf.* A company may apply to list on any of the Nasdaq Global Select Market, Global Market or Capital Market tiers in connection with an offering under Regulation A of the Securities Act.

[9] *See* Part F/S (b)(3)(A) and (c)(1)(i) of Form 1–A Regulation A Offering Statement under the Securities Act of 1933 available at *https://www.sec.gov/about/forms/form1-a.pdf.*

[10] 17 CFR 210.3–12.

[11] *See, e.g.,* Securities and Exchange Commission vs. Longfin Corp., Case No. 18-cv-2977 (DLC) (S.D.N.Y., filed April 4, 2018), available at *https://www.sec.gov/litigation/complaints/2018/comp-pr2018-61.pdf.*

[12] *See, e.g.,* ''Most Mini-IPOs Fail the Market Test'', Barron's (February 13, 2018), available at *https://www.barrons.com/articles/most-mini-ipos-fail-the-market-test-1518526753. See also,* ''Longfin Collapse Puts Focus on Lax IPO Rules'', Wall Street Journal (April 3, 2018), available at *https://www.wsj.com/articles/longfin-collapse-puts-focus-on-lax-ipo-rules-1522788520?mod=cx_picks&cx_navSource=cx_picks&cx_tag=contextual&cx_artPos=5#cxrecs_s.*

[13] *See, e.g.,* H.R. Rep. No. 206, 112th Cong. 1st Sess. at 13 (2011), available at *https://www.congress.gov/congressional-report/112th-congress/house-report/206. See also* Congressional Record Volume 157, Number 166 (Wednesday, Nov. 2, 2011), p. H7231, available at *https://www.congress.gov/congressional-record/2011/11/02/house-section/article/H7229-1.*

[14] *See, e.g.,* Letter from the North American Securities Administrators Association, Inc., to Elizabeth M. Murphy (March 24, 2014), available at *http://www.nasaa.org/wp-content/uploads/2011/07/NASAA-Comment-File-S7-11-13-03242014.pdf.*

[15] Nasdaq has also proposed to revise its initial listing criteria to exclude restricted securities from the Exchange's calculations of a company's publicly held shares, market value of publicly held shares and round lot holders in another filing, and these requirements would also apply to Regulation A companies. *See* Securities Exchange Act Release No. 85503 (April 3, 2019) (SR–NASDAQ–2019–009) (''Notice of Filing of Proposed Rule Change to Revise the Exchange's Initial Listing Standards Related to Liquidity'').

[16] *See https://listingcenter.nasdaq.com/assets/Liquidity_Measures_Comment_Solicitation.pdf.*

[17] 15 U.S.C. 78f(b).

[18] 15 U.S.C. 78f(b)(5).

A offering will be more likely to have a developed business plan upon which investors can rely, was able to successfully fund its initial phase of operations, and will be better prepared to satisfy public company requirements, including reporting and corporate governance requirements.

The Exchange believes that this proposal does not result in unfair discrimination between companies because companies relying on Regulation A are subject to limited accounting and disclosure requirements, which exposes investors, many of which may be non-accredited, to increased risk. The Exchange believes that this proposal will help lower the risk to such investors by helping to assure that a company was able to fund its initial phase of operations, has an established business plan and a history of operations upon which investors can rely and is more likely to be ready for the rigors of being a public company. For the foregoing reasons, the Exchange believes it is not unfair to impose the requirement for a minimum operating history of at least two years only on companies relying on Regulation A and not on companies conducting a traditional initial public offering on Form S–1.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act. All companies seeking to list on the Exchange in connection with an offering under Regulation A would be affected in the same manner by this change. While this is an additional requirement that would not apply to a company that does not rely upon Regulation A, Nasdaq believes that to the extent this distinction places a burden on competition between companies, such burden is necessary and appropriate to enhance investor protection from companies with limited accounting and disclosure requirements in furtherance of the investor protection purposes of the Exchange Act. Moreover, Nasdaq also notes that companies have a choice as to whether or not to rely upon Regulation A and, therefore, can control whether they are subject to the proposed requirement.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

On October 5, 2018, Nasdaq launched a formal comment solicitation on proposals to adopt additional initial listing criteria for companies applying to list on the Exchange in connection with an offering under Regulation A (''2018 Solicitation''), a copy of which is attached hereto as *Exhibit 2.*[19] No comments were received in response to the comment solicitation.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) by order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2019–017 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2019–017. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2019–017, and should be submitted on or before May 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–08205 Filed 4–23–19; 8:45 am]

BILLING CODE 8011–01–P

[19] The Commission notes that Exhibit 2 is attached to the Exchange's Form 19b–4 relating to the proposed rule change and not to this notice.

[20] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15935 and #15936; ALABAMA Disaster Number AL–00096]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of ALABAMA

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of ALABAMA (FEMA–4426–DR), dated 04/17/2019.

Incident: Severe Storms, Straight-Line Winds, Tornadoes, and Flooding.

Incident Period: 02/19/2019 through 03/20/2019.

DATES: Issued on 04/17/2019.

Physical Loan Application Deadline Date: 06/17/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 01/17/2020.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster

Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 04/17/2019, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Cherokee, Colbert, De Kalb, Franklin, Jackson, Lamar, Madison, Marion, Morgan, Winston

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations With Credit Available Elsewhere	2.750
Non-Profit Organizations Without Credit Available Elsewhere	2.750
For Economic Injury:	
Non-Profit Organizations Without Credit Available Elsewhere	2.750

The number assigned to this disaster for physical damage is 15935B and for economic injury is 159360.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2019–08267 Filed 4–23–19; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15939 and #15940; TENNESSEE Disaster Number TN–00108]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of TENNESSEE

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of TENNESSEE (FEMA–4427–DR), dated 04/17/2019.

Incident: Severe Storms, Flooding, Landslides, and Mudslides.

Incident Period: 02/19/2019 through 03/30/2019.

DATES: Issued on 04/17/2019.

Physical Loan Application Deadline Date: 06/17/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 01/17/2020.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 04/17/2019, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties:

Bedford, Bledsoe, Blount, Campbell, Carter, Cheatham, Claiborne, Clay, Cocke, Coffee, Decatur, Dekalb, Dickson, Dyer, Fentress, Gibson, Giles, Grainger, Greene, Hamblen, Hamilton, Hancock, Hardin, Hawkins, Hickman, Houston, Humphreys, Jackson, Jefferson, Johnson, Knox, Lake, Lauderdale, Lewis, Lincoln, Marion, Marshall, Mcnairy, Moore, Morgan, Obion, Overton, Perry, Rhea, Roane, Robertson, Scott, Sequatchie, Sevier, Smith, Tipton, Unicoi, Union, Van Buren, Warren, Wayne.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere	2.750
Non-Profit Organizations Without Credit Available Elsewhere	2.750
For Economic Injury:	
Non-Profit Organizations Without Credit Available Elsewhere	2.750

The number assigned to this disaster for physical damage is 15939B and for economic injury is 159400.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2019–08268 Filed 4–23–19; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice 10747]

Office of the Secretary; Exercise of Authority Under the Immigration and Nationality Act

AGENCY: Office of the Secretary, DOS.

ACTION: Notice of determination.

Authority: 8 U.S.C. 1182(d)(3)(B)(i).

Following consultations with the Secretary of Homeland Security and the Attorney General, I hereby determine, as a matter of discretion in accordance with the authority granted to me by section 212(d)(3)(B)(i) of the Immigration and Nationality Act (INA), 8 U.S.C. 1182(d)(3)(B)(i), as amended, and in light of the foreign policy and national security interests deemed relevant in these consultations, that section 212(a)(3)(B)(vi)(III) of the INA, 8 U.S.C. 1182(a)(3)(B)(vi)(III), shall not apply to any business, organization, or group, whether public or private, solely based on its provision of material support to any foreign government sub-entity that has been designated as a foreign terrorist organization pursuant to the authority of the Secretary of State under section 219 of the INA, or its provision of material support to any foreign government sub-entity that meets the definition set out in section 212(a)(3)(B)(vi)(III) of the INA; except that this exercise of authority shall not apply to any group designated under section 219 of the INA or any group prohibited from benefiting from an exercise of authority under section 212(d)(3)(B)(i) of the INA for having engaged in terrorist activity against the United States or another democratic country, or having purposefully engaged in a pattern or practice of terrorist activity that is directed at civilians. This waiver applies both retroactively and prospectively.

This determination will be applied by appropriate officials of the Department of Homeland Security and U.S. consular officers, as applicable.

This exercise of authority may be revoked in whole or in part as a matter of discretion and without notice at any time, with respect to any and all groups subject to it.

This exercise of authority shall not be construed to prejudice, in any way, the ability of the U.S. government to commence subsequent criminal or civil proceedings in accordance with U.S. law involving any group potentially covered by this exercise of authority or any beneficiary of this exercise of authority (or any other person). This exercise of authority creates no

substantive or procedural right or benefit that is legally enforceable by any party against the United States or its agencies or officers or any other person.

In accordance with section 212(d)(3)(B)(ii) of the INA, 8 U.S.C. 1182(d)(3)(B)(ii), a report on this exercise of authority shall be provided within one week by the U.S. Department of State to the specified congressional committees.

This determination is based on an assessment related to the national security and foreign policy interests of the United States as they apply to the groups generally described herein and shall not have any application with respect to other groups or to other provisions of U.S. law.

Dated: April 15, 2019.

Michael R. Pompeo,

Secretary of State.

[FR Doc. 2019–08255 Filed 4–23–19; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF STATE

[Public Notice 10741]

Updating the State Department's List of Entities and Subentities Associated With Cuba (Cuba Restricted List)

ACTION: Updated publication of list of entities and subentities; notice.

SUMMARY: The Department of State is publishing an update to its List of Restricted Entities and Subentities Associated with Cuba (Cuba Restricted List) with which direct financial transactions are generally prohibited under the Cuban Assets Control Regulations (CACR). This Cuba Restricted List is also considered during review of license applications submitted to the Department of Commerce's Bureau of Industry and Security (BIS) pursuant to the Export Administration Regulations (EAR).

DATES: The Cuba Restricted List is updated as of April 24, 2019.

FOR FURTHER INFORMATION CONTACT: Erica Magallon tel: 202–453–8458; Office of Economic Sanctions Policy and Implementation, tel.: 202–647–7489; Office of the Coordinator for Cuban Affairs, tel.: 202–453–8456, Department of State, Washington, DC 20520.

SUPPLEMENTARY INFORMATION:

Background

On June 16, 2017, the President signed National Security Presidential Memorandum-5 on Strengthening the Policy of the United States Toward Cuba (NSPM–5). As directed by NSPM–5, on November 9, 2017, the Department of the Treasury's Office of Foreign Assets Control (OFAC) published a final rule in the **Federal Register** amending the CACR, 31 CFR part 515, and the Department of Commerce's Bureau of Industry and Security (BIS) published a final rule in the **Federal Register** amending, among other sections, the section of the Export Administration Regulations (EAR) regarding Cuba, 15 CFR 746.2. The regulatory amendment to the CACR added § 515.209, which generally prohibits direct financial transactions with certain entities and subentities identified on the State Department's Cuba Restricted List. The regulatory amendment to 15 CFR 746.2, notes BIS will generally deny applications to export or re-export items for use by entities or subentities identified on the Cuba Restricted List. The State Department is now updating the Cuba Restricted list, as published below and available on the State Department's website (*http://www.state.gov/e/eb/tfs/spi/cuba/cubarestrictedlist/index.htm*).

This update includes five additional subentities. This is the third update to the Cuba Restricted List since it was published November 9, 2017 (82 FR 52089). The first update of 26 additional subentities and five amendments was published November 15, 2018 (see 83 FR 57523), and the second update of five additional subentities was publish March 9, 2019 (see 84 FR 8939). The State Department will continue to update the Cuba Restricted List periodically.

The publication of the updated Cuba Restricted List further implements the directive in paragraph 3(a)(i) of NSPM–5 for the Secretary of State to identify the entities or subentities, as appropriate, that are under the control of, or act for or on behalf of, the Cuban military, intelligence, or security services or personnel, and publish a list of those identified entities and subentities with which direct financial transactions would disproportionately benefit such services or personnel at the expense of the Cuban people or private enterprise in Cuba.

Electronic Availability

This document and additional information concerning the Cuba Restricted List are available from the Department of State's website (*http://www.state.gov/e/eb/tfs/spi/cuba/*).

List of Restricted Entities and Subentities Associated With Cuba as of April 24, 2019

Below is the U.S. Department of State's list of entities and subentities under the control of, or acting for or on behalf of, the Cuban military, intelligence, or security services or personnel with which direct financial transactions would disproportionately benefit such services or personnel at the expense of the Cuban people or private enterprise in Cuba. For information regarding the prohibition on direct financial transactions with these entities, please see 31 CFR 515.209. All entities and subentities were listed effective November 9, 2017, unless otherwise indicated.

* * * *Entities or subentities owned or controlled by another entity or subentity on this list are not treated as restricted unless also specified by name on the list.* * * *

Ministries

MINFAR—Ministerio de las Fuerzas Armadas Revolucionarias
MININT—Ministerio del Interior

Holding Companies

CIMEX—Corporación CIMEX S.A.
Compañía Turística Habaguanex S.A.
GAESA—Grupo de Administración Empresarial S.A.
Gaviota—Grupo de Turismo Gaviota
UIM—Unión de Industria Militar

Hotels in Havana and Old Havana

Aparthotel Montehabana
Gran Hotel Manzana Kempinski
H10 Habana Panorama
Hostal Valencia
Hotel Ambos Mundos
Hotel Armadores de Santander
Hotel Beltrán de Santa Cruz
Hotel Conde de Villanueva
Hotel del Tejadillo
Hotel el Bosque
Hotel el Comendador
Hotel el Mesón de la Flota
Hotel Florida
Hotel Habana 612
Hotel Kohly
Hotel Los Frailes
Hotel Marqués de Prado Ameno
Hotel Palacio del Marqués de San Felipe y Santiago de Bejucal
Hotel Palacio O'Farrill
Hotel Park View
Hotel Raquel
Hotel San Miguel
Hotel Santa Isabel *Effective* April 24, 2019
Hotel Telégrafo
Hotel Terral
Iberostar Grand Packard Hotel *Effective November 15, 2018*
Memories Miramar Havana
Memories Miramar Montehabana
SO/Havana Paseo del Prado *Effective November 15, 2018*

Hotels in Santiago de Cuba

Villa Gaviota Santiago

Hotels in Varadero

Blau Marina Varadero Resort
also Fiesta Americana Punta Varadero *Effective November 15, 2018*
also Fiesta Club Adults Only *Effective March 12, 2019*
Grand Memories Varadero
Hotel El Caney Varadero *Effective* April 24, 2019
Hotel Las Nubes *Effective November 15, 2018*
Hotel Oasis *Effective November 15, 2018*
Iberostar Bella Vista *Effective November 15, 2018*
Iberostar Laguna Azul
Iberostar Playa Alameda
Meliá Marina Varadero
Meliá Marina Varadero Apartamentos *Effective* April 24, 2019
Meliá Peninsula Varadero
Memories Varadero
Naviti Varadero
Ocean Varadero El Patriarca
Ocean Vista Azul
Paradisus Princesa del Mar
Paradisus Varadero
Sol Sirenas Coral

Hotels in Pinar del Rio

Hotel Villa Cabo de San Antonio
Hotel Villa Maria La Gorda y Centro Internacional de Buceo

Hotels in Baracoa

Hostal 1511
Hostal La Habanera
Hostal La Rusa
Hostal Rio Miel
Hotel El Castillo
Hotel Porto Santo
Villa Maguana

Hotels in Cayos de Villa Clara

Angsana Cayo Santa María *Effective November 15, 2018*
Dhawa Cayo Santa María
Golden Tulip Aguas Claras *Effective November 15, 2018*
Hotel Cayo Santa María
Hotel Playa Cayo Santa María
Iberostar Ensenachos
Las Salinas Plana & Spa *Effective November 15, 2018*
La Salina Noreste *Effective November 15, 2018*
La Salina Suroeste *Effective November 15, 2018*
Meliá Buenavista
Meliá Cayo Santa María
Meliá Las Dunas
Memories Azul
Memories Flamenco
Memories Paraíso
Ocean Casa del Mar
Paradisus Los Cayos *Effective November 15, 2018*
Royalton Cayo Santa María
Sercotel Experience Cayo Santa María *Effective November 15, 2018*
Sol Cayo Santa María
Starfish Cayo Santa María *Effective November 15, 2018*
Valentín Perla Blanca *Effective November 15, 2018*
Villa Las Brujas
Warwick Cayo Santa María
also Labranda Cayo Santa María Hotel *Effective November 15, 2018*

Hotels in Holguín

Blau Costa Verde Beach & Resort
also Fiesta Americana Holguín Costa Verde *Effective November 15, 2018*
Hotel Playa Costa Verde
Hotel Playa Pesquero
Memories Holguín
Paradisus Río de Oro Resort & Spa
Playa Costa Verde
Playa Pesquero Premium Service
Sol Rio de Luna y Mares
Villa Cayo Naranjo
Villa Cayo Saetia
Villa Pinares de Mayari

Hotels in Jardines del Rey

Grand Muthu Cayo Guillermo *Effective November 15, 2018*
Hotel Playa Coco Plus
Iberostar Playa Pilar
Meliá Jardines del Rey
Memories Caribe
Pestana Cayo Coco

Hotels in Topes de Collantes

Hostal Los Helechos
Kurhotel Escambray *Effective November 15, 2018*
Los Helechos
Villa Caburni

Tourist Agencies

Crucero del Sol
Gaviota Tours

Marinas

Marina Gaviota Cabo de San Antonio (Pinar del Rio)
Marina Gaviota Cayo Coco (Jardines del Rey)
Marina Gaviota Las Brujas (Cayos de Villa Clara)
Marina Gaviota Puerto Vita (Holguín)
Marina Gaviota Varadero (Varadero)

Stores in Old Havana

Casa del Abanico
Colección Habana
Florería Jardín Wagner
Joyería Coral Negro—Additional locations throughout Cuba
La Casa del Regalo
San Ignacio 415
Soldadito de Plomo
Tienda El Navegante
Tienda Muñecos de Leyenda
Tienda Museo El Reloj Cuervo y Sobrinos

Entities Directly Serving the Defense and Security Sectors

ACERPROT—Agencia de Certificación y Consultoría de Seguridad y Protección Alias Empresa de Certificación de Sistemas de Seguridad y Protección *Effective November 15, 2018*
AGROMIN—Grupo Empresarial Agropecuario del Ministerio del Interior
APCI—Agencia de Protección Contra Incendios
CAHOMA—Empresa Militar Industrial Comandante Ernesto Che Guevara
CASEG—Empresa Militar Industrial Transporte Occidente
CID NAV—Centro de Investigación y Desarrollo Naval
CIDAI—Centro de Investigación y Desarrollo de Armamento de Infantería
CIDAO—Centro de Investigación y Desarrollo del Armamento de Artillería e Instrumentos Ópticos y Ópticos Electrónicos
CORCEL—Empresa Militar Industrial Emilio Barcenas Pier
CUBAGRO—Empresa Comercializadora y Exportadora de Productos Agropecuarios y Agroindustriales
DATYS—Empresa Para El Desarrollo De Aplicaciones, Tecnologías Y Sistemas
DCM TRANS—Centro de Investigación y Desarrollo del Transporte
DEGOR—Empresa Militar Industrial Desembarco Del Granma
DSE—Departamento de Seguridad del Estado
EMIAT—Empresa Importadora Exportadora de Abastecimientos Técnicos
Empresa Militar Industrial Astilleros Astimar
Empresa Militar Industrial Astilleros Centro
Empresa Militar Industrial Yuri Gagarin
ETASE—Empresa de Transporte y Aseguramiento
Ferretería TRASVAL
GELCOM—Centro de Investigación y Desarrollo Grito de Baire
Impresos de Seguridad
MECATRONICS—Centro de Investigación y Desarrollo de Electrónica y Mecánica
NAZCA—Empresa Militar Industrial Granma
OIBS—Organización Integración para el Bienestar Social
PLAMEC—Empresa Militar Industrial Ignacio Agramonte
PNR—Policía Nacional Revolucionaria
PROVARI—Empresa de Producciones Varias
SEPSA—Servicios Especializados de Protección
SERTOD—Servicios de Telecomunicaciones a los Órganos de

la Defensa *Effective November 15, 2018*
SIMPRO—Centro de Investigación y Desarrollo de Simuladores
TECAL—Empresa de Tecnologías Alternativas
TECNOPRO—Empresa Militar Industrial ''G.B. Francisco Cruz Bourzac''
TECNOTEX—Empresa Cubana Exportadora e Importadora de Servicios, Artículos y Productos Técnicos Especializados
TGF—Tropas de Guardafronteras
UAM—Unión Agropecuaria Militar
ULAEX—Unión Latinoamericana de Explosivos
XETID—Empresa de Tecnologías de la Información Para La Defensa
YABO—Empresa Militar Industrial Coronel Francisco Aguiar Rodríguez

Additional Subentities of CIMEX

ADESA/ASAT—Agencia Servicios Aduanales (Customs Services)
Cachito (Beverage Manufacturer)
Contex (Fashion)
Datacimex
ECUSE—Empresa Cubana de Servicios
Inmobiliaria CIMEX (Real Estate)
Inversiones CIMEX
Jupiña (Beverage Manufacturer)
La Maisón (Fashion)
Najita (Beverage Manufacturer)
Publicitaria Imagen (Advertising)
Residencial Tarara S.A. (Real Estate/ Property Rental) *Effective November 15, 2018*
Ron Caney (Rum Production)
Ron Varadero (Rum Production)
Telecable (Satellite Television)
Tropicola
(Beverage Manufacturer)
Zona Especializada de Logística y Comercio (ZELCOM)

Additional Subentities of GAESA

Aerogaviota *Effective* April 24, 2019
Almacenes Universales (AUSA)
ANTEX—Corporación Antillana Exportadora
Compañía Inmobiliaria Aurea S.A. *Effective November 15, 2018*
Dirección Integrada Proyecto Mariel (DIP)
Empresa Inmobiliaria Almest (Real Estate)
GRAFOS (Advertising)
RAFIN S.A. (Financial Services)
Sociedad Mercantin Inmobiliaria Caribe (Real Estate)
TECNOIMPORT
Terminal de Contenedores de la Habana (TCH)
Terminal de Contenedores de Mariel, S.A.
UCM—Unión de Construcciones Militares
Zona Especial de Desarrollo Mariel (ZEDM)
Zona Especial de Desarrollo y Actividades Logísticas (ZEDAL)

Additional Subentities of Gaviota

AT Comercial
Diving Center—Marina Gaviota *Effective* April 24, 2019
Gaviota Hoteles Cuba *Effective March 12, 2019*
Hoteles Habaguanex *Effective March 12, 2019*
Hoteles Playa Gaviota *Effective March 12, 2019*
Manzana de Gomez
Marinas Gaviota Cuba *Effective March 12, 2019*
PhotoService
Plaza La Estrella *Effective November 15, 2018*
Plaza Las Dunas *Effective November 15, 2018*
Plaza Las Morlas *Effective November 15, 2018*
Plaza Las Salinas *Effective November 15, 2018*
Plaza Las Terrazas del Atardecer *Effective November 15, 2018*
Plaza Los Flamencos *Effective November 15, 2018*
Plaza Pesquero *Effective November 15, 2018*
Producciones TRIMAGEN S.A. (Tiendas Trimagen)

Additional Subentities of Habaguanex

Sociedad Mercantil Cubana Inmobiliaria Fenix S.A. (Real Estate)

* * * *Activities in parentheticals are intended to aid in identification, but are only representative. All activities of listed entities and subentities are subject to the applicable prohibitions.* * * *

Dated: April 17, 2019.

Manisha Singh,

Assistant Secretary, Bureau of Economic and Business Affairs, Department of State.

[FR Doc. 2019–08256 Filed 4–23–19; 8:45 am]

BILLING CODE 4710–AE–P

DEPARTMENT OF STATE

[Public Notice 10746]

Office of the Secretary; Exercise of Authority Under the Immigration and Nationality Act

AGENCY: Office of the Secretary, DOS.

ACTION: Notice of determination.

Authority: 8 U.S.C. 1182(d)(3)(B)(i).

Following consultations with the Secretary of Homeland Security and the Attorney General, I hereby determine, as a matter of discretion in accordance with the authority granted to me by section 212(d)(3)(B)(i) of the Immigration and Nationality Act (INA), 8 U.S.C. 1182(d)(3)(B)(i), as amended, and in light of the foreign policy and national security interests deemed relevant in these consultations, that section 212(a)(3)(B)(vi)(III) of the INA, 8 U.S.C. 1182(a)(3)(B)(vi)(III), shall not apply to any ministry, department, agency, division, or other group or sub-group within any foreign government; except that this exercise of authority shall not apply to any group designated under section 219 of the INA or any group prohibited from benefiting from an exercise of authority under section 212(d)(3)(B)(i) of the INA for having engaged in terrorist activity against the United States or another democratic country, or having purposefully engaged in a pattern or practice of terrorist activity that is directed at civilians. This waiver applies both retroactively and prospectively.

This determination will be applied by appropriate officials of the Department of Homeland Security and U.S. consular officers, as applicable.

This exercise of authority may be revoked in whole or in part as a matter of discretion and without notice at any time, with respect to any and all groups subject to it.

This exercise of authority shall not be construed to prejudice, in any way, the ability of the U.S. government to commence subsequent criminal or civil proceedings in accordance with U.S. law involving any group potentially covered by this exercise of authority or any beneficiary of this exercise of authority or any beneficiary of this exercise of authority (or any other person). This exercise of authority creates no substantive or procedural right or benefit that is legally enforceable by any party against the United States or its agencies or officers or any other person.

In accordance with section 212(d)(3)(B)(ii) of the INA, 8 U.S.C. 1182(d)(3)(B)(ii), a report on this exercise of authority shall be provided within one week by the U.S. Department of State to the specified congressional committees.

This determination is based on an assessment related to the national security and foreign policy interests of the United States as they apply to the groups generally described herein and shall not have any application with respect to other groups or to other provisions of U.S. law.

Dated; April 15, 2019.

Michael R. Pompeo,

Secretary of State.

[FR Doc. 2019–08254 Filed 4–23–19; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Availability of Environmental Assessment for Washington, DC to Baltimore Loop Project

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of availability.

SUMMARY: The FHWA is announcing the availability of the Environmental Assessment (Draft) for public review. The Environmental Assessment (Draft) was prepared for the Washington, DC to Baltimore Loop Project, and was submitted by the Maryland Department of Transportation State Highway Administration (MDOT SHA) in conjunction with The Boring Company, a private company. The Environmental Assessment (Draft) was prepared pursuant to the National Environmental Policy Act of 1969 (NEPA). The project is also being reviewed under Section 106 of the National Historic Preservation Act, and a draft Section 106 Programmatic Agreement (PA) has been prepared for the project. Interested parties are invited to comment on both the Environmental Assessment (Draft) and the draft PA.

DATES: Comments on the Environmental Assessment (Draft) and the draft PA must be received on or before June 10, 2019.

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

- *Project Website: https://www.dcbaltimoreloop.com.* Follow the instructions for submitting comments on the website.
- *Mail:* Ms. Donna Buscemi, Maryland Department of Transportation State Highway Administration, 707 N. Calvert Street, MS C–301, Baltimore, MD 21202. Please include ''Washington, DC to Baltimore Loop Project'' in your subject line.

Electronic copies may be downloaded from the Project website and hard copies of the Environmental Assessment (Draft) and the draft PA may also be viewed at the following locations, by appointment only:

- FHWA Maryland Division, George H. Fallon Federal Building, 31 Hopkins Plaza, Baltimore, MD 21201, (410) 962–4440.
- FHWA District of Columbia Division, 1200 New Jersey Avenue SE, East Building, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Ms. Donna Buscemi, Project Sponsor Liaison, Maryland Department of Transportation State Highway Administration, Office of Planning and Preliminary Engineering, 707 N Calvert Street, MS C–301, Baltimore, MD 21202, (410) 545–8500.

SUPPLEMENTARY INFORMATION: The Washington, DC to Baltimore Loop Project is proposed, and will be completely funded by, The Boring Company. The purpose of the proposed action is to construct an alternative, high speed option for traveling between Washington, District of Columbia, and Baltimore, Maryland.

The Proposed Action consists of the construction of approximately 35.3 miles of parallel, twin underground tunnels (Main Artery Tunnels) between Washington, DC and Baltimore, MD. The proposed project would extend beneath public right-of-way of the Route 50 and Baltimore-Washington Parkway, with termini at 55 New York Avenue Northeast in Washington, DC and Oriole Park at Camden Yards, 333 Camden Street, Baltimore, MD.

Battery-powered, autonomous electric vehicles, traveling at speeds of up to 150 miles per hour, would transport passengers in the Main Artery Tunnels between the two termini. Proposed project components include: Two access points at the Washington, DC and Baltimore, MD termini; two Main Artery Tunnels; up to 70 ventilation shafts; and 4 launch shaft sites for tunnel boring machines, at least one of which would be converted into a maintenance terminal for autonomous electric vehicles pods.

The Environmental Assessment (Draft) evaluates the existing environmental conditions within the project area, along with the potential environmental impacts of the No Build and Build alternatives for the proposed project.

Issued on: April 18, 2019.

Gregory Murrill,

Division Administrator, Federal Highway Administration.

[FR Doc. 2019–08245 Filed 4–23–19; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in California

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by the California Department of Transportation (Caltrans), pursuant to 23 U.S.C. 327.

SUMMARY: The FHWA, on behalf of Caltrans, is issuing this notice to announce actions taken by Caltrans that are final. The actions relate to a proposed highway project, State Route 57 Northbound Improvement Project (PM 11.5–12.5) in the County of Orange, State of California. Those actions grant licenses, permits, and approvals for the project.

DATES: By this notice, the FHWA, on behalf of Caltrans, is advising the public of final agency actions subject to 23 U.S.C. 139(*l*)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before September 23, 2019. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: For Caltrans: Smita Deshpande, Chief Generalist Branch, Division of Environmental Analysis, California Department of Transportation, District 12, 1750 East 4th Street, Suite 100, Santa Ana, CA 92705, 8am-4pm, (657) 328–6151, *smita.deshpande@dot.ca.gov.*

SUPPLEMENTARY INFORMATION: Effective July 1, 2007, the Federal Highway Administration (FHWA) assigned, and the California Department of Transportation (Caltrans) assumed, environmental responsibilities for this project pursuant to 23 U.S.C. 327. Notice is hereby given that the Caltrans have taken final agency actions subject to 23 U.S.C. 139(*l*)(1) by issuing licenses, permits, and approvals for the following highway project in the State of California: Caltrans proposes to widen the northbound side of the State Route (SR) 57 freeway from 0.3 mile south of the Orangewood Avenue undercrossing (post mile [PM] 11.5) north to the Katella Avenue undercrossing (PM 12.5), a distance of about one mile. Project includes the proposed construction of a 550-foot section of the fifth general purpose (GP) lane in the northbound direction of SR 57 through the Katella Avenue interchange, upgrades to the non-standard median and sight distances, and reconfiguration of the existing on- and off-ramps to improve operation between the Orangewood Avenue interchange and the Katella Avenue interchange. The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Final Environmental Assessment (FEA)/Finding of No Significant Impact (FONSI) for the project, issued March 29, 2019, and in other documents in the Caltrans' project records. The FEA,

FONSI and other project records are available by contacting Caltrans at the addresses provided above. The Caltrans FEA and FONSI and other project records can be viewed and downloaded from the project website at *http://www.dot.ca.gov/d12/DEA/57/0M9701.* This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. Council on Environmental Quality Regulations
2. National Environmental Policy Act of 1969, as amended, 42 U.S.C. 4321 *et seq.*
3. Federal-Aid Highway Act of 1970, 23 U.S.C. 109
4. Department of Transportation Act of 1966, Section 4(f)
5. Clean Air Act Amendments of 1990
6. Clean Water Act of 1977 and 1987
7. Federal Water Pollution Control Act of 1972
8. Noise Control Act of 1972
9. Endangered Species Act of 1973
10. Executive Order 11990, Protection of Wetlands
11. Executive Order 13112, Invasive Species Act
12. Executive Order 13186, Migratory Birds
13. Fish and Wildlife Coordination Act of 1934, as amended
14. National Historic Preservation Act of 1966, as amended
15. Executive Order 11988, Floodplain Management
16. Department of Transportation (DOT) Executive Order 5650.2—Floodplain Management and Protection (April 23, 1979)
17. Title VI of the Civil Rights Act of 1964, as amended

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(*l*)(1)

Issued on: April 17, 2019.

Tashia Clemons,

Director, Planning and Environment, Federal Highway Administration, Sacramento, California.

[FR Doc. 2019–08159 Filed 4–23–19; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2018–0333]

Agency Information Collection Activities; Renewal of a Currently-Approved Information Collection: Motor Carrier Identification Report

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FMCSA announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for its review and approval and invites public comment. FMCSA requests renewal of an ICR titled, ''Motor Carrier Identification Report,'' which is used to identify FMCSA regulated entities, help prioritize the agency's activities, aid in assessing the safety outcomes of those activities, and for statistical purposes. On April 26, 2016, OMB approved a revision to this collection. As a result of the revision, which is continued in this renewal, all entities needing to file registration and biennial update information to FMCSA will use Form MCS–150 or MCS–150B to submit their information. Form MCS–150 or MCS–150B will also be used by a the small number of Mexico-domiciled carriers that seek authority to operate beyond the United States municipalities on the United States-Mexico border and their commercial zones. This ICR is necessary to ensure regulated entities are registered with the DOT.

DATES: Please send your comments by May 24, 2019. OMB must receive your comments by this date in order to act quickly on the ICR.

ADDRESSES: All comments should reference Federal Docket Management System (FDMS) Docket Number FMCSA–2018–0333. Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/Federal Motor Carrier Safety Administration, and sent via electronic mail to *oira_submission@omb.eop.gov,* or faxed to (202) 395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Mr. Jeffrey Secrist, Office of Registration and Safety Information, Department of Transportation, FMCSA, West Building 6th Floor, 1200 New Jersey Avenue SE, Washington, DC 20590. Telephone: 202–385–2367; email *Jeffrey.secrist@dot.gov.* Office hours are from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

SUPPLEMENTARY INFORMATION:

Title: Motor Carrier Identification Report.

OMB Control Number: 2126–0013.

Type of Request: Renewal of a currently-approved collection.

Respondents: Motor carriers, freight forwarders, intermodal equipment providers, brokers, motor carriers with hazardous materials safety permit, cargo tank facilities and Mexican motor carriers.

Estimated Number of Respondents: 1,602,511 respondents [1,596,121 respondents for IC–1 + 3,811 respondents for IC–2 + 2,579 respondents for IC–3].

Estimated Time per Response: 20 minutes for new filings and 7.5 minutes for biennial updates and changes to complete the Form MCS–150.

Expiration Date: April 30, 2019.

Frequency of Response: On occasion and biennially.

Estimated Total Annual Burden: 119,878 hours [119,071 hours for IC–1 + 278 hours for IC–2 + 529 hours for IC–3].

Background: Title 49, United States Code Section 504(b)(2) provides the Secretary of Transportation (Secretary) with authority to require carriers, lessors, associations, or classes of these entities to file annual, periodic, and special reports containing answers to questions asked by the Secretary. The Secretary may also prescribe the form of records required to be prepared or compiled and the time period during which records must be preserved (See § 504(b)(1) and (d)). FMCSA will use this data to administer its safety programs using a database of entities that are subject to its regulations. This database necessitates that these entities notify FMCSA of their existence. For example, under 49 CFR 390.19(a), FMCSA requires all motor carriers beginning operations to file a Form MCS–150 titled, ''Motor Carrier Identification Report,'' or MCS–150B titled, ''Combined Motor Carrier Identification Report and HM Permit Applications.'' This report is filed by all motor carriers conducting operations in interstate, intrastate transporting

hazardous materials or international commerce before beginning operations. It asks the respondent to provide the name of the business entity that owns and controls the motor carrier operation; address and telephone of principal place of business; assigned identification number(s), type of operation, types of cargo usually transported; number of vehicles owned, term leased and trip leased; driver information; and certification statement signed by an individual authorized to sign documents on behalf of the business entity.

Existing applicants will use the MCS–150 or MCS–150B to update their information in the Motor Carrier Management Information System. Applicants filing for the first time will be required to file on-line. Form MCS–150 or MCS–150B will be used for Mexico-domiciled carriers that seek authority to operate beyond the United States municipalities on the United States-Mexico border and their commercial zones. The information collected from the respondents is readily available to the public. This ICR captures the burden of continued use of the MCS–150 or MCS–150B for motor carriers updating their registration information and for the registration of Mexico-domiciled carriers.

Summary of Changes

The MCS–150 is being revised. The hazardous material declarations, Class 3A, Class 3B, and Div. 2.2 (Ammonia), are being removed from the form. They are obsolete and do not require new or existing applicants to identify those declarations when applying for a USDOT number as a hazardous materials motor carrier.

The remaining hazardous materials entries on the forms and their respective instructions are being redesignated alphabetically to reflect the removal of the Class 3A, Class 3B, and Div. 2.2 (Ammonia) entries.

In the Filing Options section of the instructions for the forms, the Agency name is corrected.

In the hazardous materials list in the instructions for the forms, the entry for Combustible Liquid is revised to correct the 49 CFR reference.

The instructions for the forms are being revised to clarify the definitions of ''Intrastate Hazardous Materials Carrier'' and ''Intrastate Non-Hazardous Materials Carrier.''

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FMCSA to perform its functions; (2) the accuracy of the estimated burden; (3) ways for the FMCSA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the collected information.

Issued under the authority delegated in 49 CFR 1.87.

G. Kelly Regal,

Associate Administrator for Office of Research and Information Technology.

[FR Doc. 2019–08264 Filed 4–23–19; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[U.S. DOT Docket No. NHTSA–2019–0019]

Reports, Forms, and Record Keeping Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Request for public comment on a proposed collection of information.

SUMMARY: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). Under the procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatements of previously approved collections. This document describes one collection of information for which NHTSA intends to seek OMB approval.

DATES: Comments must be received on or before June 24, 2019.

ADDRESSES: You may submit comments identified by DOT Docket ID Number NHTSA—NHTSA–2019–0019 using any of the following methods:

Electronic submissions: Go to *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

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

Hand Delivery: West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Fax: 1–202–493–2251.

Instructions: Each submission must include the Agency name and the Docket number for this Notice. Note that all comments received will be posted without change to *http://www.regulations.gov* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Amy Berning, Research Psychologist, NHTSA–NPD–130, 1200 New Jersey Avenue SE, W44–237, Washington, DC 20590. Ms. Berning's phone number is 202–366–5587, and her email address is *amy.berning@dot.gov*.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulations (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following:

(i) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) How to enhance the quality, utility, and clarity of the information to be collected; and

(iv) How 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, *e.g.,* permitting electronic submissions of responses.

In compliance with these requirements, NHTSA asks public comment on the following proposed collection of information:

Title: Prevalence of Alcohol and Other Drug Use Among Motor Vehicle Crash Victims Admitted to Select Trauma Centers.

OMB Control Number: None.

Form No.: None.

Type of Information Collection Request: Approval of a New Information Collection.

Type of Review Requested: Regular.

The research study will involve the use of information, including blood samples, that was originally collected in the course of clinical treatment. Generally, under 5 U.S.C. 1320.3(h)(5), information does not include ''[f]acts or

opinions obtained initially or in follow-on requests, from individuals (including individuals in control groups) under treatment or clinical examination in connection with research on or prophylaxis to prevent a clinical disorder, direct treatment of that disorder, or the interpretation of biological analyses of body fluids, tissues, or other specimens, or the identification or classification of such specimens.'' However, as provided in 5 U.S.C. 1320.3(h), OMB may determine that any specific item constitutes ''information.'' NHTSA has consulted with OMB on a proposed research study and OMB has determined that, for the purpose of NHTSA's research study, the collection of the blood samples and de-identified information, including patient demographics, cause of injury, and injury severity, is a collection of information for which NHTSA must seek clearance from OMB.

Respondents: Participants will include approximately 7,500 people seriously injured in a motor vehicle crash (MVC) arriving at one of the selected trauma centers or morgues immediately after the crash injury was incurred. As such, participants will include seriously-injured and fatally-injured drivers and other crash-involved road users (*e.g.,* passengers, pedestrians, bicyclists, scooter riders).

Estimated Time per Participant: The trauma centers and medical examiners at the selected study sites universally draw patients' blood for clinical treatment or autopsy purposes. The trauma centers and medical examiners also collect other information such as patient demographics, cause of injury, injury severity, and drugs administered during treatment as part of their normal operating procedures. The only blood that will be used in this study will be de-identified blood samples that were collected, but not used, during their routine clinical procedures. The study will also use other de-identified information that was collected as part of their routine clinical documentation procedures. Again, this information would be collected even in the absence of NHTSA's research study. As such, NHTSA does not estimate any burden on the participants.

Total Estimated Annual Burden Hours: 0.00 hours per year.

Frequency of Collection: The collection is part of a one-time study. The trauma centers will provide de-identified information on a patient every time an individual presents to the trauma center as an MVC victim. When available, blood samples from MVC victims that were already collected as part of routine clinical procedures will be de-identified and provided for toxicological analyses. Similarly, the medical examiners will provide de-identified information on the fatally-injured MVC victims in the morgue and will provide a blood sample, when available, after all clinical procedures are complete.

Abstract: The National Highway Traffic Safety Administration (NHTSA) seeks to examine the prevalence of legal and illegal drugs in the systems of seriously- or fatally-injured drivers and other crash-involved road users presenting directly to the selected trauma centers or medical examiners. The contracted trauma centers and medical examiners will provide the study with de-identified blood samples, when available, that were already collected during their routine clinical treatment activities. The study will then conduct independent drug toxicology testing to determine the prevalence of alcohol and other drugs in the systems of the participants. The trauma centers and medical examiners will also provide the study with other de-identified participant classification information such as patient demographics, cause of injury, and injury severity. The trauma centers and medical examiners will provide this already-collected and de-identified information to the study in accordance with all applicable Federal, State, and local regulations governing the sharing of such information and as approved by the study Institutional Review Board.

Description of the Need for the Information and Proposed Use of the Information: NHTSA's mission is to save lives, prevent injuries and reduce traffic-related health care and other economic costs. The agency develops, promotes and implements educational, and enforcement programs with the goal of ending preventable tragedies and reducing economic costs associated with vehicle use and highway travel. There is a dearth of information on drug prevalence for seriously-injured MVC victims with only a couple studies exploring the issue in the United States (*e.g.,* Walsh, et al., 2004 [1]) and Canada (*e.g.,* Brubacher et al., 2016 [2]). This study seeks to help fill a gap in the state of knowledge concerning drug prevalence among MVC victims who are seriously- or fatally-injured, and present directly to a trauma center or morgue. While the sample is not nationally representative and will not be used for national estimates, the results of this research will produce information on a large sample of MVC victims, and will assist NHTSA in better understanding the prevalence of different drugs among the seriously- and-fatally-injured at the participating trauma centers and morgues.

Authority: 44 U.S.C. Section 3506(c)(2)(A).

Issued in Washington, DC on April 19, 2019.

Jon Krohmer,

Associate Administrator, Acting, Research and Program Development.

[FR Doc. 2019–08263 Filed 4–23–19; 8:45 am]

BILLING CODE 4910–59–P

[1] Walsh, J. M., Flegel, R., Cangianelli, L. A., Atkins, R., Soderstrom, C.A., & Kerns, T. J. (2004). Epidemiology of alcohol and other drug use among motor vehicle crash victims admitted to a trauma center. *Traffic Injury Prevention,* 5(3), 254–60.

[2] Brubacher, J., Chan, H., Martz, W., Schreiber, W., Abridge, M., Eppler, J., Lund, A., Macdonald, S., Drummer, O., Purssell, R., Andolfatto, G., Mann, R., & Brant, R. (2016). Prevalence of alcohol and drug use in injured British Columbia drivers. *BMJ Open,* 6(3), e009278.

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. DOT–OST–2019–0057]

Privacy Act of 1974; Department of Transportation, National Highway Traffic Safety Administration; DOT/NHTSA–415; Vehicle Owner Questionnaire (VOQ) System

AGENCY: National Highway Traffic Safety Administration, Department of Transportation.

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the National Highway Traffic Safety Administration (NHTSA) proposes to update, reissue, and rename a previously published Department of Transportation (DOT) system of records titled, ''Department of Transportation—DOT/NHTSA 415 Artemis/Vehicle Owner Complaint Information.'' This system of records allows NHTSA to collect and retain complaints, letters communicating vehicle or equipment concerns, and supporting documentation which may include photos, videos, police accident reports, repair invoices or medical information (collectively, ''vehicle owner questionnaires'' or ''VOQs'') submitted by or on behalf of vehicle or equipment owners and lessees (consumers). NHTSA updated the notice with regards to: System Name to *Vehicle Owner Questionnaire (VOQ) System* to appropriately identify the specific records maintained in the Artemis system covered by the Privacy Act; System Location to include NHTSA's current address and the location of the

Federal disaster recovery facility in Stennis, MS; System Managers to update the name and contact information for the system's current points of contact; Authority for Maintenance of the System to reflect the system's underlying authority; Purposes to provide clarity and facilitate understanding of NHTSA investigation and recall processes; Categories of Records to provide greater clarity of the type of records and information included in the system; Record Source Categories to provide additional information about the mechanisms used by NHTSA for collecting records in the system; and Routine Uses to modify an existing routine use to permit sharing of records with manufacturers named in VOQs earlier in NHTSA's investigation and recall processes than permitted under the previously published system of records notice (SORN), unless a consumer ''opts-out'' at the time of collection, and to provide additional details and clarification about NTHSA referrals of complaints to other agencies; and Policies and Practices for Storage, Retrieval, Retention and Disposal of Records, respectively, to provide additional information about the location of the system, methods of retrieval, individuals permitted to retrieve records, and to specify the applicable NARA record retention schedule; Administration, Technical and Physical Safeguards to detail the privacy-risk mitigating controls applicable to the system. Additionally, this notice includes non-substantive changes to simplify and clarify the language, formatting, and text of the previously published notice to align with the requirements of Office of Management and Budget Memoranda A–108. This updated system, *Vehicle Owner Questionnaire (VOQ) System,* will be included in the Department of Transportation's inventory of record systems.

DATES: Written comments must be submitted on or before May 24, 2019. The modified system will be effective immediately with the exception of the modified routine use which will be effective May 24, 2019.

ADDRESSES: You may submit comments, identified by docket number DOT–OST–2019–0057 by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Department of Transportation Docket Management, Room W12–140, 1200 New Jersey Ave. SE, Washington, DC 20590.

Instructions: You must include the agency name and docket number, DOT–OST–2019–0057. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov.* In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

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

FOR FURTHER INFORMATION CONTACT: For system-related questions please contact Jeff Giuseppe (202–366–1605), *ODI_Privacy@dot.gov,* Associate Administrator, Enforcement, NHTSA, 1200 New Jersey Ave. SE, Washington, DC 20590. For privacy questions, please contact: Claire W. Barrett (202–366–8135), *privacy@dot.gov.* Departmental Chief Privacy Officer, Department of Transportation, 1200 New Jersey Ave. SE, Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, NHTSA proposes to update, reissue, and rename a previously published DOT system of records titled, ''Department of Transportation—DOT/NHTSA 415 Artemis/Vehicle Owner Complaint Information.'' The updated system of records consists of VOQs submitted by or on behalf of consumers.

Under 49 U.S.C. Chapter 301, NHTSA Office of Defects Investigation (ODI), is responsible for identifying, investigating and ensuring the remedy, through safety recalls conducted by manufacturers, of safety-related defects and non-compliance issues in motor vehicles and items of motor vehicle equipment. To accomplish this, ODI collects and evaluates information from several different sources: Consumers, motor vehicle and equipment manufacturers, State and local law enforcement, insurance companies, automobile dealers, advocacy groups, and other entities. Among the types of information collected by ODI are VOQs that can be submitted through NHTSA's website *https://www.NHTSA.gov,* through a telephone hotline where an operator inputs the consumer's information into an electronic form, or a hard copy form sent to NHSTA by mail. ODI also receives letters from consumers and their Congressional representatives communicating vehicle and equipment concerns that the Agency, in addition to or in place of the questionnaire form. This system enables NHTSA to facilitate the defect investigation and recall processes, which may include contacting consumers regarding their complaints or recalls affecting their vehicle. ODI relies on the Advanced Retrieval (Tire, Equipment, Motor Vehicles) Information System (ARTEMIS) to provide centralized storage, document management and data analysis tools for all information collected in support of the defect investigation process, including VOQs. NHTSA uses the information in this system to help the Agency identify, investigate and ensure that manufactures remedy, through recall, replacement or repair, (1) potential safety defects and failures to comply with Federal Motor Vehicle Safety Standards (FMVSS) in motor vehicles and items of motor vehicle equipment, and (2) problems with the scope, administration, notification or remedy of a recall. NHTSA also may use the email addresses and Vehicle Identification Numbers (VINs) collected, to contact consumers whose vehicles are the subject of VOQs, and to notify consumers via email of open recalls applicable to the vehicles or equipment referenced in their VOQs.

Changes to the System Name, System Location, System Managers, Authority, Purpose, Categories of Individuals Covered by the System, Categories of Records in the System, Record Source Categories, Policies and Practices for Storage, Retrieval, Retention and Disposal of Records, and Safeguards improve transparency, but do not reflect substantive changes to the Notice. In particular, NHTSA's change to the System Name is intended to clarify for members of the public that only VOQs (as defined above) and not all documents stored in ARTEMIS, are part of the VOQ Privacy Act system of records that is the subject of this notice.

Changes to the SORN include:

1. System Name to *Vehicle Owner Questionnaire (VOQ) System* to appropriately identify the specific records maintained in the Artemis system covered by the Privacy Act;

2. System Location to include NHTSA's current address and the location of the Federal disaster recovery facility in Stennis, MS;

3. System Managers to update the name and contact information for the system's current points of contact;

4. Authority for Maintenance of the System to reflect the system's underlying authority;

5. Purposes to provide clarity and facilitate understanding of NHTSA investigation and recall processes;

6. Categories of Records to provide greater clarity of the type of records and information included in the system;

7. Record Source Categories to provide additional information about the mechanisms used by NHTSA for collecting records in the system;

8. Routine Uses to modify an existing routine use to permit sharing of records with manufacturers named in VOQs earlier in NHTSA's investigation and recall processes than permitted under the previously published SORN, unless a consumer ''opts-out'' at the time of collection;

9. Routine uses to replace a general routine use permitting NHTSA to refer complaints to other state or federal agencies with three separate routines uses specifying that NHTSA may share consumer complaints with the National Transportation Safety Board (NTSB) in connect with NTSB investigations of surface transportation incidents, and highway accidents and incidents including those at railway grade crossings; to the Consumer Product Safety Commission to support enforcement of consumer product safety laws; to the Federal Trade Commission in matters involving potential unfair or deceptive practices;

10. Routine uses to add a routine use permitting NHTSA to share with the Department of Homeland Security consumer complaints indicative of a cybersecurity vulnerability impacting critical infrastructure;

11. Routine Uses to remove internal uses of the information in the VOQ by ODI which are more appropriately addressed in the system's Purpose.

12. Policies and Practices for Storage, Retrieval, Retention and Disposal of Records, respectively, to provide additional information about the location of the system, methods of retrieval, individuals permitted to retrieve records, and to specify the applicable NARA record retention schedule;

13. Administration, Technical and Physical Safeguards to detail the privacy-risk mitigating controls applicable to the system.

14. Additionally, this notice includes non-substantive changes to simplify and clarify the language, formatting, and text of the previously published notice to align with the requirements of Office of Management and Budget Memoranda A–108. This updated system, *Vehicle Owner Questionnaire (VOQ) System,* will be included in the Department of Transportation's inventory of record systems.

NHTSA routinely publishes VOQs without personally identifiable information (PII) on its public facing website. A critical piece of information included in a VOQ is the VIN. A VIN is coded information that a vehicle manufacturer assigns to each vehicle it produces. This code contains seventeen alphanumeric characters that provide information about the vehicle. The first eleven characters identify the manufacturer and various generic attributes of the vehicle, such as the make, model, model year, body style, engine type, wheel base, supplemental restraint system and production plant, etc. The last six characters are the number sequentially assigned by the manufacturer in the production process. This sequential number is the part of the VIN that identifies a specific vehicle such as build history, standard or optional equipment packages and service history (and makes it possible through a search of public records to determine the identity of the owner). Because the VIN provides significant data, a VIN is critical to NHTSA's and a manufacturer's assessment and evaluation of potential safety issues in motor vehicles. NHTSA publishes the first eleven characters of the seventeen characters of VIN because, without the last six characters, the VIN cannot be linked to an individual. The public, including vehicle equipment manufacturers, can view these complaints with the truncated VIN and access the general make, model, model year attributes of the vehicle. Without the full seventeen character VIN, a manufacturer is unable to identify the precise vehicle that has experienced a potential safety related defect. Without such information, a manufacturer is unable to learn of vehicle specific information and focus on or identify potential safety issues.

The previously published SORN permitted NHTSA to share PII, including the full VIN, in VOQs with the manufacturer of the vehicle or equipment identified in a VOQ only after the agency has opened a formal investigation or a manufacturer has commenced a recall. In NHTSA's view, providing manufacturers and other stakeholders earlier access to PII in VOQs is critical to improving highway safety because earlier access will help manufacturers to identify the specific vehicle and its attributes that is subject to the complaint and remedy safety defects and noncompliance issues in a more timely manner than under the previously published SORN. Modifying this routine use will permit NHTSA to share VOQs with manufacturers on a routine basis as soon as is practicable after receipt by the Agency. Sharing these records at an earlier stage than permitted under the previously published SORN is compatible with the original vehicle safety purposes of the system because it allows NHTSA to provide manufacturers with information necessary to definitively identify the build history, equipment options, and repair history of a vehicles identified in a VOQ, and to identify, investigate and work with NHTSA to remedy a potential safety defect, failure to comply with an FMVSS or recall administration, scope or remedy issue.

To limit the potential privacy risks of sharing consumer contact information with manufacturer of the vehicles or equipment identified in the VOQ, NHTSA updated its collection instrument (see 2127–0008) to include explicit opt-out. Consumers who choose to opt-out will not have their information shared with the manufacturer of the vehicles or equipment identified in the VOQs unless the Agency opens an investigation or a recall is initiated. The Agency takes consumer privacy seriously and has included this new ''opt out'' feature in the VOQ form in order to provide consumers with additional control over their personal information. To enhance transparency, the ''opt-out'' appears in a prominent place in the electronic form maintained on the Department's public website, and will be communicated to consumers by hotline operators at the end of each hotline call. If consumers, at the point and time of collection, either check an ''opt out'' box on the VOQ form or direct the hotline operator collecting their information over the telephone to do so, NHTSA will not share with manufacturers the personal information provided in response to VOQ questions unless the Agency opens up a defect investigation or a recall takes place. At that point, an existing routine use permits the Agency to share their VOQs with the manufacturer of the vehicles or equipment identified in the VOQs. In addition to the approximately 70,000 VOQs filed annually directly with NHTSA, the Agency also receives approximately 1500 letters per year

from consumers or consumers' Congressional representatives communicating vehicle and equipment concerns that the Agency may convert into VOQs. It is not practicable for NHTSA to provide this small subset of consumers with the opportunity to ''opt out'' of sharing their personal information with the manufacturer of the vehicles or equipment identified in their letters. For this reason, NHTSA will pursue a privacy-positive course of action and assign ''opt-out'' status to the VOQs generated from these letters. NHTSA will not share their personal information with the manufacturer of the vehicles or equipment identified in these letters unless the Agency opens a defect investigation or a recall is commenced.

To further enhance transparency, NHTSA is adding a routine use concerning comments received in the free form narrative section of the web based VOQ form and VOQs received through the hotline. The publicly available VOQs are on NHTSA's website, accessed through *NHTSA.gov*. As part of the online VOQ form, NHTSA has a free text narrative section that requests that the consumer ''In your own words, tell us what happened.'' NHTSA provides notice to the consumer that any text submitted will be made public without edits. Once the individual submits the online form, NHTSA publishes these comments without edit and other non-personal identifying information in the VOQ to NHTSA's public website. In order to advise the public how NHTSA uses the narrative comments in a VOQ, NTHSA is establish a routine use this system of records. This routine use is compatible with the purpose of collection, which is to provide the public with information concerning potential safety related defects and noncompliance with a federal motor vehicle safety standard.

Finally, NHTSA is replacing pre-existing, generally-worded, routine use that permits NTHSA to share consumer complaints with ''appropriate State or Federal agenc[ies] for actions involving matters of law or regulation beyond the responsibility'' of NHSTA with three separate routine uses that specify the agencies with and purposes for which NHTSA shares information. This does not reflect a change in the types of disclosures NTSHA has or will make under the routine use, but is merely intended to provide clarity and transparency into how NHTSA shares information with other agencies. NHTSA also is updating its routine uses to permit disclosure to DHS when the consumer complaint evidences a potential cybersecurity vulnerability impacting transportation critical infrastructure. These routine uses are compatible with the purpose of the collection as a ''necessary and proper'' use of the information, as discussed more below. Individuals who provide VOQ information to NHTSA do so because they are seeking Federal agency intervention to address a potential issue with their vehicle. When the potential issue relates to a matter outside of NHTSA's jurisdiction, individuals may expect that NHTSA will share the information with the Federal agencies having jurisdiction for the matter. Thus, this routine use with compatible with the purpose of the collection, which is to identify, investigate and remedy potential safety defects.

NHTSA is updating this Notice to include Departmental general routine uses previously incorporated by reference, to the extent that they are compatible with the purposes of this System. As recognized by the Office of Management and Budget (OMB) in its Privacy Act Implementation Guidance and Responsibilities (65 FR 19746, July 9, 1975), the routine uses include all proper and necessary uses of information in the system, even if such uses occur infrequently. NHTSA has included in this Notice general routine uses for disclosures to law enforcement when the record, on its face, indicates a violation of law, to DOJ for litigation purposes, or when necessary in investigating or responding to a breach of this system or other agencies' systems. NHTSA must work with DOT to take appropriate action to address any apparent violations of the law, and to share information with legal counsel in the Department of Justice when necessary for litigation. OMB has long recognized that these types of routine uses are ''proper and necessary'' uses of information and qualify as compatible with agency systems. 65 FR 19476. In addition, by OMB Memorandum M–17–12, OMB directed agencies to include routine uses that will permit sharing of information when needed to investigate, respond to, and mitigate a breach of a Federal information system. NHTSA also has included routine uses that permit sharing with the National Archives and Records Administration when necessary for an inspection, to any Federal government agency engaged in audit or oversight related to this system, or when DOT determines that the disclosure will detect, prevent, or mitigate terrorism activity. These types of disclosures are necessary and proper uses of information in this system because they further DOT's obligation to fulfil its records management and program management responsibilities by facilitating accountability to agencies charged with oversight in these areas, and the Department's obligation under Intelligence Reform and Terrorism Prevention Act of 2004, Public Law 108–456, and Executive Order 13388 (Oct. 25, 2005) to share information necessary and relevant to detect, prevent, disrupt, preempt, or mitigate the effects of terrorist activities against the territory, people, and interests of the United States.

Finally, this system includes a routine use to permit sharing with our contractors, consultants, experts, grantees, and others when necessary to fulfill a NHTSA function related to this System. Agencies routinely engage assistance of these types of individuals in the fulfillment of their duties, such as contract support necessary to maintain the database in which these records are housed. NHTSA relies on contract support to maintain this system, and disclosures for this purpose are compatible with the purpose of the collection.

SYSTEM NAME AND NUMBER:

Vehicle Owner Questionnaire System DOT/NHTSA 415.

SECURITY CLASSIFICATION:

Unclassified, Sensitive.

SYSTEM LOCATION:

Records are maintained at the Department of Transportation Headquarters, 1200 New Jersey Ave., Washington, DC 20590, and at the Federal disaster recovery facility in Stennis, MS.

SYSTEM MANAGER(S):

Stephen A. Ridella, Ph.D., Director, Office of Defects Investigation, National Highway Traffic Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, 202–366–4703, *ODI_Privacy@dot.gov*.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

49 U.S.C. 30116, 30118–22, 30166.

PURPOSE OF THE SYSTEM:

To assist NHTSA to identify, investigate and ensure that manufactures remedy, through recall, replacement or repair, potential safety defects and failures to comply with FMVSS in motor vehicles and items of motor vehicle equipment. To assist NHTSA to identify, investigate and ensure that manufactures remedy problems with the scope, administration, notification or remedy of a recall. For these purposes, NHTSA routinely retrieves VOQs by name or

assigned identifier to contact motor vehicle drivers or owners experiencing safety problems or witnesses and other individuals with information relevant to the agency's investigative or remedial efforts.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Owners of motor vehicles and motor vehicle equipment, as well as users of leased motor vehicles and motor vehicle equipment, who have filed, or on whose behalf have been filed VOQs, or who send letters to the agency directly or through their representatives (*e.g.,* advocates, attorneys or Congressmen) concerning motor vehicle safety.

CATEGORIES OF RECORDS IN THE SYSTEM:

The standard questionnaire format collects information that assists NHTSA to identify and identify potential defects, recall issues, and instances of noncompliance. The information submitted by or on behalf of an individual includes the following:

- Vehicle identification number (VIN).
- Make, model and year of relevant vehicle.
- Part affected.
- A narrative field that permits the individual to describe in his or her own words what happened.
- Photographs/supporting documentation.
- Date of incident.
- Was there a crash.
- Was there a fire.
- Was there an injury or fatality.
- Speed at time.
- Number of miles on the vehicle.
- First and last name.
- Email address.
- Street address.
- Telephone/alt telephone number.

Individuals may also submit supporting documentation with a questionnaire or letter. NHTSA does not control the data submitted in these records and it may include personal information. Supporting documentation includes:

- Repair invoices.
- Insurance claims.
- Vehicle crash information.
- Police accident reports.
- Photographs and video image recordings of vehicles, parts, bodies or body parts.

RECORD SOURCE CATEGORIES:

Consumers, to include; vehicle owners, drivers of leased vehicles, and individuals or organizations submitting VOQs to NHTSA on their behalf.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the information contained in this system may be disclosed outside of DOT as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

SYSTEM SPECIFIC ROUTINE USES:

1. To manufacturers prior to the initiation of a formal investigation by the Department, an entire VOQ information to respond to consumer complaints and research the cause of the complaint, except when consumers ''opt out'' of such sharing at the point and time of collection. Information from individuals who submit VOQs by means other than the NHTSA website will be treated as if the individual has opt-out;

2. To manufacturers, after the Agency opens an investigation, to allow them to investigate owner complaints and researching the root cause of the alleged problem;

3. To the National Transportation Safety Board (NTSB) an entire VOQ to support NTSB investigations of surface transportation incidents, highway accidents and incidents, including incidents at railway grade crossings;

4. To the Consumer Product Safety Commission (CPSC) an entire VOQ to support identification of violations and enforcement of consumer product safety laws;

5. To the Federal Trade Commission an entire VOQ in matters involving potential unfair or deceptive trade practices;

6. To the Department of Homeland Security (DHS) if the VOQ is indicative of a cybersecurity vulnerability impacting critical infrastructure; and

7. To members of the public through *NHTSA.gov* website, information included in the narrative portion of the form questionnaire. Individuals are notified at the time of the VOQ submission that all information provided in the narrative will be made publicly available without edit.

DEPARTMENT GENERAL ROUTINE USES:

The U.S. Department of Transportation has established general routine uses applicable to all systems maintained by DOT. The following DOT general routine uses apply to this system of records:

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

2a. Routine Use for Disclosure for Use in Litigation. It shall be a routine use of the records in this system of records to disclose them to the Department of Justice or other Federal agency conducting litigation when—

(a) DOT, or any agency thereof, or

(b) Any employee of DOT or any agency thereof (including a member of the Coast Guard), in his/her official capacity, or

(c) Any employee of DOT or any agency thereof (including a member of the Coast Guard), in his/her individual capacity where the Department of Justice has agreed to represent the employee, or

(d) The United States or any agency thereof, where DOT determines that litigation is likely to affect the United States, is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice or other Federal agency conducting the litigation is deemed by DOT to be relevant and necessary in the litigation, provided, however, that in each case, DOT determines that disclosure of the records in the litigation is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

2b. Routine Use for Agency Disclosure in Other Proceedings. It shall be a routine use of records in this system to disclose them in proceedings before any court or adjudicative or administrative body before which DOT or any agency thereof, appears, when—

(a) DOT, or any agency thereof, or

(b) Any employee of DOT or any agency thereof (including a member of the Coast Guard) in his/her official capacity, or

(c) Any employee of DOT or any agency thereof (including a member of the Coast Guard) in his/her individual capacity where DOT has agreed to represent the employee, or

(d) The United States or any agency thereof, where DOT determines that the proceeding is likely to affect the United States, is a party to the proceeding or has an interest in such proceeding, and DOT determines that use of such records is relevant and necessary in the proceeding, provided, however, that in each case, DOT determines that

disclosure of the records in the proceeding is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

3. One or more records from a system of records may be disclosed routinely to the National Archives and Records Administration in records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

4. DOT may disclose records from this system, as a routine use, to appropriate agencies, entities, and persons when (1) DOT suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; (2) DOT has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by DOT or another agency or entity) that rely upon the compromised information; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DOT's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

5. DOT may disclose records from this system, as a routine use, to the Office of Government Information Services for the purpose of (a) resolving disputes between FOIA requesters and Federal agencies and (b) reviewing agencies' policies, procedures, and compliance in order to recommend policy changes to Congress and the President.

6. DOT may disclose records from this system, as a routine use, to contractors and their agents, experts, consultants, and others performing or working on a contract, service, cooperative agreement, or other assignment for DOT, when necessary to accomplish an agency function related to this system of records.

7. DOT may disclose records from this system, as a routine use, to an agency, organization, or individual for the purpose of performing audit or oversight operations related to this system of records, but only such records as are necessary and relevant to the audit or oversight activity. This routine use does not apply to intra-agency sharing authorized under Section (b)(1) of the Privacy Act.

8. DOT may disclose from this system, as a routine use, records consisting of, or relating to, terrorism information (6 U.S.C. 485(a)(5)), homeland security information (6 U.S.C. 482(f)(1)), or Law enforcement information (Guideline 2 Report attached to White House Memorandum, ''Information Sharing Environment, November 22, 2006) to a Federal, State, local, tribal, territorial, foreign government and/or multinational agency, either in response to its request or upon the initiative of the Component, for purposes of sharing such information as is necessary and relevant for the agencies to detect, prevent, disrupt, preempt, and mitigate the effects of terrorist activities against the territory, people, and interests of the United States of America, as contemplated by the Intelligence Reform and Terrorism Prevention Act of 2004 (Pub. L. 108–458) and Executive Order 13388 (October 25, 2005).

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic systems and hard copy at DOT Headquarters, 1200 New Jersey Ave. SE, Washington, DC 20590 and at the Federal disaster recovery facility in Stennis, MS.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

NHTSA staff and agents routinely retrieve VOQs by consumer name or personal identifier.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Pursuant to approved NARA Schedule N1–416–05–003 (Office of Defect Investigation Files), NHTSA: (1) Destroys VOQ information provided by consumers 15 years after receipt; (2) destroys investigation files, including any VOQs in the files, 15 years after the date of the resolution of an investigation when the investigation did not lead to a court decision; and (3) retains on a permanent basis investigation files, including any VOQs in the files, when an investigation leads to a court decision, but transfers legal custody of the files to NARA after 15 years. Original hard copy records collected from consumers and others are scanned into ARTEMIS and then destroyed.

ADMINISTRATIVE, TECHNICAL AND PHYSICAL SAFEGUARDS:

The VOQ system is protected by a multi-layer security approach to prevent unauthorized access to personally identifiable information through appropriate administrative, physical, and technical safeguards. Protective strategies include: Implementing physical access controls at DOT facilities; ensuring confidentiality of communications using tools such as encryption, authentication of sending parties, and compartmentalizing databases; and employing auditing software and personnel screening to ensure that all personnel with access to data are screened through background investigations commensurate with the level of access required to perform their duties. Records maintained in hard copy are stored in locked file cabinets until they can be scanned and uploaded to ARTEMIS and subsequently destroyed.

RECORD ACCESS PROCEDURES:

An individual wishing to gain access to any record pertaining to him or her in the system should send his or her name, address, telephone number, and a description of the record(s) sought to the U.S. Department of Transportation, Privacy Act Officer, Office of the Chief Information Officer, 1200 New Jersey Avenue SE, Washington, DC 20590.

CONTESTING RECORD PROCEDURES:

An individual seeking to contest information contained in a record pertaining to him or her in this system should address written inquiries to the U.S. Department of Transportation, Privacy Act Officer, Office of the Chief Information Officer, 1200 New Jersey Avenue SE, Washington, DC 20590. Inquiries should include name, address, telephone number, and a description of the record and information being contested.

NOTIFICATION PROCEDURES:

An individual seeking to determine whether a record pertaining to him or her is contained in this system should address written inquiries to the U.S. Department of Transportation, Privacy Act Officer, Office of the Chief Information Officer, 1200 New Jersey Avenue SE, Washington, DC 20590. Inquiries should include name, address, telephone number, and identify the system that is the subject of the inquiry.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

The last full **Federal Register** Notice pertaining to this system that contained all SORN elements was published on September 3, 2004 (69 FR 53971–53972).

Issued in Washington, DC on April 18, 2019.

Claire W. Barrett,

Departmental Chief Privacy Officer, Department of Transportation.

[FR Doc. 2019–08171 Filed 4–23–19; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Rev. Proc. 2003–39

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Revenue Procedure 2003–39, LKE (Like-Kind Exchanges) Auto Leasing Programs.

DATES: Written comments should be received on or before June 24, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this notice should be directed to Martha R. Brinson, at (202)317–5753, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Revenue Procedure 2003–39, LKE (Like-Kind Exchanges) Auto Leasing Programs.

OMB Number: 1545–1834.

Abstract: Revenue Procedure 2003–39 provides safe harbors for certain aspects of the qualification under § 1031 of certain exchanges of property pursuant to LKE Programs for federal income tax purposes.

Current Actions: There are no changes being made to the revenue procedure at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for profit organizations.

Estimated Number of Respondents: 8,600.

Estimated Average Time per Respondent: 1 hour.

Estimated Total Annual Burden Hours: 8,600.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request For Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments will be of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: April 18, 2019.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2019–08187 Filed 4–23–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Joint Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Joint Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Thursday, May 30, 2019.

FOR FURTHER INFORMATION CONTACT: Gilbert Martinez at 1–888–912–1227 or (737) 800–4060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Joint Committee will be held Thursday, May 30, 2019, at 1:00 p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. For more information please contact Gilbert Martinez at 1–888–912–1227 or (737–800–4060), or write TAP Office 3651 S. IH–35, STOP 1005 AUSC, Austin, TX 78741, or post comments to the website: *http://www.improveirs.org.*

The agenda will include various committee issues for submission to the IRS and other TAP related topics. Public input is welcomed.

Dated: April 18, 2019.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2019–08197 Filed 4–23–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee on Cemeteries and Memorials, Notice of Meeting, Amended

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act that a meeting of the Advisory Committee on Cemeteries and Memorials will be held on May 7–May 8, 2019. The meeting sessions will take place at the Veterans of Foreign Wars Memorial Building, 200 Maryland Avenue NE, Washington, DC 20002. The meeting sessions will begin as follows:

Date	Time
May 7, 2019.	8:30 a.m. to 4:30 p.m. EST.
May 8, 2019.	8:30 a.m. to 3:30 p.m. EST.

The meeting sessions are open to the public. If you're interested in attending the meeting virtually, the dial in number for both days is 1–800–767–1750, 02668#.

The purpose of the Committee is to advise the Secretary of Veterans Affairs on the administration of national cemeteries, soldiers' lots and plots, the selection of new national cemetery sites, the erection of appropriate memorials, and the adequacy of Federal burial benefits. The Committee will make recommendations to the Secretary regarding such activities.

On Tuesday, May 7, 2019, the Committee agenda will include remarks by the VA Leadership, Ethics refresher training, briefing from the Advisory Committee Management Office, introductions of new member

appointments, and status updates from NCA Staff and Ex-Officios.

On May 8, 2019, the agenda will include status updates on the National Cemetery Scheduling Office, Pre-Need Burial Eligibility Determinations, burial needs for Native American Veterans, status updates from NCA Staff and Ex-Officio, recommendations new charges, and next steps.

Any member of the public wishing to attend the meeting should contact Ms. Christine Hamilton, Designated Federal Officer, at (202) 461–5681. The Committee will also accept written comments. Comments may be transmitted electronically to the Committee at *Christine.hamilton1@va.gov* or mailed to the National Cemetery Administration (40A1), 810 Vermont Avenue NW, Room 400, Washington, DC 20420. In the public's communications with the Committee, the writers must identify themselves and state the organizations, associations, or persons they represent.

Dated: April 19, 2019.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2019–08223 Filed 4–23–19; 8:45 am]

BILLING CODE P

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 412

Medicare Program; Inpatient Rehabilitation Facility (IRF) Prospective Payment System for Federal Fiscal Year 2020 and Updates to the IRF Quality Reporting Program; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS–1710–P]

RIN 0938–AT67

Medicare Program; Inpatient Rehabilitation Facility (IRF) Prospective Payment System for Federal Fiscal Year 2020 and Updates to the IRF Quality Reporting Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would update the prospective payment rates for inpatient rehabilitation facilities (IRFs) for federal fiscal year (FY) 2020. As required by the Social Security Act (the Act), this proposed rule includes the classification and weighting factors for the IRF prospective payment system's (PPS) case-mix groups (CMGs) and a description of the methodologies and data used in computing the prospective payment rates for FY 2020. We are proposing to rebase and revise the IRF market basket to reflect a 2016 base year rather than the current 2012 base year. Additionally, we are proposing to replace the previously finalized unweighted motor score with a weighted motor score to assign patients to CMGs and remove one item from the score beginning with FY 2020 and to revise the CMGs and update the CMG relative weights and average length of stay values beginning with FY 2020, based on analysis of 2 years of data (FY 2017 and FY 2018). We are proposing to update the IRF wage index to use the concurrent FY inpatient prospective payment system (IPPS) wage index beginning with FY 2020. We are soliciting comments on stakeholder concerns regarding the appropriateness of the wage index used to adjust IRF payments. We are proposing to amend the regulations to clarify that the determination as to whether a physician qualifies as a rehabilitation physician (that is, a licensed physician with specialized training and experience in inpatient rehabilitation) is made by the IRF. For the IRF Quality Reporting Program (QRP), we are proposing to adopt two new measures, modify an existing measure, and adopt new standardized patient assessment data elements. We also propose to expand data collection to all patients, regardless of payer, as well as proposing updates related to the system used for the submission of data and related regulation text.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, not later than 5 p.m. on June 17, 2019.

ADDRESSES: In commenting, please refer to file code CMS–1710–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1710–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1710–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Gwendolyn Johnson, (410) 786–6954, for general information.

Catie Kraemer, (410) 786–0179, for information about the IRF payment policies and payment rates.

Kadie Derby, (410) 786–0468, for information about the IRF coverage policies.

Kate Brooks, (410) 786–7877, for information about the IRF quality reporting program.

SUPPLEMENTARY INFORMATION: The IRF PPS Addenda along with other supporting documents and tables referenced in this proposed rule are available through the internet on the CMS website at *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/.*

Executive Summary

A. Purpose

This proposed rule would update the prospective payment rates for IRFs for FY 2020 (that is, for discharges occurring on or after October 1, 2019, and on or before September 30, 2020) as required under section 1886(j)(3)(C) of the Act. As required by section 1886(j)(5) of the Act, this proposed rule includes the classification and weighting factors for the IRF PPS's case-mix groups and a description of the methodologies and data used in computing the prospective payment rates for FY 2020. This proposed rule would also rebase and revise the IRF market basket to reflect a 2016 base year, rather than the current 2012 base year. Additionally, this proposed rule proposes to replace the previously finalized unweighted motor score with a weighted motor score to assign patients to CMGs and remove one item from the score beginning in FY 2020 and to revise the CMGs and update the CMG relative weights and average length of stay values beginning with FY 2020, based on analysis of 2 years of data (FY 2017 and FY 2018). We are also proposing to update the IRF wage index to use the concurrent IPPS wage index for the IRF PPS beginning with FY 2020. We are also soliciting comments on stakeholder concerns regarding the appropriateness of the wage index used to adjust IRF payments. We are also proposing to amend the regulations at § 412.622 to clarify that the determination as to whether a physician qualifies as a rehabilitation physician (that is, a licensed physician with specialized training and experience in inpatient rehabilitation) is made by the IRF. For the IRF Quality Reporting Program (QRP), we are proposing to adopt two new measures, modify an existing measure, and adopt new standardized patient assessment data elements. We also propose to expand data collection to all patients, regardless of payer, as well as proposing updates related to the system used for the submission of data and related regulation text.

B. Summary of Major Provisions

In this proposed rule, we use the methods described in the FY 2019 IRF PPS final rule (83 FR 38514) to update the prospective payment rates for FY 2020 using updated FY 2018 IRF claims and the most recent available IRF cost report data, which is FY 2017 IRF cost report data. This proposed rule also proposes to rebase and revise the IRF market basket to reflect a 2016 base year rather than the current 2012 base year. Additionally, this proposed rule proposes to replace the previously finalized unweighted motor score with a weighted motor score to assign patients to CMGs and remove one item

from the score beginning with FY 2020 and to revise the CMGs and update the CMG relative weights and average length of stay values beginning with FY 2020, based on analysis of 2 years of data (FY 2017 and FY 2018). We are also proposing to use the concurrent IPPS wage index for the IRF PPS beginning in FY 2020. We are also soliciting comments on stakeholder concerns regarding the appropriateness of the wage index used to adjust IRF payments. We are also proposing to amend the regulations at § 412.622 to clarify that the determination as to whether a physician qualifies as a rehabilitation physician (that is, a licensed physician with specialized training and experience in inpatient rehabilitation) is made by the IRF. We are also proposing to update requirements for the IRF QRP.

C. Summary of Impacts

Provision Description	Transfers
FY 2020 IRF PPS payment rate update	The overall economic impact of this proposed rule is an estimated $195 million in increased payments from the Federal government to IRFs during FY 2020.
Provision Description	**Costs**
Proposed IRF QRP requirements	The total addition in costs in FY 2020 for IRFs as a result of the proposed quality reporting requirements is estimated to be $8.1 million.

I. Background

A. Historical Overview of the IRF PPS

Section 1886(j) of the Act provides for the implementation of a per-discharge PPS for inpatient rehabilitation hospitals and inpatient rehabilitation units of a hospital (collectively, hereinafter referred to as IRFs). Payments under the IRF PPS encompass inpatient operating and capital costs of furnishing covered rehabilitation services (that is, routine, ancillary, and capital costs), but not direct graduate medical education costs, costs of approved nursing and allied health education activities, bad debts, and other services or items outside the scope of the IRF PPS. Although a complete discussion of the IRF PPS provisions appears in the original FY 2002 IRF PPS final rule (66 FR 41316) and the FY 2006 IRF PPS final rule (70 FR 47880), we are providing a general description of the IRF PPS for FYs 2002 through 2019.

Under the IRF PPS from FY 2002 through FY 2005, the prospective payment rates were computed across 100 distinct CMGs, as described in the FY 2002 IRF PPS final rule (66 FR 41316). We constructed 95 CMGs using rehabilitation impairment categories (RICs), functional status (both motor and cognitive), and age (in some cases, cognitive status and age may not be a factor in defining a CMG). In addition, we constructed five special CMGs to account for very short stays and for patients who expire in the IRF.

For each of the CMGs, we developed relative weighting factors to account for a patient's clinical characteristics and expected resource needs. Thus, the weighting factors accounted for the relative difference in resource use across all CMGs. Within each CMG, we created tiers based on the estimated effects that certain comorbidities would have on resource use.

We established the federal PPS rates using a standardized payment conversion factor (formerly referred to as the budget-neutral conversion factor). For a detailed discussion of the budget-neutral conversion factor, please refer to our FY 2004 IRF PPS final rule (68 FR 45684 through 45685). In the FY 2006 IRF PPS final rule (70 FR 47880), we discussed in detail the methodology for determining the standard payment conversion factor.

We applied the relative weighting factors to the standard payment conversion factor to compute the unadjusted prospective payment rates under the IRF PPS from FYs 2002 through 2005. Within the structure of the payment system, we then made adjustments to account for interrupted stays, transfers, short stays, and deaths. Finally, we applied the applicable adjustments to account for geographic variations in wages (wage index), the percentage of low-income patients, location in a rural area (if applicable), and outlier payments (if applicable) to the IRFs' unadjusted prospective payment rates.

For cost reporting periods that began on or after January 1, 2002, and before October 1, 2002, we determined the final prospective payment amounts using the transition methodology prescribed in section 1886(j)(1) of the Act. Under this provision, IRFs transitioning into the PPS were paid a blend of the federal IRF PPS rate and the payment that the IRFs would have received had the IRF PPS not been implemented. This provision also allowed IRFs to elect to bypass this blended payment and immediately be paid 100 percent of the federal IRF PPS rate. The transition methodology expired as of cost reporting periods beginning on or after October 1, 2002 (FY 2003), and payments for all IRFs now consist of 100 percent of the federal IRF PPS rate.

Section 1886(j) of the Act confers broad statutory authority upon the Secretary to propose refinements to the IRF PPS. In the FY 2006 IRF PPS final rule (70 FR 47880) and in correcting amendments to the FY 2006 IRF PPS final rule (70 FR 57166), we finalized a number of refinements to the IRF PPS case-mix classification system (the CMGs and the corresponding relative weights) and the case-level and facility-level adjustments. These refinements included the adoption of the Office of Management and Budget's (OMB) Core-Based Statistical Area (CBSA) market definitions; modifications to the CMGs, tier comorbidities; and CMG relative weights, implementation of a new teaching status adjustment for IRFs; rebasing and revising the market basket index used to update IRF payments, and updates to the rural, low-income percentage (LIP), and high-cost outlier adjustments. Beginning with the FY 2006 IRF PPS final rule (70 FR 47908 through 47917), the market basket index used to update IRF payments was a market basket reflecting the operating and capital cost structures for freestanding IRFs, freestanding inpatient psychiatric facilities (IPFs), and long-term care hospitals (LTCHs) (hereinafter referred to as the rehabilitation, psychiatric, and long-term care (RPL) market basket). Any reference to the FY 2006 IRF PPS final rule in this proposed rule also includes the provisions effective in the correcting amendments. For a detailed discussion of the final key policy changes for FY 2006, please refer to the FY 2006 IRF PPS final rule.

In the FY 2007 IRF PPS final rule (71 FR 48354), we further refined the IRF PPS case-mix classification system (the

CMG relative weights) and the case-level adjustments, to ensure that IRF PPS payments would continue to reflect as accurately as possible the costs of care. For a detailed discussion of the FY 2007 policy revisions, please refer to the FY 2007 IRF PPS final rule.

In the FY 2008 IRF PPS final rule (72 FR 44284), we updated the prospective payment rates and the outlier threshold, revised the IRF wage index policy, and clarified how we determine high-cost outlier payments for transfer cases. For more information on the policy changes implemented for FY 2008, please refer to the FY 2008 IRF PPS final rule.

After publication of the FY 2008 IRF PPS final rule (72 FR 44284), section 115 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110–173, enacted on December 29, 2007) (MMSEA) amended section 1886(j)(3)(C) of the Act to apply a zero percent increase factor for FYs 2008 and 2009, effective for IRF discharges occurring on or after April 1, 2008. Section 1886(j)(3)(C) of the Act required the Secretary to develop an increase factor to update the IRF prospective payment rates for each FY. Based on the legislative change to the increase factor, we revised the FY 2008 prospective payment rates for IRF discharges occurring on or after April 1, 2008. Thus, the final FY 2008 IRF prospective payment rates that were published in the FY 2008 IRF PPS final rule (72 FR 44284) were effective for discharges occurring on or after October 1, 2007, and on or before March 31, 2008, and the revised FY 2008 IRF prospective payment rates were effective for discharges occurring on or after April 1, 2008, and on or before September 30, 2008. The revised FY 2008 prospective payment rates are available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html.*

In the FY 2009 IRF PPS final rule (73 FR 46370), we updated the CMG relative weights, the average length of stay values, and the outlier threshold; clarified IRF wage index policies regarding the treatment of ''New England deemed'' counties and multi-campus hospitals; and revised the regulation text in response to section 115 of the MMSEA to set the IRF compliance percentage at 60 percent (the ''60 percent rule'') and continue the practice of including comorbidities in the calculation of compliance percentages. We also applied a zero percent market basket increase factor for FY 2009 in accordance with section 115 of the MMSEA. For more information on the policy changes implemented for FY 2009, please refer to the FY 2009 IRF PPS final rule.

In the FY 2010 IRF PPS final rule (74 FR 39762) and in correcting amendments to the FY 2010 IRF PPS final rule (74 FR 50712), we updated the prospective payment rates, the CMG relative weights, the average length of stay values, the rural, LIP, teaching status adjustment factors, and the outlier threshold; implemented new IRF coverage requirements for determining whether an IRF claim is reasonable and necessary; and revised the regulation text to require IRFs to submit patient assessments on Medicare Advantage (MA) (formerly called Medicare Part C) patients for use in the 60 percent rule calculations. Any reference to the FY 2010 IRF PPS final rule in this proposed rule also includes the provisions effective in the correcting amendments. For more information on the policy changes implemented for FY 2010, please refer to the FY 2010 IRF PPS final rule.

After publication of the FY 2010 IRF PPS final rule (74 FR 39762), section 3401(d) of the Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted on March 23, 2010), as amended by section 10319 of the same Act and by section 1105 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted on March 30, 2010) (collectively, hereinafter referred to as ''PPACA''), amended section 1886(j)(3)(C) of the Act and added section 1886(j)(3)(D) of the Act. Section 1886(j)(3)(C) of the Act requires the Secretary to estimate a multifactor productivity (MFP) adjustment to the market basket increase factor, and to apply other adjustments as defined by the Act. The productivity adjustment applies to FYs from 2012 forward. The other adjustments apply to FYs 2010 to 2019.

Sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(i) of the Act defined the adjustments that were to be applied to the market basket increase factors in FYs 2010 and 2011. Under these provisions, the Secretary was required to reduce the market basket increase factor in FY 2010 by a 0.25 percentage point adjustment. Notwithstanding this provision, in accordance with section 3401(p) of the PPACA, the adjusted FY 2010 rate was only to be applied to discharges occurring on or after April 1, 2010. Based on the self-implementing legislative changes to section 1886(j)(3) of the Act, we adjusted the FY 2010 prospective payment rates as required, and applied these rates to IRF discharges occurring on or after April 1, 2010, and on or before September 30, 2010. Thus, the final FY 2010 IRF prospective payment rates that were published in the FY 2010 IRF PPS final rule (74 FR 39762) were used for discharges occurring on or after October 1, 2009, and on or before March 31, 2010, and the adjusted FY 2010 IRF prospective payment rates applied to discharges occurring on or after April 1, 2010, and on or before September 30, 2010. The adjusted FY 2010 prospective payment rates are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRF-Rules-and-Related-Files.html.*

In addition, sections 1886(j)(3)(C) and (D) of the Act also affected the FY 2010 IRF outlier threshold amount because they required an adjustment to the FY 2010 RPL market basket increase factor, which changed the standard payment conversion factor for FY 2010. Specifically, the original FY 2010 IRF outlier threshold amount was determined based on the original estimated FY 2010 RPL market basket increase factor of 2.5 percent and the standard payment conversion factor of $13,661. However, as adjusted, the IRF prospective payments were based on the adjusted RPL market basket increase factor of 2.25 percent and the revised standard payment conversion factor of $13,627. To maintain estimated outlier payments for FY 2010 equal to the established standard of 3 percent of total estimated IRF PPS payments for FY 2010, we revised the IRF outlier threshold amount for FY 2010 for discharges occurring on or after April 1, 2010, and on or before September 30, 2010. The revised IRF outlier threshold amount for FY 2010 was $10,721.

Sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(i) of the Act also required the Secretary to reduce the market basket increase factor in FY 2011 by a 0.25 percentage point adjustment. The FY 2011 IRF PPS notice (75 FR 42836) and the correcting amendments to the FY 2011 IRF PPS notice (75 FR 70013) described the required adjustments to the FY 2010 and FY 2011 IRF PPS prospective payment rates and outlier threshold amount for IRF discharges occurring on or after April 1, 2010, and on or before September 30, 2011. It also updated the FY 2011 prospective payment rates, the CMG relative weights, and the average length of stay values. Any reference to the FY 2011 IRF PPS notice in this proposed rule also includes the provisions effective in the correcting amendments. For more information on the FY 2010 and FY 2011 adjustments or the updates for FY 2011, please refer to the FY 2011 IRF PPS notice.

In the FY 2012 IRF PPS final rule (76 FR 47836), we updated the IRF prospective payment rates, rebased and revised the RPL market basket, and established a new QRP for IRFs in accordance with section 1886(j)(7) of the Act. We also consolidated, clarified, and revised existing policies regarding IRF hospitals and IRF units of hospitals to eliminate unnecessary confusion and enhance consistency. For more information on the policy changes implemented for FY 2012, please refer to the FY 2012 IRF PPS final rule.

The FY 2013 IRF PPS notice (77 FR 44618) described the required adjustments to the FY 2013 prospective payment rates and outlier threshold amount for IRF discharges occurring on or after October 1, 2012, and on or before September 30, 2013. It also updated the FY 2013 prospective payment rates, the CMG relative weights, and the average length of stay values. For more information on the updates for FY 2013, please refer to the FY 2013 IRF PPS notice.

In the FY 2014 IRF PPS final rule (78 FR 47860), we updated the prospective payment rates, the CMG relative weights, and the outlier threshold amount. We also updated the facility-level adjustment factors using an enhanced estimation methodology, revised the list of diagnosis codes that count toward an IRF's 60 percent rule compliance calculation to determine ''presumptive compliance,'' revised sections of the inpatient rehabilitation facility patient assessment instrument (IRF–PAI), revised requirements for acute care hospitals that have IRF units, clarified the IRF regulation text regarding limitation of review, updated references to previously changed sections in the regulations text, and updated requirements for the IRF QRP. For more information on the policy changes implemented for FY 2014, please refer to the FY 2014 IRF PPS final rule.

In the FY 2015 IRF PPS final rule (79 FR 45872) and the correcting amendments to the FY 2015 IRF PPS final rule (79 FR 59121), we updated the prospective payment rates, the CMG relative weights, and the outlier threshold amount. We also revised the list of diagnosis codes that count toward an IRF's 60 percent rule compliance calculation to determine ''presumptive compliance,'' revised sections of the IRF–PAI, and updated requirements for the IRF QRP. Any reference to the FY 2015 IRF PPS final rule in this proposed rule also includes the provisions effective in the correcting amendments. For more information on the policy changes implemented for FY 2015, please refer to the FY 2015 IRF PPS final rule.

In the FY 2016 IRF PPS final rule (80 FR 47036), we updated the prospective payment rates, the CMG relative weights, and the outlier threshold amount. We also adopted an IRF-specific market basket that reflects the cost structures of only IRF providers, a blended 1-year transition wage index based on the adoption of new OMB area delineations, a 3-year phase-out of the rural adjustment for certain IRFs due to the new OMB area delineations, and updates for the IRF QRP. For more information on the policy changes implemented for FY 2016, please refer to the FY 2016 IRF PPS final rule.

In the FY 2017 IRF PPS final rule (81 FR 52056) and the correcting amendments to the FY 2017 IRF PPS final rule (81 FR 59901), we updated the prospective payment rates, the CMG relative weights, and the outlier threshold amount. We also updated requirements for the IRF QRP. Any reference to the FY 2017 IRF PPS final rule in this proposed rule also includes the provisions effective in the correcting amendments. For more information on the policy changes implemented for FY 2017, please refer to the FY 2017 IRF PPS final rule.

In the FY 2018 IRF PPS final rule (82 FR 36238), we updated the prospective payment rates, the CMG relative weights, and the outlier threshold amount. We also revised the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) diagnosis codes that are used to determine presumptive compliance under the ''60 percent rule,'' removed the 25 percent payment penalty for IRF–PAI late transmissions, removed the voluntary swallowing status item (Item 27) from the IRF–PAI, summarized comments regarding the criteria used to classify facilities for payment under the IRF PPS, provided for a subregulatory process for certain annual updates to the presumptive methodology diagnosis code lists, adopted the use of height/weight items on the IRF–PAI to determine patient body mass index (BMI) greater than 50 for cases of single-joint replacement under the presumptive methodology, and updated requirements for the IRF QRP. For more information on the policy changes implemented for FY 2018, please refer to the FY 2018 IRF PPS final rule.

In the FY 2019 IRF PPS final rule (83 FR 38514), we updated the prospective payment rates, the CMG relative weights, and the outlier threshold amount. We also alleviated administrative burden for IRFs by removing the FIM™ instrument and associated Function Modifiers from the IRF–PAI beginning in FY 2020 and revised certain IRF coverage requirements to reduce the amount of required paperwork in the IRF setting beginning in FY 2019. Additionally, we incorporated certain data items located in the Quality Indicators section of the IRF–PAI into the IRF case-mix classification system using analysis of 2 years of data (FY 2017 and FY 2018) beginning in FY 2020. For the IRF QRP, we adopted a new measure removal factor, removed two measures from the IRF QRP measure set, and codified a number of program requirements in our regulations. For more information on the policy changes implemented for FY 2019, please refer to the FY 2019 IRF PPS final rule.

B. Provisions of the PPACA Affecting the IRF PPS in FY 2012 and Beyond

The PPACA included several provisions that affect the IRF PPS in FYs 2012 and beyond. In addition to what was previously discussed, section 3401(d) of the PPACA also added section 1886(j)(3)(C)(ii)(I) of the Act (providing for a ''productivity adjustment'' for fiscal year 2012 and each subsequent fiscal year). The productivity adjustment for FY 2020 is discussed in section V.D. of this proposed rule. Section 1886(j)(3)(C)(ii)(II) of the Act provides that the application of the productivity adjustment to the market basket update may result in an update that is less than 0.0 for a fiscal year and in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year.

Sections 3004(b) of the PPACA and section 411(b) of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10, enacted on April 16, 2015) (MACRA) also addressed the IRF PPS. Section 3004(b) of PPACA reassigned the previously designated section 1886(j)(7) of the Act to section 1886(j)(8) of the Act and inserted a new section 1886(j)(7) of the Act, which contains requirements for the Secretary to establish a QRP for IRFs. Under that program, data must be submitted in a form and manner and at a time specified by the Secretary. Beginning in FY 2014, section 1886(j)(7)(A)(i) of the Act requires the application of a 2 percentage point reduction to the market basket increase factor otherwise applicable to an IRF (after application of subparagraphs (C)(iii) and (D) of section 1886(j)(3) of the Act) for a fiscal year if the IRF does not comply with the requirements of the IRF QRP for that fiscal year. Application of the 2

percentage point reduction may result in an update that is less than 0.0 for a fiscal year and in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year. Reporting-based reductions to the market basket increase factor are not cumulative; they only apply for the FY involved. Section 411(b) of MACRA amended section 1886(j)(3)(C) of the Act by adding clause (iii), which required us to apply for FY 2018, after the application of section 1886(j)(3)(C)(ii) of the Act, an increase factor of 1.0 percent to update the IRF prospective payment rates.

C. Operational Overview of the Current IRF PPS

As described in the FY 2002 IRF PPS final rule (66 FR 41316), upon the admission and discharge of a Medicare Part A Fee-for-Service (FFS) patient, the IRF is required to complete the appropriate sections of a patient assessment instrument (PAI), designated as the IRF–PAI. In addition, beginning with IRF discharges occurring on or after October 1, 2009, the IRF is also required to complete the appropriate sections of the IRF–PAI upon the admission and discharge of each Medicare Advantage (MA) patient, as described in the FY 2010 IRF PPS final rule (74 FR 39762 and 74 FR 50712). All required data must be electronically encoded into the IRF–PAI software product. Generally, the software product includes patient classification programming called the Grouper software. The Grouper software uses specific IRF–PAI data elements to classify (or group) patients into distinct CMGs and account for the existence of any relevant comorbidities.

The Grouper software produces a five-character CMG number. The first character is an alphabetic character that indicates the comorbidity tier. The last four characters are numeric characters that represent the distinct CMG number. Free downloads of the Inpatient Rehabilitation Validation and Entry (IRVEN) software product, including the Grouper software, are available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Software.html.*

Once a Medicare Part A FFS patient is discharged, the IRF submits a Medicare claim as a Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191, enacted on August 21, 1996) (HIPAA) compliant electronic claim or, if the Administrative Simplification Compliance Act of 2002 (Pub. L. 107–105, enacted on December 27, 2002) (ASCA) permits, a paper claim (a UB–04 or a CMS–1450 as appropriate) using the five-character CMG number and sends it to the appropriate Medicare Administrative Contractor (MAC). In addition, once a MA patient is discharged, in accordance with the Medicare Claims Processing Manual, chapter 3, section 20.3 (Pub. L. 100–04), hospitals (including IRFs) must submit an informational-only bill (Type of Bill (TOB) 111), which includes Condition Code 04 to their MAC. This will ensure that the MA days are included in the hospital's Supplemental Security Income (SSI) ratio (used in calculating the IRF LIP adjustment) for fiscal year 2007 and beyond. Claims submitted to Medicare must comply with both ASCA and HIPAA.

Section 3 of the ASCA amended section 1862(a) of the Act by adding paragraph (22), which requires the Medicare program, subject to section 1862(h) of the Act, to deny payment under Part A or Part B for any expenses for items or services for which a claim is submitted other than in an electronic form specified by the Secretary. Section 1862(h) of the Act, in turn, provides that the Secretary shall waive such denial in situations in which there is no method available for the submission of claims in an electronic form or the entity submitting the claim is a small provider. In addition, the Secretary also has the authority to waive such denial in such unusual cases as the Secretary finds appropriate. For more information, see the ''Medicare Program; Electronic Submission of Medicare Claims'' final rule (70 FR 71008). Our instructions for the limited number of Medicare claims submitted on paper are available at *http://www.cms.gov/manuals/downloads/clm104c25.pdf.*

Section 3 of the ASCA operates in the context of the administrative simplification provisions of HIPAA, which include, among others, the requirements for transaction standards and code sets codified in 45 CFR part 160 and part 162, subparts A and I through R (generally known as the Transactions Rule). The Transactions Rule requires covered entities, including covered health care providers, to conduct covered electronic transactions according to the applicable transaction standards. (See the CMS program claim memoranda at *http://www.cms.gov/ElectronicBillingEDITrans/* and listed in the addenda to the Medicare Intermediary Manual, Part 3, section 3600).

The MAC processes the claim through its software system. This software system includes pricing programming called the ''Pricer'' software. The Pricer software uses the CMG number, along with other specific claim data elements and provider-specific data, to adjust the IRF's prospective payment for interrupted stays, transfers, short stays, and deaths, and then applies the applicable adjustments to account for the IRF's wage index, percentage of low-income patients, rural location, and outlier payments. For discharges occurring on or after October 1, 2005, the IRF PPS payment also reflects the teaching status adjustment that became effective as of FY 2006, as discussed in the FY 2006 IRF PPS final rule (70 FR 47880).

D. Advancing Health Information Exchange

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of interoperable health information technology and to promote nationwide health information exchange to improve health care. The Office of the National Coordinator for Health Information Technology (ONC) and CMS work collaboratively to advance interoperability across settings of care, including post-acute care.

To further interoperability in post-acute care, we developed a Data Element Library (DEL) to serve as a publicly-available centralized, authoritative resource for standardized data elements and their associated mappings to health IT standards. The DEL furthers CMS' goal of data standardization and interoperability, which is also a goal of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act). These interoperable data elements can reduce provider burden by allowing the use and exchange of healthcare data, support provider exchange of electronic health information for care coordination, person-centered care, and support real-time, data driven, clinical decision making. Standards in the Data Element Library (*https://del.cms.gov/*) can be referenced on the CMS website and in the ONC Interoperability Standards Advisory (ISA). The 2019 ISA is available at *https://www.healthit.gov/isa.*

The 21st Century Cures Act (Pub. L. 114–255, enacted on December 13, 2016) (Cures Act), requires HHS to take new steps to enable the electronic sharing of health information ensuring interoperability for providers and settings across the care continuum. In another important provision, Congress defined ''information blocking'' as practices likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health

information, and established new authority for HHS to discourage these practices. In March 2019, ONC and CMS published the proposed rules, ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program,'' (84 FR 7424) and ''Interoperability and Patient Access'' (84 FR 7610) to promote secure and more immediate access to health information for patients and healthcare providers through the implementation of information blocking provisions of the Cures Act and the use of standardized application programming interfaces (APIs) that enable easier access to electronic health information. These two proposed rules are open for public comment at *www.regulations.gov.* We invite providers to learn more about these important developments and how they are likely to affect IRFs.

II. Summary of Provisions of the Proposed Rule

In this proposed rule, we propose to update the IRF prospective payment rates for FY 2020 and to rebase and revise the IRF market basket to reflect a 2016 base year rather than the current 2012 base year. We are also proposing to replace the previously finalized unweighted motor score with a weighted motor score to assign patients to CMGs and remove one item from the score beginning with FY 2020 and to revise the CMGs and update the CMG relative weights and average length of stay values beginning with FY 2020, based on analysis of 2 years of data (FY 2017 and FY 2018). We are also proposing to use the concurrent IPPS wage index for the IRF PPS beginning with FY 2020. We are also soliciting comments on stakeholder concerns regarding the appropriateness of the wage index used to adjust IRF payments. We are proposing to amend the regulations at § 412.622 to clarify that the determination as to whether a physician qualifies as a rehabilitation physician (that is, a licensed physician with specialized training and experience in inpatient rehabilitation) is made by the IRF.

The proposed policy changes and updates to the IRF prospective payment rates for FY 2020 are as follows:

- Describe a proposed weighted motor score to replace the previously finalized unweighted motor score to assign a patient to a CMG, the removal of one item from the score, and revisions to the CMGs beginning on October 1, 2019, based on analysis of 2 years of data (FY 2017 and FY 2018) using the Quality Indicator items in the IRF–PAI. This includes proposed revisions to the CMG relative weights and average length of stay values for FY 2020, in a budget neutral manner, as discussed in section III. of this proposed rule.
- Describe the proposed rebased and revised IRF market basket to reflect a 2016 base year rather than the current 2012 base year as discussed in section V. of this proposed rule.
- Update the IRF PPS payment rates for FY 2020 by the proposed market basket increase factor, based upon the most current data available, with a proposed productivity adjustment required by section 1886(j)(3)(C)(ii)(I) of the Act, as described in section V. of this proposed rule.
- Describe the proposed update to the IRF wage index to use the concurrent IPPS wage index and the FY 2020 proposed labor-related share in a budget-neutral manner, as described in section V. of this proposed rule.
- Describe the continued use of FY 2014 facility-level adjustment factors, as discussed in section IV. of this proposed rule.
- Describe the calculation of the IRF standard payment conversion factor for FY 2020, as discussed in section V. of this proposed rule.
- Update the outlier threshold amount for FY 2020, as discussed in section VI. of this proposed rule.
- Update the cost-to-charge ratio (CCR) ceiling and urban/rural average CCRs for FY 2020, as discussed in section VI. of this proposed rule.
- Describe the proposed amendments to the regulations at § 412.622 to clarify that the determination as to whether a physician qualifies as a rehabilitation physician (that is, a licensed physician with specialized training and experience in inpatient rehabilitation) is made by the IRF, as discussed in section VII. of this proposed rule.
- Updates to the requirements for the IRF QRP, as discussed in section VIII. of this proposed rule.

III. Proposed Refinements to the Case-Mix Classification System Beginning With FY 2020

A. Background

Section 1886(j)(2)(A) of the Act requires the Secretary to establish case-mix groups for payment under the IRF PPS and a method of classifying specific IRF patients within these groups. Under section 1886(j)(2)(B) of the Act, the Secretary must assign each case-mix group an appropriate weighting factor that reflects the relative facility resources used for patients classified within the group as compared to patients classified within other groups. Additionally, section 1886(j)(2)(C)(i) of the Act requires the Secretary from time to time to adjust the established classifications and weighting factors as appropriate to reflect changes in treatment patterns, technology, case-mix, number of payment units for which payment is made under title XVIII of the Act, and other factors which may affect the relative use of resources. Such adjustments must be made in a manner so that changes in aggregate payments under the classification system are a result of real changes and are not a result of changes in coding that are unrelated to real changes in case mix.

In the FY 2019 IRF PPS final rule (83 FR 38533 through 38549), we finalized the removal of the Functional Independence Measure (FIM™) instrument and associated Function Modifiers from the IRF–PAI and the incorporation of an unweighted additive motor score derived from 19 data items located in the Quality Indicators section of the IRF–PAI beginning with FY 2020 (83 FR 38535 through 38536, 38549). As discussed in section III.B of this proposed rule, based on further analysis to examine the potential impact of weighting the motor score, we are proposing to replace the previously finalized unweighted motor score with a weighted motor score and remove one item from the score beginning with FY 2020.

Additionally, as noted in the FY 2019 IRF PPS final rule (83 FR 38534), the incorporation of the data items from the Quality Indicator section of the IRF–PAI into the IRF case-mix classification system necessitates revisions to the CMGs to ensure that IRF payments are calculated accurately. We finalized the use of data items from the Quality Indicators section of the IRF–PAI to construct the functional status scores used to classify IRF patients in the IRF case-mix classification system for purposes of establishing payment under the IRF PPS beginning with FY 2020, but modified our proposal based on public comments to incorporate two years of data (FYs 2017 and 2018) into our analyses used to revise the CMG definitions (83 FR 38549). We stated that any changes to the proposed CMG definitions resulting from the incorporation of an additional year of data (FY 2018) into the analysis would be addressed in future rulemaking prior to their implementation beginning in FY 2020. As discussed in section III.C of this proposed rule, we are proposing to revise the CMGs based on analysis of 2 years of data (FYs 2017 and 2018) beginning with FY 2020. We are also proposing to update the relative weights and average length of stay values

associated with the revised CMGs beginning with FY 2020.

B. Proposed Use of a Weighted Motor Score Beginning With FY 2020

As noted in the FY 2019 IRF PPS final rule (83 FR 38535), the IRF case-mix classification system currently uses a weighted motor score based on FIM™ data items to assign patients to CMGs under the IRF PPS through FY 2019. More information on the development and implementation of this motor score can be found in the FY 2006 IRF PPS final rule (70 FR 47896 through 47900). In the FY 2019 IRF PPS final rule (83 FR 38535 through 38536, 38549), we finalized the incorporation of an unweighted additive motor score derived from 19 data items located in the Quality Indicators section of the IRF–PAI beginning with FY 2020. We did not propose a weighted motor score at the time, because we believed that the unweighted motor score would facilitate greater understanding among the provider community, as it is less complex. However, we also noted that we would take comments in favor of a weighted motor score into consideration in future analysis. In response to feedback we received from various stakeholders and professional organizations regarding the use of an unweighted motor score and requesting that we consider weighting the motor score, we extended our contract with Research Triangle Institute, International (RTI) to examine the potential impact of weighting the motor score. Based on this analysis, discussed further below, we now believe that a weighted motor score would improve the accuracy of payments to IRFs, and we are proposing to replace the previously finalized unweighted motor score with a weighted motor score to assign patients to CMGs beginning with FY 2020.

The previously finalized motor score is calculated by summing the scores of the 19 data items, with equal weight applied to each item. The 19 data items are (83 FR 38535):

- GG0130A1 Eating.
- GG0130B1 Oral hygiene.
- GG0130C1 Toileting hygiene.
- GG0130E1 Shower/bathe self.
- GG0130F1 Upper-body dressing.
- GG0130G1 Lower-body dressing.
- GG0130H1 Putting on/taking off footwear.
- GG0170A1 Roll left and right.
- GG0170B1 Sit to lying.
- GG0170C1 Lying to sitting on side of bed.
- GG0170D1 Sit to stand.
- GG0170E1 Chair/bed-to-chair transfer.
- GG0170F1 Toilet transfer.
- GG0170I1 Walk 10 feet.
- GG0170J1 Walk 50 feet with two turns.
- GG0170K1 Walk 150 feet.
- GG0170M1 One step curb.
- H0350 Bladder continence.
- H0400 Bowel continence.

In response to feedback we received from various stakeholders and professional organizations requesting that we consider applying weights to the motor score, we extended our contract with RTI to explore the potential of applying unique weights to each of the 19 items in the motor score.

As part of their analysis, RTI examined the degree to which the items used to construct the motor score were related to one another and adjusted their weighting methodology to account for their findings. RTI considered a number of different weighting methodologies to develop a weighted index that would increase the predictive power of the IRF case-mix classification system while at the same time maintaining simplicity. RTI used regression analysis to explore the relationship of the motor score items to costs. This analysis was undertaken to determine the impact of each of the items on cost and then to weight each item in the index according to its relative impact on cost. Based on findings from this analysis, we are proposing to remove the item GG0170A1 Roll left and right from the motor score as this item was found to have a high degree of multicollinearity with other items in the motor score and behaved unexpectedly across the regression models considered in the development of the weighted index. Using the revised motor score composed of the remaining 18 items identified above, RTI designed a weighting methodology for the motor score that could be applied uniformly across all RICs. For a more detailed discussion of the analysis used to construct the weighted motor score, we refer readers to the March 2019 technical report entitled ''Analyses to Inform the Use of Standardized Patient Assessment Data Elements in the Inpatient Rehabilitation Facility Prospective Payment System'', available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Research.html.* Findings from this analysis suggest that the use of a weighted motor score index slightly improves the ability of the IRF PPS to predict patient costs. Based on this analysis, we believe it is appropriate to utilize a weighted motor score for the purpose of determining IRF payments.

Table 1 shows the proposed weights for each component of the motor score, averaged to 1, obtained through the regression analysis.

TABLE 1—PROPOSED MOTOR SCORE WEIGHT INDEX

Item	Weight
GG0130A1—Eating	2.7
GG0130B1—Oral hygiene	0.3
GG0130C1—Toileting hygiene	2.0
GG0130E1—Shower bathe self	0.7
GG0130F1—Upper-body dressing	0.5
GG0130G1—Lower-body dressing	1.0
GG0130H1—Putting on/taking off footwear	1.0
GG0170B1—Sit to lying	0.1
GG0170C1—Lying to sitting on side of bed	0.1
GG0170D1—Sit to stand	1.1
GG0170E1—Chair/bed-to-chair transfer	1.1
GG0170F1—Toilet transfer	1.6
GG0170I1—Walk 10 feet	0.8
GG0170J1—Walk 50 feet with two turns	0.8
GG0170K1—Walk 150 feet	0.8
GG0170M1—One-step curb	1.4
H0350—Bladder Continence	1.3
H0400—Bowel Continence	0.7

We are proposing to determine the motor score by applying each of the weights indicated in Table 1 to the score of each corresponding item, as finalized in the FY 2019 IRF PPS final rule (83 FR 38535 through 38537), and then summing the weighted scores for each of the 18 items that compose the motor score.

We invite public comments on the proposal to replace the previously finalized unweighted motor score with a weighted motor score to assign patients to CMGs under the IRF PPS and our proposal to remove the item GG0170A1 Roll left and right from the calculation of the motor score beginning with FY 2020, that is, for all discharges beginning on or after October 1, 2019.

C. Proposed Revisions to the CMGs and Proposed Updates to the CMG Relative Weights and Average Length of Stay Values Beginning With FY 2020

In the FY 2019 IRF PPS final rule (83 FR 38549), we finalized the use of data items from the Quality Indicators section of the IRF–PAI to construct the functional status scores used to classify IRF patients in the IRF case-mix classification system for purposes of establishing payment under the IRF PPS beginning with FY 2020, but modified our proposal based on public comments to incorporate two years of data (FY 2017 and FY 2018) into our analyses used to revise the CMG definitions. We stated that any changes to the proposed CMG definitions resulting from the incorporation of an additional year of data (FY 2018) into the analysis would be addressed in future rulemaking prior to their implementation beginning in FY 2020. Additionally, we stated that we would also update the relative weights and average length of stay values

associated with any revised CMG definitions in future rulemaking.

We have continued our contract with RTI to support us in developing proposed revisions to the CMGs used under the IRF PPS based on analysis of 2 years of data (FY 2017 and FY 2018). The process RTI uses for its analysis, which is based on a Classification and Regression Tree (CART) algorithm, is described in detail in the FY 2019 IRF PPS final rule (83 FR 38536 through 38540). RTI has used this analysis to revise the CMGs utilizing FY 2017 and FY 2018 claim and assessment data and to develop revised CMGs that reflect the use of the data items collected in the Quality Indicators section of the IRF–PAI, incorporating the proposed weighted motor score, described in section III.B of this proposed rule. To develop the proposed revised CMGs, RTI used CART analysis to divide patients into payment groups based on similarities in their clinical characteristics and relative costs. As part of this analysis, RTI imposed some typically-used constraints on the payment group divisions (for example, on the minimum number of cases that could be in the resulting payment groups and the minimum dollar payment amount differences between groups) to identify the optimal set of payment groups. For a more detailed discussion of the analysis used to revise the CMGs for FY 2020, we refer readers to the March 2019 technical report entitled, ''Analyses to Inform the Use of Standardized Patient Assessment Data Elements in the Inpatient Rehabilitation Facility Prospective Payment System'' available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Research.html.*

As noted in the FY 2019 IRF PPS final rule (83 FR 38533 through 38549), we finalized the construction of a motor score, a memory score, and a communication score to be considered for use in our ongoing analysis to revise the CMGs based on FY 2017 and FY 2018 data. In developing the proposed CMGs using both FY 2017 and FY 2018 data, cognitive status as reflected through the communication score emerged as a potential split point for CMGs in RICs 12 and 16 as shown in Table 2.

TABLE 2: CART-Based CMGs for RIC 12 (Osteoarthritis) and RIC 16 (Pain Syndrome)

RIC	CMG	Avg. Cost	Rule 1	Rule 2	Rule 3
12	01	$ 10,925.68	Motor>=59.45	Communication<7.50	
12	02	$ 12,833.57	Motor>=59.45	Communication>=7.50	
12	03	$ 13,403.56	Motor>=49.90	Motor<59.45	Age>=81.50
12	04	$ 14,842.63	Motor>=49.90	Motor<59.45	Age<81.50
12	05	$ 15,192.18	Motor<49.90	Communication<6.50	
12	06	$ 17,251.37	Motor<49.90	Communication>=6.50	
16	01	$ 11,459.93	Motor>=65.55		
16	02	$ 13,900.25	Motor>=56.65	Motor<65.55	
16	03	$ 14,922.40	Motor<56.65	Age>=71.50	Communication<6.50
16	04	$ 16,570.66	Motor<56.65	Age>=71.50	Communication>=6.50
16	05	$ 18,070.13	Motor<56.65	Age<71.50	

As similarly discussed in the FY 2019 IRF PPS final rule (83 FR 38537 through 38546), the inclusion of the communication score in these CMG definitions would result in lower payments for patients with higher cognitive deficits. As we believe it would be inappropriate to establish lower payments for patients with higher cognitive impairments, we are proposing to combine the CMGs within these RICs as shown in Table 3. As the CMGs we are proposing to combine within these RICs are only differentiated by a communication score, our proposal to consolidate the CMGs in these 2 RICs results in the exclusion of the communication score from the definitions of the proposed CMGs presented in Table 3 of this proposed rule. We would like to note that while the memory score did not emerge as a potential split point in the CART analysis and the communication score was not ultimately selected as a determinant for the proposed CMGs, both scores were considered as possible elements in developing the proposed CMGs.

After developing the revised CMGs, RTI calculated the relative weights and average length of stay values for each revised CMG using the same methodologies that we have used to update the CMG relative weights and average length of stay values each fiscal year since 2009 when we implemented an update to this methodology. More information about the methodology used to update the CMG relative weights can be found in the FY 2009 IRF PPS final rule (73 FR 46372 through 46374). For FY 2020, we propose to use the FY 2017 and FY 2018 IRF claims and FY 2017 IRF cost report data to update the CMG relative weights and average length of stay values. In calculating the CMG relative weights, we use a hospital-specific relative value method to estimate operating (routine and ancillary services) and capital costs of IRFs. As noted in the FY 2019 IRF PPS final rule (83 FR 38521), this is the same methodology that we have used to update the CMG relative weights and average length of stay values each fiscal year since we implemented an update to the methodology in the FY 2009 IRF PPS final rule (73 FR 46372 through 46374). More information on the methodology used to update calculate the CMG relative weights and average length of stay values can found in the March 2019 technical report entitled ''Analyses to Inform the Use of Standardized Patient Assessment Data Elements in the Inpatient Rehabilitation Facility Prospective Payment System'' available at *https://www.cms.gov/*

Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Research.html. Consistent with the methodology that we have used to update the IRF classification system in each instance in the past, we are proposing to update the relative weights associated with the revised CMGs for FY 2020 in a budget neutral manner by applying a budget neutrality factor to the standard payment amount. To calculate the appropriate budget neutrality factor for use in updating the FY 2020 CMG relative weights, we use the following steps:

Step 1. Calculate the estimated total amount of IRF PPS payments for FY 2020 (with no changes to the CMG relative weights).

Step 2. Calculate the estimated total amount of IRF PPS payments for FY 2020 by applying the changes to the CMGs and the associated CMG relative weights (as described in this proposed rule).

Step 3. Divide the amount calculated in step 1 by the amount calculated in step 2 to determine the budget neutrality factor (1.0016) that would maintain the same total estimated aggregate payments in FY 2020 with and without the changes to the CMGs and the associated CMG relative weights.

Step 4. Apply the budget neutrality factor (1.0016) to the FY 2019 IRF PPS standard payment amount after the application of the budget-neutral wage adjustment factor.

In section V.H. of this proposed rule, we discuss the proposed use of the existing methodology to calculate the standard payment conversion factor for FY 2020.

In Table 3, we present the proposed revised CMGs and their respective descriptions, as well as the comorbidity tiers, corresponding relative weights and the average length of stay values for each proposed CMG and tier for FY 2020. The average length of stay for each CMG is used to determine when an IRF discharge meets the definition of a short-stay transfer, which results in a per diem case level adjustment.

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TABLE 3: Proposed Relative Weights and Average Length of Stay Values for the Proposed Case-Mix Groups

CMG	CMG Description (M=motor, A=age)	Relative Weight				Average Length of Stay			
		Tier 1	Tier 2	Tier 3	No Comorbidity Tier	Tier 1	Tier 2	Tier 3	No Comorbidity Tier
0101	Stroke M >=72.00	1.0619	0.9248	0.8562	0.8152	11	11	10	10
0102	Stroke M >=63.90 and M <72.00	1.3354	1.1631	1.0768	1.0253	13	13	12	12
0103	Stroke M >=55.90 and M <63.90	1.5859	1.3812	1.2787	1.2175	15	15	14	14
0104	Stroke M >=50.40 and M <55.90	1.8612	1.6210	1.5008	1.4289	17	18	16	16
0105	Stroke M >=40.90 and M <50.40	2.2333	1.9450	1.8008	1.7146	20	21	19	19
0106	Stroke M <40.90 and A >=84.50	2.4326	2.1186	1.9615	1.8676	23	22	21	21
0107	Stroke M <40.90 and A <84.50	2.8402	2.4736	2.2902	2.1805	27	26	24	24
0201	Traumatic brain injury M >=65.20	1.3159	1.0824	0.9892	0.9214	12	13	11	11
0202	Traumatic brain injury M >=55.05 and M <65.20	1.6232	1.3351	1.2201	1.1365	14	15	14	13
0203	Traumatic brain injury M >=49.90 and M <55.05	1.8426	1.5156	1.3851	1.2902	16	17	15	15
0204	Traumatic brain injury M >=34.65 and M <49.90	2.1349	1.7560	1.6048	1.4949	20	20	17	17
0205	Traumatic brain injury M <34.65	2.6896	2.2123	2.0218	1.8832	32	24	22	19
0301	Non-traumatic brain injury M >=69.20	1.1831	0.9602	0.8920	0.8326	11	11	10	10
0302	Non-traumatic brain injury M >=54.40 and M <69.20	1.5158	1.2303	1.1428	1.0668	13	13	13	12
0303	Non-traumatic brain injury M >=44.65 and M <54.40	1.8380	1.4917	1.3857	1.2935	16	16	15	15
0304	Non-traumatic brain injury M <44.65 and A >=78.50	2.0873	1.6941	1.5737	1.4689	20	18	17	16
0305	Non-traumatic brain injury M <44.65 and A <78.50	2.2569	1.8317	1.7015	1.5883	21	20	18	17

CMG	CMG Description (M=motor, A=age)	Relative Weight				Average Length of Stay			
		Tier 1	Tier 2	Tier 3	No Comorbidity Tier	Tier 1	Tier 2	Tier 3	No Comorbidity Tier
0401	Traumatic spinal cord injury M >=59.15	1.3469	1.1477	1.0636	0.9766	13	12	12	12
0402	Traumatic spinal cord injury M >=46.35 and M <59.15	1.8182	1.5493	1.4358	1.3184	15	17	16	15
0403	Traumatic spinal cord injury M >=38.10 and M <46.35	2.4146	2.0575	1.9067	1.7508	23	23	20	19
0404	Traumatic spinal cord injury M <32.45 and A <61.50	3.1660	2.6978	2.5001	2.2956	34	31	28	23
0405	Traumatic spinal cord injury M >=32.45 and M <38.10	2.8545	2.4323	2.2541	2.0697	32	27	25	22
0406	Traumatic spinal cord injury M >=25.65 and M <32.45 and A >=61.50	3.2618	2.7794	2.5757	2.3651	37	32	27	26
0407	Traumatic spinal cord injury M <25.65 and A >=61.50	4.0436	3.4456	3.1931	2.9319	48	37	31	34
0501	Non-traumatic spinal cord injury M >=60.70	1.3019	1.0564	0.9906	0.9048	13	12	11	11
0502	Non-traumatic spinal cord injury M >=48.90 and M <60.70	1.7346	1.4075	1.3198	1.2055	16	15	15	14
0503	Non-traumatic spinal cord injury M >=40.40 and M <48.90	2.2683	1.8406	1.7259	1.5764	20	20	19	18
0504	Non-traumatic spinal cord injury M <40.40	2.8297	2.2961	2.1530	1.9666	29	24	23	21
0601	Neurological M >=66.60	1.3267	1.0265	0.9678	0.8781	12	11	11	10
0602	Neurological M >=53.90 and M <66.60	1.6480	1.2750	1.2022	1.0908	14	14	13	12

CMG	CMG Description (M=motor, A=age)	Relative Weight				Average Length of Stay			
		Tier 1	Tier 2	Tier 3	No Comorbidity Tier	Tier 1	Tier 2	Tier 3	No Comorbidity Tier
0603	Neurological M >=44.50 and M <53.90	1.9518	1.5101	1.4238	1.2918	16	16	15	14
0604	Neurological M <44.50	2.2464	1.7380	1.6387	1.4868	20	18	17	16
0701	Fracture of lower extremity M >=62.65	1.2794	1.0312	0.9863	0.8968	12	12	11	11
0702	Fracture of lower extremity M >=52.50 and M <62.65	1.6238	1.3089	1.2519	1.1383	15	15	14	13
0703	Fracture of lower extremity M >=44.00 and M <52.50	1.9191	1.5469	1.4795	1.3452	17	17	16	15
0704	Fracture of lower extremity M <44.00	2.1286	1.7157	1.6410	1.4921	18	18	17	17
0801	Replacement of lower extremity M >=69.00	1.0169	0.8507	0.7719	0.7148	10	10	9	9
0802	Replacement of lower extremity M >=56.80 and M <69.00	1.2485	1.0444	0.9477	0.8776	11	12	11	10
0803	Replacement of lower extremity M >=45.45 and M <56.80	1.5244	1.2752	1.1571	1.0716	14	14	13	12
0804	Replacement of lower extremity M <45.45	1.8673	1.5621	1.4175	1.3127	16	16	15	14
0901	Other orthopedic M >=64.95	1.2142	0.9706	0.9040	0.8322	11	11	10	10
0902	Other orthopedic M >=52.70 and M <64.95	1.5326	1.2251	1.1411	1.0504	13	14	13	12
0903	Other orthopedic M >=44.50 and M <52.70	1.8104	1.4471	1.3479	1.2408	16	16	15	14
0904	Other orthopedic M <44.50	2.0421	1.6324	1.5204	1.3996	18	17	16	16
1001	Amputation, lower extremity M >=64.00	1.3062	1.1101	1.0101	0.9273	12	13	11	11
1002	Amputation, lower extremity M >=51.90 and M <64.00	1.6752	1.4237	1.2954	1.1893	15	15	14	13

CMG	CMG Description (M=motor, A=age)	Relative Weight				Average Length of Stay			
		Tier 1	Tier 2	Tier 3	No Comorbidity Tier	Tier 1	Tier 2	Tier 3	No Comorbidity Tier
1003	Amputation, lower extremity M >=46.00 and M <51.90	1.9319	1.6419	1.4939	1.3716	17	18	16	15
1004	Amputation, lower extremity M <46.00	2.1597	1.8354	1.6701	1.5332	18	19	18	17
1101	Amputation, non-lower extremity M >=58.60	1.4170	1.1613	1.0781	0.9074	13	12	12	10
1102	Amputation, non-lower extremity M >=51.05 and M <58.60	1.8127	1.4856	1.3792	1.1608	16	15	14	13
1103	Amputation, non-lower extremity M <51.05	2.0274	1.6616	1.5426	1.2983	17	19	15	14
1201	Osteoarthritis M >=59.45	1.3177	1.0136	0.9807	0.9023	12	12	11	11
1202	Osteoarthritis M >=49.90 and M <59.45 and A >=81.50	1.6088	1.2376	1.1974	1.1017	14	14	13	13
1203	Osteoarthritis M >=49.90 and M <59.45 and A <81.50	1.6351	1.2578	1.2170	1.1197	13	14	14	12
1204	Osteoarthritis M <49.90	1.8585	1.4297	1.3833	1.2727	15	16	15	15
1301	Rheumatoid, other arthritis M >=64.35	1.1632	0.9757	0.9217	0.8541	10	10	10	10
1302	Rheumatoid, other arthritis M >=49.45 and M <64.35	1.4774	1.2394	1.1708	1.0848	13	15	13	12
1303	Rheumatoid, other arthritis M <49.45 and A >=73.50	1.8461	1.5486	1.4629	1.3555	14	18	16	15
1304	Rheumatoid, other arthritis M <49.45 and A <73.50	1.9350	1.6232	1.5334	1.4208	17	17	16	15
1401	Cardiac M >=68.80	1.1626	0.9450	0.8778	0.7879	11	11	10	9
1402	Cardiac M >=59.10 and M <68.80	1.4251	1.1584	1.0760	0.9658	13	13	12	11
1403	Cardiac M >=48.60 and M <59.10	1.6815	1.3668	1.2696	1.1396	15	15	14	13
1404	Cardiac M <48.60	1.9763	1.6065	1.4922	1.3394	18	17	15	14

CMG	CMG Description (M=motor, A=age)	Relative Weight				Average Length of Stay			
		Tier 1	Tier 2	Tier 3	No Comorbidity Tier	Tier 1	Tier 2	Tier 3	No Comorbidity Tier
1501	Pulmonary M >=69.70	1.2419	1.0543	0.9813	0.9318	11	11	10	10
1502	Pulmonary M >=57.15 and M <69.70	1.5077	1.2799	1.1913	1.1312	13	13	12	12
1503	Pulmonary M >=44.60 and M <57.15	1.7841	1.5145	1.4096	1.3386	15	14	14	14
1504	Pulmonary M <44.60	2.0487	1.7391	1.6187	1.5371	20	17	15	15
1601	Pain syndrome M >=65.55	1.1679	0.9313	0.8775	0.8092	10	11	10	10
1602	Pain syndrome M >=56.65 and M <65.55	1.4665	1.1694	1.1019	1.0160	14	12	12	12
1603	Pain syndrome M <56.65 and A >=71.50	1.7158	1.3682	1.2893	1.1888	13	14	14	14
1604	Pain syndrome M <56.65 and A <71.50	1.7564	1.4006	1.3197	1.2169	14	14	15	13
1701	Major multiple trauma without brain or spinal cord injury M >=59.70	1.3943	1.0931	1.0271	0.9379	12	12	12	11
1702	Major multiple trauma without brain or spinal cord injury M >=47.00 and M <59.70	1.8097	1.4187	1.3331	1.2173	15	15	15	14
1703	Major multiple trauma without brain or spinal cord injury M >=37.80 and M <47.00	2.1547	1.6892	1.5872	1.4494	19	19	17	16
1704	Major multiple trauma without brain or spinal cord injury M <37.80	2.3848	1.8696	1.7567	1.6042	21	20	19	17
1801	Major multiple trauma with brain or spinal cord injury M >=71.60	1.0749	0.9247	0.8435	0.7703	12	10	10	9

CMG	CMG Description (M=motor, A=age)	Relative Weight				Average Length of Stay			
		Tier 1	Tier 2	Tier 3	No Comorbidity Tier	Tier 1	Tier 2	Tier 3	No Comorbidity Tier
1802	Major multiple trauma with brain or spinal cord injury M >=56.30 and M <71.60	1.4822	1.2751	1.1632	1.0623	13	15	13	12
1803	Major multiple trauma with brain or spinal cord injury M >=43.40 and M <56.30	1.9134	1.6460	1.5015	1.3712	20	18	16	15
1804	Major multiple trauma with brain or spinal cord injury M >=38.55 and M <43.40	2.2702	1.9530	1.7815	1.6270	24	21	19	18
1805	Major multiple trauma with brain or spinal cord injury M >=30.30 and M <38.55	2.6189	2.2530	2.0552	1.8769	28	23	21	21
1806	Major multiple trauma with brain or spinal cord injury M <30.30	3.4786	2.9925	2.7299	2.4930	41	31	29	26
1901	Guillain-Barré M >=60.85	1.2923	1.0458	1.0194	0.9800	14	13	12	12
1902	Guillain-Barré M >=49.80 and M <60.85	1.8782	1.5199	1.4816	1.4244	18	17	15	16
1903	Guillain-Barré M >=40.80 and M <49.80	2.5312	2.0483	1.9967	1.9196	27	22	22	21
1904	Guillain-Barré M <40.80	3.5306	2.8571	2.7850	2.6775	40	30	29	29
2001	Miscellaneous M >=65.95	1.2374	1.0001	0.9368	0.8491	11	11	10	10
2002	Miscellaneous M >=55.30 and M <65.95	1.5236	1.2315	1.1535	1.0455	14	13	12	12
2003	Miscellaneous M >=46.80 and M <55.30	1.7648	1.4264	1.3361	1.2110	16	15	14	14
2004	Miscellaneous M <46.80 and A >=78.50	1.9471	1.5737	1.4740	1.3360	18	17	16	15

CMG	CMG Description (M=motor, A=age)	Relative Weight				Average Length of Stay			
		Tier 1	Tier 2	Tier 3	No Comorbidity Tier	Tier 1	Tier 2	Tier 3	No Comorbidity Tier
2005	Miscellaneous M <46.80 and A <78.50	2.0925	1.6912	1.5841	1.4358	19	18	16	16
2101	Burns M >=53.90	1.5396	1.2552	1.1924	1.0556	14	13	14	12
2102	Burns M <53.90	2.1835	1.7802	1.6912	1.4970	22	19	16	17
5001	Short-stay cases, length of stay is 3 days or fewer				0.1815				3
5101	Expired, orthopedic, length of stay is 13 days or fewer				0.5698				6
5102	Expired, orthopedic, length of stay is 14 days or more				1.7898				18
5103	Expired, not orthopedic, length of stay is 15 days or fewer				0.6737				7
5104	Expired, not orthopedic, length of stay is 16 days or more				2.1977				22

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A list of the FY 2019 CMGs can be found in the FY 2019 IRF PPS final rule (83 FR 38521 through 38523). The following would be the most significant differences between the FY 2019 CMGs and the proposed revised CMGs:

- There would be more CMGs than before (97 instead of 92 currently).
- There would be fewer CMGs in RICs 1, 2, 5, and 8 while there would be more CMGs in RICs 3, 4, 10, 11, 12, 13, 16, 18, 19, and 21.
- A patient's age would affect assignment for CMGs in RICs 1, 3, 4, 12, 13, 16, and 20 whereas it currently affects assignment for CMGs in RICs 1, 4, and 8.

We are proposing to utilize the CMGs identified in Table 3 to classify IRF patients for purposes of establishing payment under the IRF PPS beginning with FY 2020, that is, for all discharges on or after October 1, 2019. We are proposing to implement these revisions in a budget neutral manner. For more information on the specific impacts of this proposal, we refer readers to Table 4. We are also proposing to update the CMG relative weights and average length of stay values associated with the proposed CMGs based on the data items from the Quality Indicators section of the IRF–PAI.

TABLE 4—DISTRIBUTIONAL EFFECTS OF THE PROPOSED CHANGES TO THE CMGS

Facility classification	Number of IRFs	Number of cases	Estimated impact of proposed CMG revisions
(1)	(2)	(3)	(4)
Total	1,119	409,982	0.0
Urban unit	696	166,872	2.5
Rural unit	136	21,700	2.9
Urban hospital	276	216,894	−2.2
Rural hospital	11	4,516	−3.6
Urban For-Profit	357	211,280	−1.8
Rural For-Profit	36	7,920	0.1
Urban Non-Profit	522	150,310	1.6
Rural Non-Profit	90	15,166	2.2
Urban Government	93	22,176	3.1
Rural Government	21	3,130	4.1
Urban	972	383,766	−0.1

TABLE 4—DISTRIBUTIONAL EFFECTS OF THE PROPOSED CHANGES TO THE CMGS—Continued

Facility classification	Number of IRFs	Number of cases	Estimated impact of proposed CMG revisions
(1)	(2)	(3)	(4)
Rural	147	26,216	1.8
Urban by region			
Urban New England	29	16,260	−2.3
Urban Middle Atlantic	135	51,539	−1.6
Urban South Atlantic	147	77,315	−0.5
Urban East North Central	165	50,466	2.3
Urban East South Central	56	27,966	−0.6
Urban West North Central	74	20,822	1.0
Urban West South Central	184	84,068	−0.5
Urban Mountain	83	30,294	−0.6
Urban Pacific	99	25,036	2.1
Rural by region			
Rural New England	5	1,317	−2.4
Rural Middle Atlantic	12	1,248	1.2
Rural South Atlantic	16	3,639	−2.4
Rural East North Central	23	4,061	1.5
Rural East South Central	21	4,523	3.9
Rural West North Central	22	3,178	2.4
Rural West South Central	40	7,332	3.6
Rural Mountain	5	626	1.8
Rural Pacific	3	292	3.0
Teaching status			
Non-teaching	1,014	362,675	−0.2
Resident to ADC less than 10%	60	34,000	0.7
Resident to ADC 10%–19%	31	11,784	2.6
Resident to ADC greater than 19%	14	1,523	4.3
Disproportionate share patient percentage (DSH PP)			
DSH PP = 0%	29	5,300	−1.3
DSH PP <5%	139	60,003	−1.6
DSH PP 5%–10%	299	127,442	−0.7
DSH PP 10%–20%	371	139,001	0.0
DSH PP greater than 20%	281	78,236	2.1

Table 4 shows how we estimate that the application of the proposed revisions to the case-mix system for FY 2020 would affect particular groups. Table 4 categorizes IRFs by geographic location, including urban or rural location, and location for CMS's 9 Census divisions of the country. In addition, Table 4 divides IRFs into those that are separate rehabilitation hospitals (otherwise called freestanding hospitals in this section), those that are rehabilitation units of a hospital (otherwise called hospital units in this section), rural or urban facilities, ownership (otherwise called for-profit, non-profit, and government), by teaching status, and by disproportionate share patient percentage (DSH PP). The proposed changes to the case-mix classification system are expected to affect the overall distribution of payments across CMGs. Note that, because we propose to implement the revisions to the case-mix classification system in a budget-neutral manner, total estimated aggregate payments to IRFs would not be affected as a result of the proposed revisions to the CMGs and the CMG relative weights. However, these proposed revisions may affect the distribution of payments across CMGs. For a provider specific impact analysis of this proposed change, we refer readers to the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRF-Rules-and-Related-Files.html.*

We invite public comment on the proposed revisions to the CMGs based on analysis of 2 years of data (FYs 2017 and 2018) and the proposed updates to the relative weights and average length of stay values associated with the revised CMGs beginning with FY 2020, that is, for all discharges beginning on or after October 1, 2019.

IV. Facility-Level Adjustment Factors

Section 1886(j)(3)(A)(v) of the Act confers broad authority upon the Secretary to adjust the per unit payment rate by such factors as the Secretary determines are necessary to properly reflect variations in necessary costs of treatment among rehabilitation facilities. Under this authority, we currently adjust the prospective payment amount associated with a CMG to account for facility-level characteristics such as an IRF's LIP, teaching status, and location in a rural area, if applicable, as described in § 412.624(e).

Based on the substantive changes to the facility-level adjustment factors that were adopted in the FY 2014 IRF PPS final rule (78 FR 47860, 47868 through 47872), in the FY 2015 IRF PPS final rule (79 FR 45872, 45882 through 45883), we froze the facility-level adjustment factors at the FY 2014 levels for FY 2015 and all subsequent years (unless and until we propose to update them again through future notice-and-comment rulemaking). For FY 2020, we will continue to hold the adjustment factors at the FY 2014 levels as we continue to monitor the most current IRF claims data available and continue to evaluate and monitor the effects of the FY 2014 changes.

V. Proposed FY 2020 IRF PPS Payment Update

A. Background

Section 1886(j)(3)(C) of the Act requires the Secretary to establish an increase factor that reflects changes over time in the prices of an appropriate mix of goods and services included in the covered IRF services. According to section 1886(j)(3)(A)(i) of the Act, the increase factor shall be used to update the IRF prospective payment rates for each FY. Section 1886(j)(3)(C)(ii)(I) of the Act requires the application of a productivity adjustment. Thus, we propose to update the IRF PPS payments for FY 2020 by a market basket increase factor as required by section 1886(j)(3)(C) of the Act based upon the most current data available, with a productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act.

We have utilized various market baskets through the years in the IRF PPS. For a discussion of these market baskets, we refer readers to the FY 2016 IRF PPS final rule (80 FR 47046).

Beginning with FY 2016, we finalized the use of a 2012-based IRF market basket, using Medicare cost report data for both freestanding and hospital-based IRFs (80 FR 47049 through 47068). Beginning with FY 2020, we are proposing to rebase and revise the IRF market basket to reflect a 2016 base year. In the following discussion, we provide an overview of the proposed market basket and describe the methodologies used to determine the operating and capital portions of the proposed 2016-based IRF market basket.

B. Overview of the Proposed 2016-Based IRF Market Basket

The proposed 2016-based IRF market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres 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 relative to a base period are not measured.

The index itself is constructed in three steps. First, a base period is selected (in this proposed rule, the base period is 2016), total base period costs are estimated for a set of mutually exclusive and exhaustive cost categories, and each category is calculated as a proportion of total costs. These proportions are called cost weights. Second, each cost category is matched to an appropriate price or wage variable, referred to as a price proxy. In nearly every instance where we have selected price proxies for the various market baskets, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). In cases where a publicly available price series is not available (for example, a price index for malpractice insurance), we have collected price data from other sources and subsequently developed our own index to capture changes in prices for these types of costs. Finally, the cost weight for each cost category is multiplied by the established price proxy. The sum of these products (that is, the cost weights multiplied by their price levels) for all cost categories yields the composite index level of the market basket for the given time period. Repeating this step for other periods produces a series of market basket levels over time. Dividing the composite index level of one period by the composite index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As previously noted, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to furnish IRF services. The effects on total costs resulting from changes in the mix of goods and services purchased after the base period are not measured. For example, an IRF hiring more nurses after the base period to accommodate the needs of patients would increase the volume of goods and services purchased by the IRF, but would not be factored into the price change measured by a fixed-weight IRF market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect recent changes in the mix of goods and services that IRFs purchase (hospital inputs) to furnish inpatient care between base periods.

C. Proposed Rebasing and Revising of the IRF PPS Market Basket

As discussed in the FY 2016 IRF PPS final rule (80 FR 47050), the 2012-based IRF market basket reflects the Medicare cost reports for both freestanding and hospital-based facilities.

Beginning with FY 2020, we are proposing to rebase and revise the 2012-based IRF market basket to a 2016 base year reflecting both freestanding and hospital-based IRFs. Below we provide a detailed description of our methodology used to develop the proposed 2016-based IRF market basket. This proposed methodology is generally similar to the methodology used to develop the 2012-based IRF market basket with the exception of the proposed derivation of the Home Office Contract Labor cost weight using the Medicare cost report data as described in section V.C.a.(6) of this proposed rule.

1. Development of Cost Categories and Weights for the Proposed 2016-Based IRF Market Basket

a. Use of Medicare Cost Report Data

We are proposing a 2016-based IRF market basket that consists of seven major cost categories and a residual derived from the 2016 Medicare cost reports (CMS Form 2552–10) for freestanding and hospital-based IRFs. The seven cost categories are Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals, Professional Liability Insurance (PLI), Home Office Contract Labor, and Capital. The residual category reflects all remaining costs not captured in the seven cost categories. The 2016 cost reports include providers whose cost reporting period began on or after October 1, 2015, and prior to September 30, 2016. We selected 2016 as the base year because we believe that the Medicare cost reports for this year represent the most recent, complete set of Medicare cost report data available for developing the proposed IRF market basket at this time.

Since our goal is to establish cost weights that were reflective of case mix and practice patterns associated with the services IRFs provide to Medicare beneficiaries, as we did for the 2012-based IRF market basket, we are proposing to limit the cost reports used to establish the 2016-based IRF market basket to those from facilities that had a Medicare average length of stay (LOS) that was relatively similar to their

facility average LOS. We believe that this requirement eliminates statistical outliers and ensures a more accurate market basket that reflects the costs generally incurred during a Medicare-covered stay. The Medicare average LOS for freestanding IRFs is calculated from data reported on line 14 of Worksheet S–3, part I. The Medicare average LOS for hospital-based IRFs is calculated from data reported on line 17 of Worksheet S–3, part I. We propose to include the cost report data from IRFs with a Medicare average LOS within 15 percent (that is, 15 percent higher or lower) of the facility average LOS to establish the sample of providers used to estimate the 2016-based IRF market basket cost weights. We are proposing to apply this LOS edit to the data for IRFs to exclude providers that serve a population whose LOS would indicate that the patients served are not consistent with a LOS of a typical Medicare patient. We note that this is the same LOS edit that we applied to develop the 2012-based IRF market basket. This process resulted in the exclusion of about eight percent of the freestanding and hospital-based IRF Medicare cost reports. Of those excluded, about 18 percent were freestanding IRFs and 82 percent were hospital-based IRFs. This ratio is relatively consistent with the ratio of the universe of freestanding to hospital-based IRF providers.

We then used the cost reports for IRFs that met this requirement to calculate the costs for the seven major cost categories (Wages and Salaries, Employee Benefits, Contract Labor, Professional Liability Insurance, Pharmaceuticals, Home Office Contract Labor, and Capital) for the market basket. For comparison, the 2012-based IRF market basket utilized the Bureau of Economic Analysis Benchmark Input-Output data rather than Medicare cost report data to derive the Home Office Contract Labor cost weight. A more detailed discussion of this methodological change is provided in section V.C.1.a.(6). of this proposed rule.

Similar to the 2012-based IRF market basket major cost weights, the proposed 2016-based IRF market basket cost weights reflect Medicare allowable costs (routine, ancillary and capital)—costs that are eligible for reimbursement through the IRF PPS. We propose to define Medicare allowable costs for freestanding facilities as the following lines on Worksheet A and Worksheet, part I (CMS Form 2552–10): 30 through 35, 50 through 76 (excluding 52 and 75), 90 through 91 and 93. We propose to define Medicare allowable costs for hospital-based facilities as the following lines on Worksheet A and Worksheet B, part I (CMS Form 2552–10): 41, 50 through 76 (excluding 52 and 75), 90 through 91, and 93.

For freestanding IRFs, total Medicare allowable costs would be equal to the total costs as reported on Worksheet B, part I, column 26 for the lines listed above. For hospital-based IRFs, total Medicare allowable costs would be equal to total costs for the IRF inpatient unit after the allocation of overhead costs (Worksheet B, part I, column 26, line 41) and a proportion of total ancillary costs. We propose to calculate the portion of ancillary costs attributable to the hospital-based IRF for a given ancillary cost center by multiplying total facility ancillary costs for the specific cost center (as reported on Worksheet B, part I, column 26) by the ratio of IRF Medicare ancillary costs for the cost center (as reported on Worksheet D–3, column 3 for hospital-based IRFs) to total Medicare ancillary costs for the cost center (equal to the sum of Worksheet D–3, column 3 for all relevant PPS [that is, IPPS, IRF, IPF and skilled nursing facility (SNF)]). We propose to use these methods to derive levels of total costs for IRF providers. This is the same methodology used for the 2012-based IRF market basket. With this work complete, we then set about deriving cost levels for the seven major cost categories and then derive a residual cost weight reflecting all other costs not classified.

(1) Wages and Salaries Costs

For freestanding IRFs, we are proposing to derive Wages and Salaries costs as the sum of routine inpatient salaries, ancillary salaries, and a proportion of overhead (or general service cost centers in the Medicare cost reports) salaries as reported on Worksheet A, column 1. Since overhead salary costs are attributable to the entire IRF, we only include the proportion attributable to the Medicare allowable cost centers. We are proposing to estimate the proportion of overhead salaries that are attributed to Medicare allowable costs centers by multiplying the ratio of Medicare allowable area salaries (Worksheet A, column 1, lines 50 through 76 (excluding 52 and 75), 90 through 91, and 93) to total salaries (Worksheet A, column 1, line 200) times total overhead salaries (Worksheet A, column 1, lines 4 through 18). This is the same methodology used in the 2012-based IRF market basket.

For hospital-based IRFs, we are proposing to derive Wages and Salaries costs as the sum of inpatient routine salary costs (Worksheet A, column 1, line 41) for the hospital-based IRF and the overhead salary costs attributable to this IRF inpatient unit; and ancillary salaries plus a portion of overhead salary costs attributable to the ancillary departments utilized by the hospital-based IRF.

We are proposing to calculate hospital-based ancillary salary costs for a specific cost center (Worksheet A, column 1, lines 50 through 76 (excluding 52 and 75), 90 through 91, and 93) using salary costs from Worksheet A, column 1, multiplied by the ratio of IRF Medicare ancillary costs for the cost center (as reported on Worksheet D–3, column 3, for IRF subproviders) to total Medicare ancillary costs for the cost center (equal to the sum of Worksheet D–3, column 3, for all relevant PPS units [that is, IPPS, IRF, IPF and a SNF]). For example, if hospital-based IRF Medicare physical therapy costs represent 30 percent of the total Medicare physical therapy costs for the entire facility, then 30 percent of total facility physical therapy salaries (as reported in Worksheet A, column 1, line 66) would be attributable to the hospital-based IRF. We believe it is appropriate to use only a portion of the ancillary costs in the market basket cost weight calculations since the hospital-based IRF only utilizes a portion of the facility's ancillary services. We believe the ratio of reported IRF Medicare costs to reported total Medicare costs provides a reasonable estimate of the ancillary services utilized, and costs incurred, by the hospital-based IRF.

We are proposing to calculate the portion of overhead salary costs attributable to hospital-based IRFs by first calculating total noncapital overhead costs (Worksheet B, part I, columns 4–18, line 41, less Worksheet B, part II, columns 4–18, line 41). We then multiply total noncapital overhead costs by an overhead ratio equal to the ratio of total facility overhead salaries (as reported on Worksheet A, column 1, lines 4–18) to total facility noncapital overhead costs (as reported on Worksheet A, column 1 and 2, lines 4–18). This methodology assumes the proportion of total costs related to salaries for the overhead cost center is similar for all inpatient units (that is, acute inpatient or inpatient rehabilitation).

We are proposing to calculate the portion of overhead salaries attributable to each ancillary department by first calculating total noncapital overhead costs attributable to each specific ancillary department (Worksheet B, part I, columns 4–18 less, Worksheet B, part II, columns 4–18). We then identify the portion of these noncapital overhead

costs attributable to Wages and Salaries by multiplying these costs by the overhead ratio defined as the ratio of total facility overhead salaries (as reported on Worksheet A, column 1, lines 4–18) to total overhead costs (as reported on Worksheet A, column 1 & 2, lines 4–18). Finally, we identified the portion of these overhead salaries for each ancillary department that is attributable to the hospital-based IRF by multiplying by the ratio of IRF Medicare ancillary costs for the cost center (as reported on Worksheet D–3, column 3, for hospital-based IRFs) to total Medicare ancillary costs for the cost center (equal to the sum of Worksheet D–3, column 3, for all relevant PPS units [that is, IPPS, IRF, IPF and SNF]). This is the same methodology used to derive the 2012-based IRF market basket.

(2) Employee Benefits Costs

Effective with the implementation of CMS Form 2552–10, we began collecting Employee Benefits and Contract Labor data on Worksheet S–3, part V.

For 2016 Medicare cost report data, the majority of providers did not report data on Worksheet S–3, part V; particularly, approximately 48 percent of freestanding IRFs and 40 percent of hospital-based IRFs reported data on Worksheet S–3, part V. However, we believe we have a large enough sample to enable us to produce a reasonable Employee Benefits cost weight. Again, we continue to encourage all providers to report these data on the Medicare cost report.

For freestanding IRFs, we are proposing Employee Benefits costs would be equal to the data reported on Worksheet S–3, part V, column 2, line 2. We note that while not required to do so, freestanding IRFs also may report Employee Benefits data on Worksheet S–3, part II, which is applicable to only IPPS providers. For those freestanding IRFs that report Worksheet S–3, part II, data, but not Worksheet S–3, part V, we are proposing to use the sum of Worksheet S–3, part II, lines 17, 18, 20, and 22, to derive Employee Benefits costs. This proposed method would allow us to obtain data from about 30 more freestanding IRFs than if we were to only use the Worksheet S–3, part V, data as was done for the 2012-based IRF market basket.

For hospital-based IRFs, we are proposing to calculate total benefit costs as the sum of inpatient unit benefit costs, a portion of ancillary benefits, and a portion of overhead benefits attributable to the routine inpatient unit and a portion of overhead benefits attributable to the ancillary departments. We are proposing inpatient unit benefit costs be equal to Worksheet S–3, part V, column 2, line 4. We are proposing that the portion of overhead benefits attributable to the routine inpatient unit and ancillary departments be calculated by multiplying ancillary salaries for the hospital-based IRF and overhead salaries attributable to the hospital-based IRF (determined in the derivation of hospital-based IRF Wages and Salaries costs as described above) by the ratio of total facility benefits to total facility salaries. Total facility benefits is equal to the sum of Worksheet S–3, part II, column 4, lines 17–25, and total facility salaries is equal to Worksheet S–3, part II, column 4, line 1.

(3) Contract Labor Costs

Contract Labor costs are primarily associated with direct patient care services. Contract labor costs for other services such as accounting, billing, and legal are calculated separately using other government data sources as described in section V.C.3. of this proposed rule. To derive contract labor costs using Worksheet S–3, part V, data, for freestanding IRFs, we are proposing Contract Labor costs be equal to Worksheet S–3, part V, column 1, line 2. As we noted for Employee Benefits, freestanding IRFs also may report Contract Labor data on Worksheet S–3, part II, which is applicable to only IPPS providers. For those freestanding IRFs that report Worksheet S–3, part II data, but not Worksheet S–3, part V, we are proposing to use the sum of Worksheet S–3, part II, lines 11 and 13, to derive Contract Labor costs.

For hospital-based IRFs, we are proposing that Contract Labor costs would be equal to Worksheet S–3, part V, column 1, line 4. As previously noted, for 2016 Medicare cost report data, while there were providers that did report data on Worksheet S–3, part V, many providers did not complete this worksheet. However, we believe we have a large enough sample to enable us to produce a reasonable Contract Labor cost weight. We continue to encourage all providers to report these data on the Medicare cost report.

(4) Pharmaceuticals Costs

For freestanding IRFs, we are proposing to calculate pharmaceuticals costs using non-salary costs reported on Worksheet A, column 7, less Worksheet A, column 1, for the pharmacy cost center (line 15) and drugs charged to patients cost center (line 73).

For hospital-based IRFs, we are proposing to calculate pharmaceuticals costs as the sum of a portion of the non-salary pharmacy costs and a portion of the non-salary drugs charged to patient costs reported for the total facility. We propose that non-salary pharmacy costs attributable to the hospital-based IRF would be calculated by multiplying total pharmacy costs attributable to the hospital-based IRF (as reported on Worksheet B, part I, column 15, line 41) by the ratio of total non-salary pharmacy costs (Worksheet A, column 2, line 15) to total pharmacy costs (sum of Worksheet A, columns 1 and 2 for line 15) for the total facility. We propose that non-salary drugs charged to patient costs attributable to the hospital-based IRF would be calculated by multiplying total non-salary drugs charged to patient costs (Worksheet B, part I, column 0, line 73 plus Worksheet B, part I, column 15, line 73, less Worksheet A, column 1, line 73) for the total facility by the ratio of Medicare drugs charged to patient ancillary costs for the IRF unit (as reported on Worksheet D–3 for hospital-based IRFs, column 3, line 73) to total Medicare drugs charged to patient ancillary costs for the total facility (equal to the sum of Worksheet D–3, column 3, line 73 for all relevant PPS [that is, IPPS, IRF, IPF and SNF]).

(5) Professional Liability Insurance Costs

For freestanding IRFs, we are proposing that Professional Liability Insurance (PLI) costs (often referred to as malpractice costs) would be equal to premiums, paid losses and self-insurance costs reported on Worksheet S–2, columns 1 through 3, line 118. For hospital-based IRFs, we are proposing to assume that the PLI weight for the total facility is similar to the hospital-based IRF unit since the only data reported on this worksheet is for the entire facility, as we currently have no means to identify the proportion of total PLI costs that are only attributable to the hospital-based IRF. Therefore, hospital-based IRF PLI costs are equal to total facility PLI (as reported on Worksheet S–2, columns 1 through 3, line 118) divided by total facility costs (as reported on Worksheet A, columns 1 and 2, line 200) times hospital-based IRF Medicare allowable total costs. Our assumption is that the same proportion of expenses are used among each unit of the hospital. We welcome comments on this proposed method of deriving the PLI costs for hospital-based IRFs.

(6) Home Office/Related Organization Contract Labor Costs

For the 2016-based IRF market basket, we are proposing to determine the home office/related organization contract

labor costs using Medicare cost report data. The 2012-based IRF market basket used the 2007 Benchmark Input-Output (I–O) expense data published by the Bureau of Economic Analysis (BEA) to derive these costs (80 FR 47057). A more detailed explanation of the general methodology using the BEA I–O data is provided in section V.C.3. of this proposed rule. For freestanding and hospital-based IRFs, we are proposing to calculate the home office contract labor cost weight (using data reported on Worksheet S–3, part II, column 4, lines 14, 1401, 1402, 2550, and 2551) and total facility costs (Worksheet B, part 1, column 26, line 202). We are proposing to use total facility costs as the denominator for calculating the home office contract labor cost weight as these expenses reported on Worksheet S–3, part II reflect the entire hospital facility. Our assumption is that the same proportion of expenses are used among each unit of the hospital. For the 2012-based IRF market basket, we calculated the home office cost weight using expense data for North American Industry Classification System (NAICS) code 55, Management of Companies and Enterprises (80 FR 47067).

(7) Capital Costs

For freestanding IRFs, we are proposing that capital costs would be equal to Medicare allowable capital costs as reported on Worksheet B, part II, column 26, lines 30 through 35, 50 through 76 (excluding 52 and 75), 90 through 91, and 93.

For hospital-based IRFs, we are proposing that capital costs would be equal to IRF inpatient capital costs (as reported on Worksheet B, part II, column 26, line 41) and a portion of IRF ancillary capital costs. We calculate the portion of ancillary capital costs attributable to the hospital-based IRF for a given cost center by multiplying total facility ancillary capital costs for the specific ancillary cost center (as reported on Worksheet B, part II, column 26) by the ratio of IRF Medicare ancillary costs for the cost center (as reported on Worksheet D–3, column 3 for hospital-based IRFs) to total Medicare ancillary costs for the cost center (equal to the sum of Worksheet D–3, column 3 for all relevant PPS [that is, IPPS, IRF, IPF and SNF]). For example, if hospital-based IRF Medicare physical therapy costs represent 30 percent of the total Medicare physical therapy costs for the entire facility, then 30 percent of total facility physical therapy capital costs (as reported in Worksheet B, part II, column 26, line 66) would be attributable to the hospital-based IRF.

b. Final Major Cost Category Computation

After we derive costs for the major cost categories for each provider using the Medicare cost report data as previously described, we propose to trim the data for outliers. For the Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals, Professional Liability Insurance, and Capital cost weights, we first divide the costs for each of these six categories by total Medicare allowable costs calculated for the provider to obtain cost weights for the universe of IRF providers. We then remove those providers whose derived cost weights fall in the top and bottom 5 percent of provider specific derived cost weights to ensure the exclusion of outliers. After the outliers have been excluded, we sum the costs for each category across all remaining providers. We then divide this by the sum of total Medicare allowable costs across all remaining providers to obtain a cost weight for the proposed 2016-based IRF market basket for the given category.

The proposed trimming methodology for the Home Office Contract Labor cost weight is slightly different than the proposed trimming methodology for the other six cost categories as described above. For the Home Office Contract Labor cost weight, since we are using total facility data rather than Medicare-allowable costs associated with IRF services, we are proposing to trim the freestanding and hospital-based IRF cost weights separately. For each of the providers, we first divide the home office contract labor costs by total facility costs to obtain a Home Office Contract Labor cost weight for the universe of IRF providers. We are then proposing to trim only the top 1 percent of providers to exclude outliers while also allowing providers who have reported zero home office costs to remain in the Home Office Contract Labor cost weight calculations as not all providers will incur home office costs. After removing these outliers, we are left with a trimmed data set for both freestanding and hospital-based providers. We are then proposing to sum the costs for each category (freestanding and hospital-based) across all remaining providers. We next divide this by the sum of total facility costs across all remaining providers to obtain a freestanding and hospital-based cost weight. Lastly, we are proposing to weight these two cost weights together using the Medicare-allowable costs to derive a Home Office Contract Labor cost weight for the proposed 2016-based IRF market basket.

Finally, we calculate the residual ''All Other'' cost weight that reflects all remaining costs that are not captured in the seven cost categories listed. See Table 5 for the resulting cost weights for these major cost categories that we obtain from the Medicare cost reports.

TABLE 5—MAJOR COST CATEGORIES AS DERIVED FROM MEDICARE COST REPORTS

Major cost categories	Proposed 2016-based IRF market basket (percent)	2012-based IRF market basket (percent)
Wages and Salaries	47.1	47.3
Employee Benefits	11.3	11.2
Contract Labor	1.0	0.8
Professional Liability Insurance (Malpractice)	0.7	0.9
Pharmaceuticals	5.1	5.1
Home Office Contract Labor	3.7	n/a
Capital	9.0	8.6
All Other	22.2	26.1

* Total may not sum to 100 due to rounding.

As we did for the 2012-based IRF market basket, we are proposing to allocate the Contract Labor cost weight to the Wages and Salaries and Employee Benefits cost weights based on their relative proportions under the

assumption that contract labor costs are comprised of both wages and salaries and employee benefits. The Contract Labor allocation proportion for Wages and Salaries is equal to the Wages and Salaries cost weight as a percent of the sum of the Wages and Salaries cost weight and the Employee Benefits cost weight. For this proposed rule, this rounded percentage is 81 percent; therefore, we are proposing to allocate 81 percent of the Contract Labor cost weight to the Wages and Salaries cost weight and 19 percent to the Employee Benefits cost weight. The 2012-based IRF market basket percentage was also 81 percent (80 FR 47056). Table 6 shows the Wages and Salaries and Employee Benefit cost weights after Contract Labor cost weight allocation for both the proposed 2016-based IRF market basket and 2012-based IRF market basket.

TABLE 6—WAGES AND SALARIES AND EMPLOYEE BENEFITS COST WEIGHTS AFTER CONTRACT LABOR ALLOCATION

Major cost categories	Proposed 2016-based IRF market basket	2012-based IRF market basket
Wages and Salaries	47.9	47.9
Employee Benefits	11.4	11.3

c. Derivation of the Detailed Operating Cost Weights

To further divide the ''All Other'' residual cost weight estimated from the 2016 Medicare cost report data into more detailed cost categories, we propose to use the 2012 Benchmark Input-Output (I–O) ''Use Tables/Before Redefinitions/Purchaser Value'' for NAICS 622000, Hospitals, published by the Bureau of Economic Analysis (BEA). This data is publicly available at *http://www.bea.gov/industry/io_annual.htm.* For the 2012-based IRF market basket, we used the 2007 Benchmark I–O data, the most recent data available at the time (80 FR 47057).

The BEA Benchmark I–O data are scheduled for publication every 5 years with the most recent data available for 2012. The 2007 Benchmark I–O data are derived from the 2012 Economic Census and are the building blocks for BEA's economic accounts. Thus, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed.[1] BEA also produces Annual I–O estimates; however, while based on a similar methodology, these estimates reflect less comprehensive and less detailed data sources and are subject to revision when benchmark data becomes available. Instead of using the less detailed Annual I–O data, we propose to inflate the 2012 Benchmark I–O data forward to 2016 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2012 Benchmark I–O data. We repeat this practice for each year. We then propose to calculate the cost shares that each cost category represents of the inflated 2012 data. These resulting 2016 cost shares are applied to the All Other residual cost weight to obtain the proposed detailed cost weights for the 2016-based IRF market basket. For example, the cost for Food: Direct Purchases represents 5.0 percent of the sum of the ''All Other'' 2012 Benchmark I–O Hospital Expenditures inflated to 2016; therefore, the Food: Direct Purchases cost weight represents 5.0 percent of the 2016-based IRF market basket's ''All Other'' cost category (22.2 percent), yielding a ''final'' Food: Direct Purchases cost weight of 1.1 percent in the proposed 2016-based IRF market basket (0.05 * 22.2 percent = 1.1 percent).

Using this methodology, we propose to derive seventeen detailed IRF market basket cost category weights from the proposed 2016-based IRF market basket residual cost weight (22.2 percent). These categories are: (1) Electricity, (2) Fuel, Oil, and Gasoline (3) Food: Direct Purchases, (4) Food: Contract Services, (5) Chemicals, (6) Medical Instruments, (7) Rubber & Plastics, (8) Paper and Printing Products, (9) Miscellaneous Products, (10) Professional Fees: Labor-related, (11) Administrative and Facilities Support Services, (12) Installation, Maintenance, and Repair, (13) All Other Labor-related Services, (14) Professional Fees: Nonlabor-related, (15) Financial Services, (16) Telephone Services, and (17) All Other Nonlabor-related Services. We note that for the 2012-based IRF market basket, we had a Water and Sewerage cost weight. For the proposed 2016-based IRF market basket, we are proposing to include Water and Sewerage costs in the Electricity cost weight due to the small amount of costs in this category.

For the 2012-based IRF market basket, we used the I–O data for NAICS 55 Management of Companies to derive the Home Office Contract Labor cost weight, which were classified in the Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost weights. As previously discussed, we are proposing to use the Medicare cost report data to derive the Home Office Contract Labor cost weight, which we would further classify into the Professional Fees: Labor-related or Professional Fees: Nonlabor-related categories.

d. Derivation of the Detailed Capital Cost Weights

As described in section V.C.1.a.(6) of this proposed rule, we are proposing a Capital-Related cost weight of 9.0 percent as obtained from the 2016 Medicare cost reports for freestanding and hospital-based IRF providers. We are proposing to then separate this total Capital-Related cost weight into more detailed cost categories.

Using 2016 Medicare cost reports, we are able to group Capital-Related costs into the following categories: Depreciation, Interest, Lease, and Other Capital-Related costs. For each of these categories, we are proposing to determine separately for hospital-based IRFs and freestanding IRFs what proportion of total capital-related costs the category represents.

For freestanding IRFs, we are proposing to derive the proportions for Depreciation, Interest, Lease, and Other Capital-related costs using the data reported by the IRF on Worksheet A–7, which is similar to the methodology used for the 2012-based IRF market basket.

For hospital-based IRFs, data for these four categories are not reported separately for the hospital-based IRF; therefore, we are proposing to derive these proportions using data reported on Worksheet A–7 for the total facility. We are assuming the cost shares for the overall hospital are representative for the hospital-based IRF unit. For example, if depreciation costs make up 60 percent of total capital costs for the entire facility, we believe it is

[1] *http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.*

reasonable to assume that the hospital-based IRF would also have a 60 percent proportion because it is a unit contained within the total facility. This is the same methodology used for the 2012-based IRF market basket (80 FR 47057).

To combine each detailed capital cost weight for freestanding and hospital-based IRFs into a single capital cost weight for the proposed 2016-based IRF market basket, we are proposing to weight together the shares for each of the categories (Depreciation, Interest, Lease, and Other Capital-related costs) based on the share of total capital costs each provider type represents of the total capital costs for all IRFs for 2016. Applying this methodology results in proportions of total capital-related costs for Depreciation, Interest, Lease and Other Capital-related costs that are representative of the universe of IRF providers. This is the same methodology used for the 2012-based IRF market basket (80 FR 47057 through 47058).

Lease costs are unique in that they are not broken out as a separate cost category in the proposed 2016-based IRF market basket. Rather, we are proposing to proportionally distribute these costs among the cost categories of Depreciation, Interest, and Other Capital-Related, reflecting the assumption that the underlying cost structure of leases is similar to that of capital-related costs in general. As was done under the 2012-based IRF market basket, we are proposing to assume that 10 percent of the lease costs as a proportion of total capital-related costs represents overhead and assign those costs to the Other Capital-Related cost category accordingly. We propose to distribute the remaining lease costs proportionally across the three cost categories (Depreciation, Interest, and Other Capital-Related) based on the proportion that these categories comprise of the sum of the Depreciation, Interest, and Other Capital-related cost categories (excluding lease expenses). This would result in three primary capital-related cost categories in the proposed 2016-based IRF market basket: Depreciation, Interest, and Other Capital-Related costs. This is the same methodology used for the 2012-based IRF market basket (80 FR 47058). The allocation of these lease expenses are shown in Table 6.

Finally, we are proposing to further divide the Depreciation and Interest cost categories. We are proposing to separate Depreciation into the following two categories: (1) Building and Fixed Equipment and (2) Movable Equipment. We are proposing to separate Interest into the following two categories: (1) Government/Nonprofit and (2) For-profit.

To disaggregate the Depreciation cost weight, we need to determine the percent of total Depreciation costs for IRFs that is attributable to Building and Fixed Equipment, which we hereafter refer to as the ''fixed percentage.'' For the proposed 2016-based IRF market basket, we are proposing to use slightly different methods to obtain the fixed percentages for hospital-based IRFs compared to freestanding IRFs.

For freestanding IRFs, we are proposing to use depreciation data from Worksheet A–7 of the 2016 Medicare cost reports. However, for hospital-based IRFs, we determined that the fixed percentage for the entire facility may not be representative of the hospital-based IRF unit due to the entire facility likely employing more sophisticated movable assets that are not utilized by the hospital-based IRF. Therefore, for hospital-based IRFs, we are proposing to calculate a fixed percentage using: (1) Building and fixture capital costs allocated to the hospital-based IRF unit as reported on Worksheet B, part I, line 41, and (2) building and fixture capital costs for the top five ancillary cost centers utilized by hospital-based IRFs. We propose to weight these two fixed percentages (inpatient and ancillary) using the proportion that each capital cost type represents of total capital costs in the proposed 2016-based IRF market basket. We are proposing to then weight the fixed percentages for hospital-based and freestanding IRFs together using the proportion of total capital costs each provider type represents. For both freestanding and hospital-based IRFs, this is the same methodology used for the 2012-based IRF market basket (80 FR 47058).

To disaggregate the Interest cost weight, we determined the percent of total interest costs for IRFs that are attributable to government and nonprofit facilities, which is hereafter referred to as the ''nonprofit percentage,'' as price pressures associated with these types of interest costs tend to differ from those for for-profit facilities. For the 2016-based IRF market basket, we are proposing to use interest costs data from Worksheet A–7 of the 2016 Medicare cost reports for both freestanding and hospital-based IRFs. We are proposing to determine the percent of total interest costs that are attributed to government and nonprofit IRFs separately for hospital-based and freestanding IRFs. We then are proposing to weight the nonprofit percentages for hospital-based and freestanding IRFs together using the proportion of total capital costs that each provider type represents.

Table 7 provides the proposed detailed capital cost share composition estimated from the 2016 IRF Medicare cost reports. These detailed capital cost share composition percentages are applied to the total Capital-Related cost weight of 9.0 percent explained in detail in section V.C.1.a.(6) of this proposed rule.

TABLE 7—CAPITAL COST SHARE COMPOSITION FOR THE PROPOSED 2016-BASED IRF MARKET BASKET

	Capital cost share composition before lease expense allocation (%)	Capital cost share composition after lease expense allocation (%)
Depreciation	59	73
Building and Fixed Equipment	37	45
Movable Equipment	22	28
Interest	13	16
Government/Nonprofit	8	9
For Profit	5	7
Lease	21	
Other	7	11

* Detail may not add to total due to rounding.

e. Proposed 2016-Based IRF Market Basket Cost Categories and Weights

Table 8 compares the cost categories and weights for the proposed 2016-based IRF market basket compared to the 2012-based IRF market basket.

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TABLE 8: Proposed 2016-based IRF Market Basket Cost Weights Compared to 2012-based IRF Market Basket Cost Weights

Cost Category	Proposed 2016-based IRF Market Basket Cost Weight	2012-based IRF Market Basket Cost Weight
Total	**100.0**	**100.0**
Compensation	**59.4**	**59.2**
Wages and Salaries	47.9	47.9
Employee Benefits	11.4	11.3
Utilities	**1.4**	**2.1**
Electricity	1.0	1.0
Fuel, Oil, and Gasoline	0.4	1.1
Water & Sewerage	n/a	0.1
Professional Liability Insurance	**0.7**	**0.9**
All Other Products and Services	**29.5**	**29.1**
All Other Products	**12.5**	**13.3**
Pharmaceuticals	5.1	5.1
Food: Direct Purchases	1.1	1.7
Food: Contract Services	1.2	1.0
Chemicals	0.4	0.7
Medical Instruments	2.9	2.3
Rubber & Plastics	0.4	0.6
Paper and Printing Products	0.6	1.1
Miscellaneous Products	0.8	0.8
All Other Services	**17.0**	**15.8**
Labor-Related Services	**9.2**	**8.0**
Professional Fees: Labor-related	5.0	3.5
Administrative and Facilities Support Services	0.7	0.8
Installation, Maintenance, and Repair	1.6	1.9
All Other: Labor-related Services	1.8	1.8
Nonlabor-Related Services	**7.9**	**7.8**
Professional Fees: Nonlabor-related	5.4	3.1
Financial services	0.9	2.7
Telephone Services	0.3	0.7
All Other: Nonlabor-related Services	1.3	1.3
Capital-Related Costs	**9.0**	**8.6**
Depreciation	**6.5**	**6.4**
Fixed Assets	4.1	4.1
Movable Equipment	2.5	2.3
Interest Costs	**1.5**	**1.4**
Government/Nonprofit	0.9	0.9
For Profit	0.6	0.5
Other Capital-Related Costs	**1.0**	**0.8**

*Detail may not add to total due to rounding.

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2. Selection of Price Proxies

After developing the cost weights for the proposed 2016-based IRF market basket, we select the most appropriate wage and price proxies currently available to represent the rate of price change for each expenditure category. For the majority of the cost weights, we base the price proxies on U.S. Bureau of Labor Statistics (BLS) data and group them into one of the following BLS categories:

- *Employment Cost Indexes.* Employment Cost Indexes (ECIs) measure the rate of change in employment wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the NAICS and the occupational ECIs are based on the Standard Occupational Classification System (SOC).
- *Producer Price Indexes.* Producer Price Indexes (PPIs) measure the average change over time in the selling prices received by domestic producers for their output. The prices included in the PPI are from the first commercial transaction for many products and some services (*https://www.bls.gov/ppi/*).
- *Consumer Price Indexes.* Consumer Price Indexes (CPIs) measure the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services (*https://www.bls.gov/cpi/*). CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the producer level, or if no appropriate PPIs are available.

We evaluate the price proxies using the criteria of reliability, timeliness, availability, and relevance:

- *Reliability.* Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.)
- *Timeliness.* Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market baskets are updated quarterly, and therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available.
- *Availability.* Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.
- *Relevance.* Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. The CPIs, PPIs, and ECIs that we have selected to propose in this regulation meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied.

Table 11 lists all price proxies that we propose to use for the proposed 2016-based IRF market basket. Below is a detailed explanation of the price proxies we are proposing for each cost category weight.

a. Price Proxies for the Operating Portion of the Proposed 2016-Based IRF Market Basket

(1) Wages and Salaries

We are proposing to continue to use the ECI for Wages and Salaries for All Civilian workers in Hospitals (BLS series code CIU10262200000000I) to measure the wage rate growth of this cost category. This is the same price proxy used in the 2012-based IRF market basket (80 FR 47060).

(2) Benefits

We are proposing to continue to use the ECI for Total Benefits for All Civilian workers in Hospitals to measure price growth of this category. This ECI is calculated using the ECI for Total Compensation for All Civilian workers in Hospitals (BLS series code CIU10162200000000I) and the relative importance of wages and salaries within total compensation. This is the same price proxy used in the 2012-based IRF market basket (80 FR 47060).

(3) Electricity

We are proposing to continue to use the PPI Commodity Index for Commercial Electric Power (BLS series code WPU0542) to measure the price growth of this cost category. This is the same price proxy used in the 2012-based IRF market basket (80 FR 47060).

(4) Fuel, Oil, and Gasoline

Similar to the 2012-based IRF market basket, for the 2016-based IRF market basket, we are proposing to use a blend of the PPI for Petroleum Refineries and the PPI Commodity for Natural Gas. Our analysis of the Bureau of Economic Analysis' 2012 Benchmark Input-Output data (use table before redefinitions, purchaser's value for NAICS 622000 [Hospitals]), shows that Petroleum Refineries expenses account for approximately 90 percent and Natural Gas expenses account for approximately 10 percent of Hospitals' (NAICS 622000) total Fuel, Oil, and Gasoline expenses. Therefore, we propose to use a blend of 90 percent of the PPI for Petroleum Refineries (BLS series code PCU324110324110) and 10 percent of the PPI Commodity Index for Natural Gas (BLS series code WPU0531) as the price proxy for this cost category. The 2012-based IRF market basket used a 70/30 blend of these price proxies, reflecting the 2007 I–O data (80 FR 47060). We believe that these two price proxies continue to be the most technically appropriate indices available to measure the price growth of the Fuel, Oil, and Gasoline cost category in the proposed 2016-based IRF market basket.

(5) Professional Liability Insurance

We are proposing to continue to use the CMS Hospital Professional Liability Index to measure changes in PLI premiums. To generate this index, we collect commercial insurance premiums for a fixed level of coverage while holding non-price factors constant (such as a change in the level of coverage). This is the same proxy used in the 2012-based IRF market basket (80 FR 47060).

(6) Pharmaceuticals

We are proposing to continue to use the PPI for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. This is the same proxy used in the 2012-based IRF market basket (80 FR 47060).

(7) Food: Direct Purchases

We are proposing to continue to use the PPI for Processed Foods and Feeds (BLS series code WPU02) to measure the price growth of this cost category. This

is the same proxy used in the 2012-based IRF market basket (80 FR 47060).

(8) Food: Contract Purchases

We are proposing to continue to use the CPI for Food Away From Home (BLS series code CUUR0000SEFV) to measure the price growth of this cost category. This is the same proxy used in the 2012-based IRF market basket (80 FR 47060 through 47061).

(9) Chemicals

Similar to the 2012-based IRF market basket, we are proposing to use a four part blended PPI as the proxy for the chemical cost category in the proposed 2016-based IRF market basket. The proposed blend is composed of the PPI for Industrial Gas Manufacturing, Primary Products (BLS series code PCU325120325120P), the PPI for Other Basic Inorganic Chemical Manufacturing (BLS series code PCU32518–32518–), the PPI for Other Basic Organic Chemical Manufacturing (BLS series code PCU32519–32519–), and the PPI for Other Miscellaneous Chemical Product Manufacturing (BLS series code PCU325998325998). We note that the four part blended PPI used in the 2012-based IRF market basket is composed of the PPI for Industrial Gas Manufacturing (BLS series code PCU325120325120P), the PPI for Other Basic Inorganic Chemical Manufacturing (BLS series code PCU32518–32518–), the PPI for Other Basic Organic Chemical Manufacturing (BLS series code PCU32519–32519–), and the PPI for Soap and Cleaning Compound Manufacturing (BLS series code PCU32561–32561–). For the proposed 2016-based IRF market basket, we are proposing to derive the weights for the PPIs using the 2012 Benchmark I–O data. The 2012-based IRF market basket used the 2007 Benchmark I–O data to derive the weights for the four PPIs (80 FR 47061).

Table 9 shows the weights for each of the four PPIs used to create the proposed blended Chemical proxy for the proposed 2016 IRF market basket compared to the 2012-based blended Chemical proxy.

TABLE 9: Blended Chemical PPI Weights

Name	Proposed 2016-based IRF Weights	2012-based IRF Weights	NAICS
PPI for Industrial Gas Manufacturing	19%	32%	325120
PPI for Other Basic Inorganic Chemical Manufacturing	13%	17%	325180
PPI for Other Basic Organic Chemical Manufacturing	60%	45%	325190
PPI for Soap and Cleaning Compound Manufacturing	n/a	6%	325610
PPI for Other Miscellaneous Chemical Product Manufacturing	8%	n/a	325998

(10) Medical Instruments

We are proposing to continue to use a blend of two PPIs for the Medical Instruments cost category. The 2012 Benchmark Input-Output data shows an approximate 57/43 split between Surgical and Medical Instruments and Medical and Surgical Appliances and Supplies for this cost category. Therefore, we propose a blend composed of 57 percent of the commodity-based PPI for Surgical and Medical Instruments (BLS series code WPU1562) and 43 percent of the commodity-based PPI for Medical and Surgical Appliances and Supplies (BLS series code WPU1563). The 2012-based IRF market basket used a 50/50 blend of these PPIs based on the 2007 Benchmark I–O data (80 FR 47061).

(11) Rubber and Plastics

We are proposing to continue to use the PPI for Rubber and Plastic Products (BLS series code WPU07) to measure price growth of this cost category. This is the same proxy used in the 2012-based IRF market basket (80 FR 47061).

(12) Paper and Printing Products

We are proposing to continue to use the PPI for Converted Paper and Paperboard Products (BLS series code WPU0915) to measure the price growth of this cost category. This is the same proxy used in the 2012-based IRF market basket (80 FR 47061).

(13) Miscellaneous Products

We are proposing to continue to use the PPI for Finished Goods Less Food and Energy (BLS series code WPUFD4131) to measure the price growth of this cost category. This is the same proxy used in the 2012-based IRF market basket (80 FR 47061).

(14) Professional Fees: Labor-Related

We are proposing to continue to use the ECI for Total Compensation for Private Industry workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. This is the same proxy used in the 2012-based IRF market basket (80 FR 47061).

(15) Administrative and Facilities Support Services

We are proposing to continue to use the ECI for Total Compensation for Private Industry workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this category. This is the same proxy used in the 2012-based IRF market basket (80 FR 47061).

(16) Installation, Maintenance, and Repair

We are proposing to continue to use the ECI for Total Compensation for Civilian workers in Installation, Maintenance, and Repair (BLS series code CIU1010000430000I) to measure the price growth of this cost category. This is the same proxy used in the 2012-based IRF market basket (80 FR 47061).

(17) All Other: Labor-Related Services

We are proposing to continue to use the ECI for Total Compensation for Private Industry workers in Service Occupations (BLS series code CIU2010000300000I) to measure the price growth of this cost category. This is the same proxy used in the 2012-based IRF market basket (80 FR 47061).

(18) Professional Fees: Nonlabor-Related

We are proposing to continue to use the ECI for Total Compensation for Private Industry workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. This is the same proxy used in the 2012-based IRF market basket (80 FR 47061).

(19) Financial Services

We are proposing to continue to use the ECI for Total Compensation for Private Industry workers in Financial

Activities (BLS series code CIU201520A000000I) to measure the price growth of this cost category. This is the same proxy used in the 2012-based IRF market basket (80 FR 47061).

(20) Telephone Services

We are proposing to continue to use the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category. This is the same proxy used in the 2012-based IRF market basket (80 FR 47061).

(21) All Other: Nonlabor-Related Services

We are proposing to continue to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. This is the same proxy used in the 2012-based IRF market basket (80 FR 47061).

b. Price Proxies for the Capital Portion of the Proposed 2016-Based IRF Market Basket

(1) Capital Price Proxies Prior to Vintage Weighting

We are proposing to continue to use the same price proxies for the capital-related cost categories in the proposed 2016-based IRF market basket as were used in the 2012-based IRF market basket (80 FR 47062), which are provided in Table 10 and described below. Specifically, we are proposing to proxy:

- Depreciation: Building and Fixed Equipment cost category by BEA's Chained Price Index for Nonresidential Construction for Hospitals and Special Care Facilities (BEA Table 5.4.4. Price Indexes for Private Fixed Investment in Structures by Type).
- Depreciation: Movable Equipment cost category by the PPI for Machinery and Equipment (BLS series code WPU11).
- Nonprofit Interest cost category by the average yield on domestic municipal bonds (Bond Buyer 20-bond index).
- For-profit Interest cost category by the average yield on Moody's Aaa bonds (Federal Reserve).
- Other Capital-Related cost category by the CPI–U for Rent of Primary Residence (BLS series code CUUS0000SEHA).

We believe these are the most appropriate proxies for IRF capital-related costs that meet our selection criteria of relevance, timeliness, availability, and reliability. We are also proposing to continue to vintage weight the capital price proxies for Depreciation and Interest to capture the long-term consumption of capital. This vintage weighting method is similar to the method used for the 2012-based IRF market basket (80 FR 47062) and is described below.

(2) Vintage Weights for Price Proxies

Because capital is acquired and paid for over time, capital-related expenses in any given year are determined by both past and present purchases of physical and financial capital. The vintage-weighted capital-related portion of the proposed 2016-based IRF market basket is intended to capture the long-term consumption of capital, using vintage weights for depreciation (physical capital) and interest (financial capital). These vintage weights reflect the proportion of capital-related purchases attributable to each year of the expected life of building and fixed equipment, movable equipment, and interest. We are proposing to use vintage weights to compute vintage-weighted price changes associated with depreciation and interest expenses.

Capital-related costs are inherently complicated and are determined by complex capital-related purchasing decisions, over time, based on such factors as interest rates and debt financing. In addition, capital is depreciated over time instead of being consumed in the same period it is purchased. By accounting for the vintage nature of capital, we are able to provide an accurate and stable annual measure of price changes. Annual non-vintage price changes for capital are unstable due to the volatility of interest rate changes, and therefore, do not reflect the actual annual price changes for IRF capital-related costs. The capital-related component of the proposed 2016-based IRF market basket reflects the underlying stability of the capital-related acquisition process.

The methodology used to calculate the vintage weights for the proposed 2016-based IRF market basket is the same as that used for the 2012-based IRF market basket (80 FR 47062 through 47063) with the only difference being the inclusion of more recent data. To calculate the vintage weights for depreciation and interest expenses, we first need a time series of capital-related purchases for building and fixed equipment and movable equipment. We found no single source that provides an appropriate time series of capital-related purchases by hospitals for all of the above components of capital purchases. The early Medicare cost reports did not have sufficient capital-related data to meet this need. Data we obtained from the American Hospital Association (AHA) do not include annual capital-related purchases. However, we are able to obtain data on total expenses back to 1963 from the AHA. Consequently, we are proposing to use data from the AHA Panel Survey and the AHA Annual Survey to obtain a time series of total expenses for hospitals. We are then proposing to use data from the AHA Panel Survey supplemented with the ratio of depreciation to total hospital expenses obtained from the Medicare cost reports to derive a trend of annual depreciation expenses for 1963 through 2016. We propose to separate these depreciation expenses into annual amounts of building and fixed equipment depreciation and movable equipment depreciation as determined earlier. From these annual depreciation amounts, we derive annual end-of-year book values for building and fixed equipment and movable equipment using the expected life for each type of asset category. While data is not available that is specific to IRFs, we believe this information for all hospitals serves as a reasonable alternative for the pattern of depreciation for IRFs.

To continue to calculate the vintage weights for depreciation and interest expenses, we also need to account for the expected lives for Building and Fixed Equipment, Movable Equipment, and Interest for the proposed 2016-based IRF market basket. We are proposing to calculate the expected lives using Medicare cost report data from freestanding and hospital-based IRFs. The expected life of any asset can be determined by dividing the value of the asset (excluding fully depreciated assets) by its current year depreciation amount. This calculation yields the estimated expected life of an asset if the rates of depreciation were to continue at current year levels, assuming straight-line depreciation. We are proposing to determine the expected life of building and fixed equipment separately for hospital-based IRFs and freestanding IRFs, and then weight these expected lives using the percent of total capital costs each provider type represents. We are proposing to apply a similar method for movable equipment. Using these proposed methods, we determined the average expected life of building and fixed equipment to be equal to 22 years, and the average expected life of movable equipment to be equal to 11 years. For the expected life of interest, we believe vintage weights for interest should represent the average expected life of building and fixed equipment because, based on previous research described in the FY 1997 IPPS final rule (61 FR 46198), the expected life of hospital debt instruments and the expected life of buildings and fixed equipment are similar. We note that for the 2012-based

IRF market basket, the expected life of building and fixed equipment is 23 years, and the expected life of movable equipment is 11 years (80 FR 47062).

Multiplying these expected lives by the annual depreciation amounts results in annual year-end asset costs for building and fixed equipment and movable equipment. We then calculate a time series, beginning in 1964, of annual capital purchases by subtracting the previous year's asset costs from the current year's asset costs.

For the building and fixed equipment and movable equipment vintage weights, we are proposing to use the real annual capital-related purchase amounts for each asset type to capture the actual amount of the physical acquisition, net of the effect of price inflation. These real annual capital-related purchase amounts are produced by deflating the nominal annual purchase amount by the associated price proxy as provided earlier in this proposed rule. For the interest vintage weights, we are proposing to use the total nominal annual capital-related purchase amounts to capture the value of the debt instrument (including, but not limited to, mortgages and bonds). Using these capital-related purchase time series specific to each asset type, we are proposing to calculate the vintage weights for building and fixed equipment, for movable equipment, and for interest.

The vintage weights for each asset type are deemed to represent the average purchase pattern of the asset over its expected life (in the case of building and fixed equipment and interest, 22 years, and in the case of movable equipment, 11 years). For each asset type, we used the time series of annual capital-related purchase amounts available from 2016 back to 1964. These data allow us to derive thirty-two 22-year periods of capital-related purchases for building and fixed equipment and interest, and forty-three 11-year periods of capital-related purchases for movable equipment. For each 22-year period for building and fixed equipment and interest, or 11-year period for movable equipment, we calculate annual vintage weights by dividing the capital-related purchase amount in any given year by the total amount of purchases over the entire 22-year or 11-year period. This calculation is done for each year in the 22-year or 11-year period and for each of the periods for which we have data. We then calculate the average vintage weight for a given year of the expected life by taking the average of these vintage weights across the multiple periods of data. The vintage weights for the capital-related portion of the proposed 2016-based IRF market basket and the 2012-based IRF market basket are presented in Table 10.

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TABLE 10: Proposed 2016-Based IRF Market Basket and 2012-based IRF Market Basket Vintage Weights for Capital-Related Price Proxies

Year	Building and Fixed Equipment		Movable Equipment		Interest	
	2016-based 22 years	2012-based 23 years	2016 based 11 years	2012-based 11 years	2016 based 22 years	2012 based 23 years
1	0.035	0.029	0.071	0.069	0.021	0.017
2	0.036	0.031	0.075	0.073	0.023	0.019
3	0.038	0.034	0.080	0.077	0.025	0.022
4	0.038	0.036	0.085	0.083	0.026	0.024
5	0.040	0.037	0.087	0.087	0.029	0.026
6	0.042	0.039	0.091	0.091	0.031	0.028
7	0.042	0.040	0.095	0.096	0.033	0.030
8	0.041	0.041	0.099	0.100	0.033	0.032
9	0.042	0.042	0.102	0.103	0.036	0.035
0	0.043	0.044	0.105	0.107	0.038	0.038
1	0.046	0.045	0.110	0.114	0.042	0.040
2	0.047	0.045	--	--	0.045	0.042
3	0.048	0.045	--	--	0.048	0.044
4	0.049	0.046	--	--	0.052	0.046
5	0.050	0.046	--	--	0.055	0.048
6	0.050	0.048	--	--	0.057	0.053
7	0.051	0.049	--	--	0.060	0.057
8	0.053	0.050	--	--	0.065	0.060
9	0.053	0.051	--	--	0.068	0.063
0	0.053	0.051	--	--	0.069	0.066
1	0.052	0.051	--	--	0.070	0.067
2	0.052	0.050	--	--	0.072	0.069
3	--	0.052	--	--		0.073
Total	1.000	1.000	1.000	1.000	1.000	1.000

Note: Numbers may not add to total due to rounding.

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The process of creating vintage-weighted price proxies requires applying the vintage weights to the price proxy index where the last applied vintage weight in Table 8 is applied to the most recent data point. We have provided on the CMS website an example of how the vintage weighting price proxies are calculated, using

example vintage weights and example price indices. The example can be found at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html* in the zip file titled ''Weight Calculations as described in the IPPS FY 2010 Proposed Rule.''

c. Summary of Price Proxies of the Proposed 2016-Based IRF Market Basket

Table 11 shows both the operating and capital price proxies for the proposed 2016-based IRF market basket.

TABLE 11: Proposed Price Proxies and Cost Share Weights for use in the 2016-based IRF Market Basket

Cost Description	Price Proxies	Weight
Total		**100.0%**
Compensation		**59.4%**
Wages and Salaries	ECI for Wages and Salaries for All Civilian workers in Hospitals	47.9%
Employee Benefits	ECI for Total Benefits for All Civilian workers in Hospitals	11.4%
Utilities		**1.4%**
Electricity	PPI for Commercial Electric Power	1.0%
Fuel, Oil, and Gasoline	Blend of the PPI for Petroleum Refineries and PPI for Natural Gas	0.4%
Professional Liability Insurance		**0.7%**
Malpractice	CMS Hospital Professional Liability Insurance Premium Index	0.7%
All Other Products and Services		**29.5%**
All Other Products		**12.5%**
Pharmaceuticals	PPI for Pharmaceuticals for human use, prescription	5.1%
Food: Direct Purchases	PPI for Processed Foods and Feeds	1.1%
Food: Contract Services	CPI-U for Food Away From Home	1.2%
Chemicals	Blend of Chemical PPIs	0.4%
Medical Instruments	Blend of the PPI for Surgical and medical instruments and PPI for Medical and surgical appliances and supplies	2.9%
Rubber & Plastics	PPI for Rubber and Plastic Products	0.4%
Paper and Printing Products	PPI for Converted Paper and Paperboard Products	0.6%
Miscellaneous Products	PPI for Finished Goods Less Food and Energy	0.8%
All Other Services		**17.0%**
Labor-Related Services		**9.2%**
Professional Fees: Labor-related	ECI for Total compensation for Private industry workers in Professional and related	5.0%
Administrative and Facilities Support Services	ECI for Total compensation for Private industry workers in Office and administrative support	0.7%
Installation, Maintenance & Repair	ECI for Total compensation for Civilian workers in Installation, maintenance, and repair	1.6%
All Other: Labor-related Services	ECI for Total compensation for Private industry workers in Service occupations	1.8%
Nonlabor-Related Services		**7.9%**
Professional Fees: Nonlabor-related	ECI for Total compensation for Private industry workers in Professional and related	5.4%
Financial services	ECI for Total compensation for Private industry workers in Financial activities	0.9%
Telephone Services	CPI-U for Telephone Services	0.3%
All Other: Nonlabor-related Services	CPI-U for All Items Less Food and Energy	1.3%
Capital-Related Costs		**9.0%**
Depreciation		**6.5%**
Fixed Assets	BEA chained price index for nonresidential construction for hospitals and special care facilities - vintage weighted (22 years)	4.1%
Movable Equipment	PPI for machinery and equipment - vintage weighted (11 years)	2.5%
Interest Costs		**1.5%**
Government/Nonprofit	Average yield on domestic municipal bonds (Bond Buyer 20 bonds) - vintage weighted (22 years)	0.9%
For Profit	Average yield on Moody's Aaa bonds - vintage weighted (22 years)	0.6%
Other Capital-Related Costs	CPI-U for Rent of primary residence	**1.0%**

Note: Totals may not sum to 100.0 percent due to rounding.

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D. Proposed FY 2020 Market Basket Update and Productivity Adjustment

1. Proposed FY 2020 Market Basket Update

For FY 2020 (that is, beginning October 1, 2019 and ending September 30, 2020), we are proposing to use the proposed 2016-based IRF market basket increase factor described in section V.C. of this proposed rule to update the IRF PPS base payment rate. Consistent with historical practice, we are proposing to estimate the market basket update for the IRF PPS based on IHS Global Inc.'s (IGI's) forecast using the most recent available data. IGI is a nationally recognized economic and financial forecasting firm with which we contract to forecast the components of the market baskets and multifactor productivity (MFP).

Based on IGI's first quarter 2019 forecast with historical data through the fourth quarter of 2018, the projected proposed 2016-based IRF market basket increase factor for FY 2020 is 3.0 percent. Therefore, consistent with our historical practice of estimating market basket increases based on the best available data, we are proposing a market basket increase factor of 3.0 percent for FY 2020. We are also proposing that if more recent data are subsequently available (for example, a more recent estimate of the market basket) we would use such data to determine the FY 2020 update in the final rule. For comparison, the current 2012-based IRF market basket is also projected to increase by 3.0 percent in FY 2020 based on IGI's first quarter 2019 forecast. Table 12 compares the proposed 2016-based IRF market basket and the 2012-based IRF market basket percent changes. On average, the two indexes produce similar updates to one another, with the 5-year average historical and forecasted growth rates for both IRF market baskets equal to 2.1 percent and 3.0 percent, respectively.

TABLE 12: Proposed 2016-Based IRF Market Basket and 2012-Based IRF Market Basket Percent Changes, FY 2015 through FY 2022

	Fiscal Year (FY)	Proposed 2016-Based IRF Market Basket Index Percent Change	2012-Based IRF Market Basket Index Percent Change
Historical data	FY 2015	1.7	1.6
	FY 2016	1.8	1.8
	FY 2017	2.4	2.5
	FY 2018	2.3	2.4
	Average 2015-2018	**2.1**	**2.1**
Forecast	FY 2019	2.7	2.7
	FY 2020	3.0	3.0
	FY 2021	3.2	3.2
	FY 2022	3.1	3.1
	Average 2019-2022	**3.0**	**3.0**

Note that these market basket percent changes do not include any further adjustments as may be statutorily required.

Source: IHS Global Inc. 1st quarter 2019 forecast.

2. Proposed Productivity Adjustment

According to section 1886(j)(3)(C)(i) of the Act, the Secretary shall establish an increase factor based on an appropriate percentage increase in a market basket of goods and services. As described in sections V.C and V.D.1. of this proposed rule, we are proposing to estimate the IRF PPS increase factor for FY 2020 based on the proposed 2016-based IRF market basket. Section 1886(j)(3)(C)(ii) of the Act then requires that, after establishing the increase factor for a FY, the Secretary shall reduce such increase factor for FY 2012 and each subsequent FY, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act sets forth the definition of this productivity adjustment. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period) (the ''MFP adjustment''). The BLS publishes the official measure of private nonfarm business MFP. Please see *http://www.bls.gov/mfp* for the BLS historical published MFP data.

MFP is derived by subtracting the contribution of labor and capital input growth from output growth. The projections of the components of MFP are currently produced by IGI, a nationally recognized economic forecasting firm with which CMS contracts to forecast the components of the market basket and MFP. For more information on the productivity adjustment, we refer reader to the discussion in the FY 2016 IRF PPS final rule (80 FR 47065).

Using IGI's first quarter 2019 forecast, the MFP adjustment for FY 2020 (the 10-year moving average of MFP for the period ending FY 2020) is projected to be 0.5 percent. Thus, in accordance with section 1886(j)(3)(C) of the Act, we propose to base the FY 2020 market basket update, which is used to determine the applicable percentage increase for the IRF payments, on the most recent estimate of the proposed 2016-based IRF market basket (currently estimated to be 3.0 percent based on IGI's first quarter 2019 forecast). We propose to then reduce this percentage increase by the current estimate of the MFP adjustment for FY 2020 of 0.5 percentage point (the 10-year moving average of MFP for the period ending FY 2020 based on IGI's first quarter 2019 forecast). Therefore, the current estimate of the FY 2020 IRF update is 2.5 percent (3.0 percent market basket update, less 0.5 percentage point MFP adjustment). Furthermore, we propose that if more recent data are subsequently available (for example, a more recent estimate of the market basket and MFP adjustment), we would use such data to determine the FY 2020 market basket update and MFP adjustment in the final rule.

For FY 2020, the Medicare Payment Advisory Commission (MedPAC) recommends that a decrease of 5 percent be applied to IRF PPS payment rates. As discussed, and in accordance with section 1886(j)(3)(C) of the Act, the Secretary proposes to update IRF PPS payment rates for FY 2020 by an adjusted market basket increase factor of 2.5 percent, as section 1886(j)(3)(C) of the Act does not provide the Secretary with the authority to apply a different update factor to IRF PPS payment rates for FY 2020.

We invite public comment on these proposals.

E. Proposed Labor-Related Share for FY 2020

Section 1886(j)(6) of the Act specifies that the Secretary is to adjust the proportion (as estimated by the Secretary from time to time) of rehabilitation facilities' costs which are attributable to wages and wage-related costs, of the prospective payment rates computed under section 1886(j)(3) of the Act for area differences in wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the rehabilitation facility compared to the national average wage level for such facilities. The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. We propose to continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market. As stated in the FY 2016 IRF PPS final rule (80 FR 47068), the labor-related share was defined as the sum of the relative importance of Wages and Salaries, Employee Benefits, Professional Fees: Labor-related Services, Administrative and Facilities Support Services, Installation, Maintenance, and Repair, All Other: Labor-related Services, and a portion of the Capital Costs from the 2012-based IRF market basket.

Based on our definition of the labor-related share and the cost categories in the proposed 2016-based IRF market basket, we are proposing to include in the labor-related share for FY 2020 the sum of the FY 2020 relative importance of Wages and Salaries, Employee Benefits, Professional Fees: Labor-related, Administrative and Facilities Support Services, Installation, Maintenance, and Repair, All Other: Labor-related Services, and a portion of the Capital-Related cost weight from the proposed 2016-based IRF market basket.

Similar to the 2012-based IRF market basket (80 FR 47067), the proposed 2016-based IRF market basket includes two cost categories for nonmedical Professional Fees (including, but not limited to, expenses for legal, accounting, and engineering services). These are Professional Fees: Labor-related and Professional Fees: Nonlabor-related. For the proposed 2016-based IRF market basket, we propose to estimate the labor-related percentage of non-medical professional fees (and assign these expenses to the Professional Fees: Labor-related services cost category) based on the same method that was used to determine the labor-related percentage of professional fees in the 2012-based IRF market basket.

As was done in the 2012-based IRF market basket (80 FR 47067), we propose to determine the proportion of legal, accounting and auditing, engineering, and management consulting services that meet our definition of labor-related services based on a survey of hospitals conducted by us in 2008, a discussion of which can be found in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43850 through 43856). Based on the weighted results of the survey, we determined that hospitals purchase, on average, the following portions of contracted professional services outside of their local labor market:

- 34 percent of accounting and auditing services.
- 30 percent of engineering services.
- 33 percent of legal services.
- 42 percent of management consulting services.

We are proposing to apply each of these percentages to the respective Benchmark I–O cost category underlying the professional fees cost category to determine the Professional Fees: Nonlabor-related costs. The Professional Fees: Labor-related costs were determined to be the difference between the total costs for each Benchmark I–O category and the Professional Fees: Nonlabor-related costs. This is the same methodology that we used to separate the 2012-based IRF market basket professional fees category into Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories (80 FR 47067).

In the proposed 2016-based IRF market basket, nonmedical professional fees that are subject to allocation based on these survey results represent 4.4 percent of total costs (and are limited to those fees related to Accounting & Auditing, Legal, Engineering, and Management Consulting services). Based on our survey results, we propose to apportion 2.8 percentage points of the 4.4 percentage point figure into the Professional Fees: Labor-related share cost category and designate the remaining 1.6 percentage point into the Professional Fees: Nonlabor-related cost category.

In addition to the professional services listed, for the 2016-based IRF market basket, we are proposing to allocate a proportion of the Home Office Contract Labor cost weight, calculated using the Medicare cost reports as stated above, into the Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories. We are proposing to classify these expenses as labor-related and nonlabor-related as many facilities are not located in the same geographic area as their home office, and therefore, do not meet our definition for the labor-related share that requires the services to be purchased in the local labor market. For the 2012-based IRF market basket, we used the BEA I–O expense data for NAICS 55, Management of Companies and Enterprises, to estimate the Home Office Contract Labor cost weight (80 FR 47067). We then allocated these expenses into the Professional Fess: Labor-related and Professional Fees: Nonlabor-related cost categories.

Similar to the 2012-based IRF market basket, we are proposing for the 2016-based IRF market basket to use the Medicare cost reports for both freestanding IRF providers and hospital-based IRF providers to determine the home office labor-related percentages. The Medicare cost report requires a hospital to report information regarding their home office provider. For the 2016-based IRF market basket, we are proposing to start with the sample of IRF providers that passed the top 1 percent trim used to derive the Home Office Contract Labor cost weight as described in section V.B. of this proposed rule. For both freestanding and hospital-based providers, we are proposing to multiply each provider's Home Office Contract Labor cost weight (calculated using data from the total facility) by Medicare allowable total costs. This results in an amount of Medicare allowable home office compensation costs for each IRF. Using information on the Medicare cost report, we then compare the location of the IRF with the location of the IRF's home office. We are proposing to classify an IRF with a home office located in their respective local labor market if the IRF and its home office are located in the same Metropolitan Statistical Area. We then calculate the proportion of Medicare allowable home office compensation costs that these IRFs represent of total Medicare allowable home office compensation costs. We

propose to multiply this percentage (42 percent) by the Home Office Contract Labor cost weight (3.7 percent) to determine the proportion of costs that should be allocated to the labor-related share. Therefore, we are allocating 1.6 percentage points of the Home Office Contract Labor cost weight (3.7 percent times 42 percent) to the Professional Fees: Labor-related cost weight and 2.1 percentage points of the Home Office Contract Labor cost weight to the Professional Fees: Nonlabor-related cost weight (3.7 percent times 58 percent). For the 2012-based IRF market basket, we used a similar methodology but we relied on provider counts rather than home office/related organization contract labor compensation costs to determine the labor-related percentage (80 FR 47067).

In summary, we apportioned 2.8 percentage points of the non-medical professional fees and 1.6 percentage points of the home office/related organization contract labor cost weights into the Professional Fees: Labor-related cost category. This amount was added to the portion of professional fees that was identified to be labor-related using the I–O data such as contracted advertising and marketing costs (approximately 0.6 percentage point of total costs) resulting in a Professional Fees: Labor-related cost weight of 5.0 percent.

As stated previously, we are proposing to include in the labor-related share the sum of the relative importance of Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Facilities Support Services, Installation, Maintenance, and Repair, All Other: Labor-related Services, and a portion of the Capital-Related cost weight from the proposed 2016-based IRF market basket. The relative importance reflects the different rates of price change for these cost categories between the base year (2016) and FY 2020. Based on IGI's 1st quarter 2019 forecast for the proposed 2016-based IRF market basket, the sum of the FY 2020 relative importance for Wages and Salaries, Employee Benefits, Professional Fees: Labor-related, Administrative and Facilities Support Services, Installation Maintenance & Repair Services, and All Other: Labor-related Services is 68.7 percent. The portion of Capital costs that is influenced by the local labor market is estimated to be 46 percent, which is the same percentage applied to the 2012-based IRF market basket (80 FR 47068). Since the relative importance for Capital is 8.5 percent of the proposed 2016-based IRF market basket in FY 2020, we took 46 percent of 8.5 percent to determine the proposed labor-related share of Capital for FY 2020 of 3.9 percent. Therefore, we are proposing a total labor-related share for FY 2020 of 72.6 percent (the sum of 68.7 percent for the operating costs and 3.9 percent for the labor-related share of Capital). Table 13 shows the FY 2020 labor-related share using the proposed 2016-based IRF market basket relative importance and the FY 2019 labor-related share using the 2012-based IRF market basket relative importance.

TABLE 13—PROPOSED FY 2020 IRF LABOR-RELATED SHARE AND FY 2019 IRF LABOR-RELATED SHARE

	FY 2020 proposed labor-related share [1]	FY 2019 final labor related share [2]
Wages and Salaries	48.1	47.7
Employee Benefits	11.4	11.1
Professional Fees: Labor-related [3]	5.0	3.4
Administrative and Facilities Support Services	0.8	0.8
Installation, Maintenance, and Repair	1.6	1.9
All Other: Labor-related Services	1.8	1.8
Subtotal	68.7	66.7
Labor-related portion of capital (46%)	3.9	3.8
Total Labor-Related Share	72.6	70.5

[1] Based on the proposed 2016-based IRF Market Basket, IHS Global Insight, Inc. 1st quarter 2019 forecast.
[2] Based on the 2012-based IRF market basket as published in the FEDERAL REGISTER (83 FR 38526).
[3] Includes all contract advertising and marketing costs and a portion of accounting, architectural, engineering, legal, management consulting, and home office contract labor costs.

We invite public comment on the proposed labor-related share for FY 2020.

F. Proposed Update to the IRF Wage Index To Use Concurrent FY IPPS Wage Index Beginning With FY 2020

1. Background

Section 1886(j)(6) of the Act requires the Secretary to adjust the proportion of rehabilitation facilities' costs attributable to wages and wage-related costs (as estimated by the Secretary from time to time) by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the rehabilitation facility compared to the national average wage level for those facilities. The Secretary is required to update the IRF PPS wage index on the basis of information available to the Secretary on the wages and wage-related costs to furnish rehabilitation services. Any adjustment or updates made under section 1886(j)(6) of the Act for a FY are made in a budget-neutral manner.

2. Proposed Update to the IRF Wage Index To Use Concurrent FY IPPS Wage Index Beginning With FY 2020

When the IRF PPS was implemented in the FY 2002 IRF PPS final rule (66 FR 41358), we finalized the use of the IPPS wage data in the creation of an IRF wage index. We believed that a wage index based on IPPS wage data was the best proxy and most appropriate wage index to use in adjusting payments to IRFs, since both IPPS hospitals and IRFs compete in the same labor markets. For this reason, we believed, and continue to believe, that the wage data of IPPS hospitals accurately captures the relationship of wages and wage-related costs of IRFs in an area as compared with the national average. Therefore, in the FY 2002 IRF PPS final rule, we finalized use of the FY 1997 IPPS wage data to develop the wage index for the IRF PPS, as that was the most recent final data available.

For all subsequent years in which the IRF PPS wage index has been updated, we have continued to use the most recent final IPPS data available, which has led us to use the pre-floor, pre-reclassified IPPS wage index values from the prior fiscal year.

In the FY 2018 IRF PPS proposed rule (82 FR 20742 through 20743), we included a request for information (RFI) to solicit comments from stakeholders requesting information on CMS flexibilities and efficiencies. The purpose of the RFI was to receive feedback regarding ways in which we could reduce burden for hospitals and physicians, improve quality of care, decrease costs and ensure that patients receive the best care. We received comments from IRF industry associations, state and national hospital associations, industry groups, representing hospitals, and individual IRF providers in response to the solicitation. One of the responses we received to the RFI suggested that there is concern among IRF stakeholders about the different wage index data used in the different post-acute care settings. For the IRF PPS, we use a one-year lag of the pre-floor, pre-reclassified IPPS wage index, meaning that for the IRF PPS for FY 2019, we finalized use of the FY 2018 IPPS wage index (83 FR 38527). However, we base the wage indexes for the SNF PPS and the LTCH PPS on the concurrent year's IPPS wage index ((83 FR 39172 through 39178) and (83 FR 41731), respectively).

As we look towards a more unified post-acute care payment system, we believe that standardizing the wage index data across post-acute care settings is necessary. Therefore, we are proposing to change the IRF wage index methodology to align with other post-acute care settings. Specifically, we are proposing to change from our established policy of using the pre-floor, pre-reclassified IPPS wage index from the prior fiscal year as the basis for the IRF wage index to using, instead, the pre-floor, pre-reclassified IPPS wage index from the current fiscal year. This proposed change would use the concurrent fiscal year's pre-floor, pre-reclassified IPPS wage index for the IRF wage index beginning with FY 2020 and continuing for all subsequent years. Thus, for the FY 2020 IRF wage index, we would propose to use the FY 2020 pre-floor, pre-reclassified IPPS wage index. We are proposing to implement these revisions in a budget neutral manner. For more information on the impacts of this proposal, we refer readers to Table 14. Table 14 shows the estimated effects of maintaining the existing wage index methodology for FY 2020 compared to the effects of implementing the proposed change to the wage index methodology as described above. For a provider specific impact analysis of this proposed change, we refer readers to the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRF-Rules-and-Related-Files.html.*

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TABLE 14: Distributional Effects of the Proposed Changes to the IRF Wage Index Methodology

Facility Classification	Number of IRFs	Number of Cases	Estimated Impact of Wage Index Update Under Current Methodology	Estimated Impact of Wage Index Update Under Proposed Methodology
(1)	(2)	(3)	(4)	(5)
Total	1,119	409,982	0.0	0.0
Urban unit	696	166,872	0.1	0.1
Rural unit	136	21,700	0.0	0.4
Urban hospital	276	216,894	-0.1	-0.1
Rural hospital	11	4,516	-0.6	-0.8
Urban For-Profit	357	211,280	-0.1	-0.1
Rural For-Profit	36	7,920	-0.4	-0.3
Urban Non-Profit	522	150,310	0.1	0.1
Rural Non-Profit	90	15,166	0.0	0.4
Urban Government	93	22,176	0.4	0.0
Rural Government	21	3,130	-0.3	0.2
Urban	972	383,766	0.0	0.0
Rural	147	26,216	-0.1	0.2
Urban by region				
Urban New England	29	16,260	0.0	-0.1
Urban Middle Atlantic	135	51,539	0.2	-0.1
Urban South Atlantic	147	77,315	-0.2	-0.6
Urban East North Central	165	50,466	-0.3	-0.2
Urban East South Central	56	27,966	-0.3	-0.6
Urban West North Central	74	20,822	-0.3	0.2
Urban West South Central	184	84,068	0.2	0.4
Urban Mountain	83	30,294	-0.7	-0.7
Urban Pacific	99	25,036	1.4	1.6
Rural by region				
Rural New England	5	1,317	-0.9	-2.4
Rural Middle Atlantic	12	1,248	-0.1	0.0
Rural South Atlantic	16	3,639	-0.1	0.6
Rural East North Central	23	4,061	0.0	0.3
Rural East South Central	21	4,523	-0.6	-0.1
Rural West North Central	22	3,178	0.2	0.4
Rural West South Central	40	7,332	0.1	0.6
Rural Mountain	5	626	-0.1	1.0
Rural Pacific	3	292	-0.1	0.2
Teaching status				
Non-teaching	1,014	362,675	-0.1	0.0
Resident to ADC less than 10%	60	34,000	0.4	0.1
Resident to ADC 10%-19%	31	11,784	0.1	-0.1
Resident to ADC greater than 19%	14	1,523	0.1	0.0
Disproportionate share patient percentage (DSH PP)				
DSH PP = 0%	29	5,300	-0.5	-0.7
DSH PP <5%	139	60,003	-0.1	-0.1
DSH PP 5%-10%	299	127,442	-0.2	-0.1
DSH PP 10%-20%	371	139,001	0.0	-0.1
DSH PP greater than 20%	281	78,236	0.3	0.3

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Using the current pre-floor, pre-reclassified IPPS wage index would result in the most up-to-date wage data being the basis for the IRF wage index.

It would also result in more consistency and equity in the wage index methodology used by Medicare.

We invite comments on this proposal to align the data timeframes with that of the IPPS by using the FY 2020 pre-floor, pre-reclassified IPPS wage index as the basis for the FY 2020 IRF wage index.

3. Proposed Wage Adjustment for FY 2020 Using Concurrent IPPS Wage Index

Due to our proposal to use the concurrent IPPS wage index beginning with FY 2020, for FY 2020, we are proposing to use the policy and methodologies described in section V. of this proposed rule related to the labor market area definitions and the wage index methodology for areas with wage data. Thus, we propose to use the CBSA labor market area definitions and the FY 2020 pre-reclassification and pre-floor IPPS wage index data. In accordance with section 1886(d)(3)(E) of the Act, the FY 2020 pre-reclassification and pre-floor IPPS wage index is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2015 and before October 1, 2016 (that is, FY 2016 cost report data).

The labor market designations made by the OMB include some geographic areas where there are no hospitals and, thus, no hospital wage index data on which to base the calculation of the IRF PPS wage index. We propose to continue to use the same methodology discussed in the FY 2008 IRF PPS final rule (72 FR 44299) to address those geographic areas where there are no hospitals and, thus, no hospital wage index data on which to base the calculation for the FY 2020 IRF PPS wage index.

We invite public comment on this proposal.

4. Core-Based Statistical Areas (CBSAs) for the Proposed FY 2020 IRF Wage Index

The wage index used for the IRF PPS is calculated using the pre-reclassification and pre-floor IPPS wage index data and is assigned to the IRF on the basis of the labor market area in which the IRF is geographically located. IRF labor market areas are delineated based on the CBSAs established by the OMB. The current CBSA delineations (which were implemented for the IRF PPS beginning with FY 2016) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census, and provided guidance on the use of the delineations of these statistical areas using standards published in the June 28, 2010 **Federal Register** (75 FR 37246 through 37252). We refer readers to the FY 2016 IRF PPS final rule (80 FR 47068 through 47076) for a full discussion of our implementation of the OMB labor market area delineations beginning with the FY 2016 wage index.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provides minor updates to and supersedes OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provides detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013.

In the FY 2018 IRF PPS final rule (82 FR 36250 through 36251), we adopted the updates set forth in OMB Bulletin No. 15–01 effective October 1, 2017, beginning with the FY 2018 IRF wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 15–01, we refer readers to the FY 2018 IRF PPS final rule. In the FY 2019 IRF PPS final rule (83 FR 38527), we continued to use the OMB delineations that were adopted beginning with FY 2016 to calculate the area wage indexes, with updates set forth in OMB Bulletin No. 15–01 that we adopted beginning with the FY 2018 wage index.

On August 15, 2017, OMB issued OMB Bulletin No. 17–01, which provided updates to and superseded OMB Bulletin No. 15–01 that was issued on July 15, 2015. The attachments to OMB Bulletin No. 17–01 provide detailed information on the update to statistical areas since July 15, 2015, and are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2014 and July 1, 2015. In OMB Bulletin No. 17–01, OMB announced that one Micropolitan Statistical Area now qualifies as a Metropolitan Statistical Area. The new urban CBSA is as follows:

- Twin Falls, Idaho (CBSA 46300). This CBSA is comprised of the principal city of Twin Falls, Idaho in Jerome County, Idaho and Twin Falls County, Idaho.

The OMB bulletin is available on the OMB website at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf.*

As we indicated in the FY 2019 IRF PPS final rule (83 FR 38528), we believe that it is important for the IRF PPS to use the latest labor market area delineations available as soon as is reasonably possible to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. As discussed in the FY 2019 IPPS and LTCH PPS final rule (83 FR 20591), these updated labor market area definitions were implemented under the IPPS beginning on October 1, 2018. Therefore, we are proposing to implement these revisions for the IRF PPS beginning October 1, 2019, consistent with our historical practice of modeling IRF PPS adoption of the labor market area delineations after IPPS adoption of these delineations.

We invite public comments on these proposals.

5. Wage Adjustment

The proposed FY 2020 wage index tables (which, as discussed in section V.F above, we propose to base on the FY 2020 pre-reclassified, pre-floor FY 2020 IPPS wage index) are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRF-Rules-and-Related-Files.html.* Table A is for urban areas, and Table B is for rural areas.

To calculate the wage-adjusted facility payment for the payment rates set forth in this proposed rule, we would multiply the unadjusted federal payment rate for IRFs by the FY 2020 labor-related share based on the 2016-based IRF market basket (72.6 percent) to determine the labor-related portion of the standard payment amount. A full discussion of the calculation of the labor-related share is located in section V.E of this proposed rule. We would then multiply the labor-related portion by the applicable IRF wage index from the tables in the addendum to this proposed rule. These tables are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRF-Rules-and-Related-Files.html.* Adjustments or updates to the IRF wage index made under section 1886(j)(6) of the Act must be made in a

budget-neutral manner. We propose to calculate a budget-neutral wage adjustment factor as established in the FY 2004 IRF PPS final rule (68 FR 45689), codified at § 412.624(e)(1), as described in the steps below. We propose to use the listed steps to ensure that the proposed FY 2020 IRF standard payment conversion factor reflects the proposed updates to the IRF wage index (based on the FY 2020 IPPS wage index) and the labor-related share in a budget-neutral manner:

Step 1. Determine the total amount of the estimated FY 2019 IRF PPS payments, using the FY 2019 standard payment conversion factor and the labor-related share and the wage indexes from FY 2019 (as published in the FY 2019 IRF PPS final rule (83 FR 38514)).

Step 2. Calculate the total amount of estimated IRF PPS payments using the proposed FY 2020 standard payment conversion factor and the proposed FY 2020 labor-related share and CBSA urban and rural wage indexes.

Step 3. Divide the amount calculated in step 1 by the amount calculated in step 2. The resulting quotient is the proposed FY 2020 budget-neutral wage adjustment factor of 1.0076.

Step 4. Apply the proposed FY 2020 budget-neutral wage adjustment factor from step 3 to the FY 2020 IRF PPS standard payment conversion factor after the application of the increase factor to determine the FY 2020 proposed standard payment conversion factor.

We discuss the calculation of the proposed standard payment conversion factor for FY 2020 in section V.H. of this proposed rule.

We invite public comment on the proposed IRF wage adjustment for FY 2020.

G. Wage Index Comment Solicitation

Historically, we have calculated the IRF wage index values using unadjusted wage index values from another provider setting. Stakeholders have frequently commented on certain aspects of the IRF wage index values and their impact on payments. We are soliciting comments on concerns stakeholders may have regarding the wage index used to adjust IRF payments and suggestions for possible updates and improvements to the geographic adjustment of IRF payments.

H. Description of the Proposed IRF Standard Payment Conversion Factor and Payment Rates for FY 2020

To calculate the proposed standard payment conversion factor for FY 2020, as illustrated in Table 15, we begin by applying the proposed increase factor for FY 2020, as adjusted in accordance with sections 1886(j)(3)(C) of the Act, to the standard payment conversion factor for FY 2019 ($16,021). Applying the proposed 2.5 percent increase factor for FY 2020 to the standard payment conversion factor for FY 2019 of $16,021 yields a standard payment amount of $16,422. Then, we apply the proposed budget neutrality factor for the FY 2020 wage index and labor-related share of 1.0076, which results in a proposed standard payment amount of $16,546. We next apply the proposed budget neutrality factor for the revised CMGs and CMG relative weights of 1.0016, which results in the proposed standard payment conversion factor of $16,573 for FY 2020.

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TABLE 15: Calculations to Determine the Proposed FY 2020 Standard Payment Conversion Factor

Explanation for Adjustment	Calculations	
Standard Payment Conversion Factor for FY 2019		$16,021
Market Basket Increase Factor for FY 2020 (3.0 percent), reduced by 0.5 percentage point for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act	x	1.025
Budget Neutrality Factor for the Wage Index and Labor-Related Share	x	1.0076
Budget Neutrality Factor for the Revisions to the CMGs and CMG Relative Weights	x	1.0016
Proposed FY 2020 Standard Payment Conversion Factor	=	$16,573

We invite public comment on the proposed FY 2020 standard payment conversion factor.

After the application of the proposed CMG relative weights described in section III. of this proposed rule to the proposed FY 2020 standard payment conversion factor ($16,573), the resulting unadjusted IRF prospective payment rates for FY 2020 are shown in Table 16.

TABLE 16: Proposed FY 2020 Payment Rates

CMG	Payment Rate Tier 1	Payment Rate Tier 2	Payment Rate Tier 3	Payment Rate No Comorbidity
0101	$ 17,598.87	$ 15,326.71	$ 14,189.80	$ 13,510.31
0102	$ 22,131.58	$ 19,276.06	$ 17,845.81	$ 16,992.30
0103	$ 26,283.12	$ 22,890.63	$ 21,191.90	$ 20,177.63
0104	$ 30,845.67	$ 26,864.83	$ 24,872.76	$ 23,681.16
0105	$ 37,012.48	$ 32,234.49	$ 29,844.66	$ 28,416.07
0106	$ 40,315.48	$ 35,111.56	$ 32,507.94	$ 30,951.73
0107	$ 47,070.63	$ 40,994.97	$ 37,955.48	$ 36,137.43
0201	$ 21,808.41	$ 17,938.62	$ 16,394.01	$ 15,270.36
0202	$ 26,901.29	$ 22,126.61	$ 20,220.72	$ 18,835.21
0203	$ 30,537.41	$ 25,118.04	$ 22,955.26	$ 21,382.48
0204	$ 35,381.70	$ 29,102.19	$ 26,596.35	$ 24,774.98
0205	$ 44,574.74	$ 36,664.45	$ 33,507.29	$ 31,210.27
0301	$ 19,607.52	$ 15,913.39	$ 14,783.12	$ 13,798.68
0302	$ 25,121.35	$ 20,389.76	$ 18,939.62	$ 17,680.08
0303	$ 30,461.17	$ 24,721.94	$ 22,965.21	$ 21,437.18
0304	$ 34,592.82	$ 28,076.32	$ 26,080.93	$ 24,344.08
0305	$ 37,403.60	$ 30,356.76	$ 28,198.96	$ 26,322.90
0401	$ 22,322.17	$ 19,020.83	$ 17,627.04	$ 16,185.19
0402	$ 30,133.03	$ 25,676.55	$ 23,795.51	$ 21,849.84
0403	$ 40,017.17	$ 34,098.95	$ 31,599.74	$ 29,016.01
0404	$ 52,470.12	$ 44,710.64	$ 41,434.16	$ 38,044.98
0405	$ 47,307.63	$ 40,310.51	$ 37,357.20	$ 34,301.14
0406	$ 54,057.81	$ 46,063.00	$ 42,687.08	$ 39,196.80
0407	$ 67,014.58	$ 57,103.93	$ 52,919.25	$ 48,590.38
0501	$ 21,576.39	$ 17,507.72	$ 16,417.21	$ 14,995.25
0502	$ 28,747.53	$ 23,326.50	$ 21,873.05	$ 19,978.75
0503	$ 37,592.54	$ 30,504.26	$ 28,603.34	$ 26,125.68
0504	$ 46,896.62	$ 38,053.27	$ 35,681.67	$ 32,592.46
0601	$ 21,987.40	$ 17,012.18	$ 16,039.35	$ 14,552.75
0602	$ 27,312.30	$ 21,130.58	$ 19,924.06	$ 18,077.83
0603	$ 32,347.18	$ 25,026.89	$ 23,596.64	$ 21,409.00
0604	$ 37,229.59	$ 28,803.87	$ 27,158.18	$ 24,640.74
0701	$ 21,203.50	$ 17,090.08	$ 16,345.95	$ 14,862.67
0702	$ 26,911.24	$ 21,692.40	$ 20,747.74	$ 18,865.05
0703	$ 31,805.24	$ 25,636.77	$ 24,519.75	$ 22,294.00
0704	$ 35,277.29	$ 28,434.30	$ 27,196.29	$ 24,728.57
0801	$ 16,853.08	$ 14,098.65	$ 12,792.70	$ 11,846.38
0802	$ 20,691.39	$ 17,308.84	$ 15,706.23	$ 14,544.46
0803	$ 25,263.88	$ 21,133.89	$ 19,176.62	$ 17,759.63
0804	$ 30,946.76	$ 25,888.68	$ 23,492.23	$ 21,755.38
0901	$ 20,122.94	$ 16,085.75	$ 14,981.99	$ 13,792.05
0902	$ 25,399.78	$ 20,303.58	$ 18,911.45	$ 17,408.28
0903	$ 30,003.76	$ 23,982.79	$ 22,338.75	$ 20,563.78
0904	$ 33,843.72	$ 27,053.77	$ 25,197.59	$ 23,195.57
1001	$ 21,647.65	$ 18,397.69	$ 16,740.39	$ 15,368.14
1002	$ 27,763.09	$ 23,594.98	$ 21,468.66	$ 19,710.27
1003	$ 32,017.38	$ 27,211.21	$ 24,758.40	$ 22,731.53
1004	$ 35,792.71	$ 30,418.08	$ 27,678.57	$ 25,409.72
1101	$ 23,483.94	$ 19,246.22	$ 17,867.35	$ 15,038.34
1102	$ 30,041.88	$ 24,620.85	$ 22,857.48	$ 19,237.94
1103	$ 33,600.10	$ 27,537.70	$ 25,565.51	$ 21,516.73

CMG	Payment Rate Tier 1	Payment Rate Tier 2	Payment Rate Tier 3	Payment Rate No Comorbidity
1201	$ 21,838.24	$ 16,798.39	$ 16,253.14	$ 14,953.82
1202	$ 26,662.64	$ 20,510.74	$ 19,844.51	$ 18,258.47
1203	$ 27,098.51	$ 20,845.52	$ 20,169.34	$ 18,556.79
1204	$ 30,800.92	$ 23,694.42	$ 22,925.43	$ 21,092.46
1301	$ 19,277.71	$ 16,170.28	$ 15,275.33	$ 14,155.00
1302	$ 24,484.95	$ 20,540.58	$ 19,403.67	$ 17,978.39
1303	$ 30,595.42	$ 25,664.95	$ 24,244.64	$ 22,464.70
1304	$ 32,068.76	$ 26,901.29	$ 25,413.04	$ 23,546.92
1401	$ 19,267.77	$ 15,661.49	$ 14,547.78	$ 13,057.87
1402	$ 23,618.18	$ 19,198.16	$ 17,832.55	$ 16,006.20
1403	$ 27,867.50	$ 22,651.98	$ 21,041.08	$ 18,886.59
1404	$ 32,753.22	$ 26,624.52	$ 24,730.23	$ 22,197.88
1501	$ 20,582.01	$ 17,472.91	$ 16,263.08	$ 15,442.72
1502	$ 24,987.11	$ 21,211.78	$ 19,743.41	$ 18,747.38
1503	$ 29,567.89	$ 25,099.81	$ 23,361.30	$ 22,184.62
1504	$ 33,953.11	$ 28,822.10	$ 26,826.72	$ 25,474.36
1601	$ 19,355.61	$ 15,434.43	$ 14,542.81	$ 13,410.87
1602	$ 24,304.30	$ 19,380.47	$ 18,261.79	$ 16,838.17
1603	$ 28,435.95	$ 22,675.18	$ 21,367.57	$ 19,701.98
1604	$ 29,108.82	$ 23,212.14	$ 21,871.39	$ 20,167.68
1701	$ 23,107.73	$ 18,115.95	$ 17,022.13	$ 15,543.82
1702	$ 29,992.16	$ 23,512.12	$ 22,093.47	$ 20,174.31
1703	$ 35,709.84	$ 27,995.11	$ 26,304.67	$ 24,020.91
1704	$ 39,523.29	$ 30,984.88	$ 29,113.79	$ 26,586.41
1801	$ 17,814.32	$ 15,325.05	$ 13,979.33	$ 12,766.18
1802	$ 24,564.50	$ 21,132.23	$ 19,277.71	$ 17,605.50
1803	$ 31,710.78	$ 27,279.16	$ 24,884.36	$ 22,724.90
1804	$ 37,624.02	$ 32,367.07	$ 29,524.80	$ 26,964.27
1805	$ 43,403.03	$ 37,338.97	$ 34,060.83	$ 31,105.86
1806	$ 57,650.84	$ 49,594.70	$ 45,242.63	$ 41,316.49
1901	$ 21,417.29	$ 17,332.04	$ 16,894.52	$ 16,241.54
1902	$ 31,127.41	$ 25,189.30	$ 24,554.56	$ 23,606.58
1903	$ 41,949.58	$ 33,946.48	$ 33,091.31	$ 31,813.53
1904	$ 58,512.63	$ 47,350.72	$ 46,155.81	$ 44,374.21
2001	$ 20,507.43	$ 16,574.66	$ 15,525.59	$ 14,072.13
2002	$ 25,250.62	$ 20,409.65	$ 19,116.96	$ 17,327.07
2003	$ 29,248.03	$ 23,639.73	$ 22,143.19	$ 20,069.90
2004	$ 32,269.29	$ 26,080.93	$ 24,428.60	$ 22,141.53
2005	$ 34,679.00	$ 28,028.26	$ 26,253.29	$ 23,795.51
2101	$ 25,515.79	$ 20,802.43	$ 19,761.65	$ 17,494.46
2102	$ 36,187.15	$ 29,503.25	$ 28,028.26	$ 24,809.78
5001				$ 3,008.00
5101				$ 9,443.30
5102				$ 29,662.36
5103				$ 11,165.23
5104				$ 36,422.48

I. Example of the Methodology for Adjusting the Proposed Prospective Payment Rates

Table 17 illustrates the methodology for adjusting the proposed prospective payments (as described in section V. of this proposed rule). The following examples are based on two hypothetical Medicare beneficiaries, both classified into CMG 0107 (without comorbidities). The proposed unadjusted prospective payment rate for CMG 0107 (without comorbidities) appears in Table 16.

Example: One beneficiary is in Facility A, an IRF located in rural Spencer County, Indiana, and another beneficiary is in Facility B, an IRF located in urban Harrison County, Indiana. Facility A, a rural non-teaching hospital has a Disproportionate Share Hospital (DSH) percentage of 5 percent (which would result in a LIP adjustment of 1.0156), a wage index of 0.8281, and a rural adjustment of 14.9 percent.

Facility B, an urban teaching hospital, has a DSH percentage of 15 percent (which would result in a LIP adjustment of 1.0454 percent), a wage index of 0.8809, and a teaching status adjustment of 0.0784.

To calculate each IRF's labor and non-labor portion of the proposed prospective payment, we begin by taking the unadjusted prospective payment rate for CMG 0107 (without comorbidities) from Table 16. Then, we multiply the proposed labor-related share for FY 2020 (72.6 percent) described in section V.E. of this proposed rule by the proposed unadjusted prospective payment rate. To determine the non-labor portion of the proposed prospective payment rate, we subtract the labor portion of the federal payment from the proposed unadjusted prospective payment.

To compute the proposed wage-adjusted prospective payment, we multiply the labor portion of the proposed federal payment by the appropriate wage index located in Tables A and B. These tables are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRF-Rules-and-Related-Files.html.*

The resulting figure is the wage-adjusted labor amount. Next, we compute the proposed wage-adjusted federal payment by adding the wage-adjusted labor amount to the non-labor portion of the proposed federal payment.

Adjusting the proposed wage-adjusted federal payment by the facility-level adjustments involves several steps. First, we take the wage-adjusted prospective payment and multiply it by the appropriate rural and LIP adjustments (if applicable). Second, to determine the appropriate amount of additional payment for the teaching status adjustment (if applicable), we multiply the teaching status adjustment (0.0784, in this example) by the wage-adjusted and rural-adjusted amount (if applicable). Finally, we add the additional teaching status payments (if applicable) to the wage, rural, and LIP-adjusted prospective payment rates. Table 17 illustrates the components of the adjusted payment calculation.

TABLE 17: Example of Computing the FY 2020 IRF Prospective Payment

Steps		Rural Facility A (Spencer Co., IN)		Urban Facility B (Harrison Co., IN)	
1	Unadjusted Payment		$ 36,137.43		$36,137.43
2	Labor Share	X	0.726	X	0.726
3	Labor Portion of Payment	=	$26,235.77	=	$26,235.77
4	CBSA-Based Wage Index (shown in the Addendum, Tables A and B)	X	0.8281	X	0.8809
5	Wage-Adjusted Amount	=	$21,725.84	=	$23,111.09
6	Non-Labor Amount	+	$ 9,901.66	+	$ 9,901.66
7	Wage-Adjusted Payment	=	$31,627.50	=	$33,012.75
8	Rural Adjustment	X	1.149	X	1.000
9	Wage- and Rural-Adjusted Payment	=	$36,340.00	=	$33,012.75
10	LIP Adjustment	X	1.0156	X	1.0454
11	Wage-, Rural- and LIP-Adjusted Payment	=	$36,906.90	=	$34,511.53
12	Wage- and Rural-Adjusted Payment		$36,340.00		$33,012.75
13	Teaching Status Adjustment	X	0	X	0.0784
14	Teaching Status Adjustment Amount	=	$0.00	=	$2,588.20
15	Wage-, Rural-, and LIP-Adjusted Payment	+	$36,906.90	+	$34,511.53
16	Total Adjusted Payment	=	$36,906.90	=	$37,099.73

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Thus, the proposed adjusted payment for Facility A would be $36,906.90, and the adjusted payment for Facility B would be $37,099.73.

VI. Proposed Update to Payments for High-Cost Outliers Under the IRF PPS for FY 2020

A. Proposed Update to the Outlier Threshold Amount for FY 2020

Section 1886(j)(4) of the Act provides the Secretary with the authority to make payments in addition to the basic IRF prospective payments for cases incurring extraordinarily high costs. A case qualifies for an outlier payment if the estimated cost of the case exceeds the adjusted outlier threshold. We calculate the adjusted outlier threshold by adding the IRF PPS payment for the case (that is, the CMG payment adjusted by all of the relevant facility-level adjustments) and the adjusted threshold amount (also adjusted by all of the relevant facility-level adjustments). Then, we calculate the estimated cost of a case by multiplying the IRF's overall CCR by the Medicare allowable covered charge. If the estimated cost of the case is higher than the adjusted outlier threshold, we make an outlier payment for the case equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold.

In the FY 2002 IRF PPS final rule (66 FR 41362 through 41363), we discussed our rationale for setting the outlier threshold amount for the IRF PPS so that estimated outlier payments would equal 3 percent of total estimated payments. For the 2002 IRF PPS final rule, we analyzed various outlier policies using 3, 4, and 5 percent of the total estimated payments, and we concluded that an outlier policy set at 3 percent of total estimated payments would optimize the extent to which we could reduce the financial risk to IRFs of caring for high-cost patients, while still providing for adequate payments for all other (non-high cost outlier) cases.

Subsequently, we updated the IRF outlier threshold amount in the FYs 2006 through 2019 IRF PPS final rules and the FY 2011 and FY 2013 notices (70 FR 47880, 71 FR 48354, 72 FR 44284, 73 FR 46370, 74 FR 39762, 75 FR 42836, 76 FR 47836, 76 FR 59256, 77 FR

44618, 78 FR 47860, 79 FR 45872, 80 FR 47036, 81 FR 52056, 82 FR 36238, and 83 FR 38514, respectively) to maintain estimated outlier payments at 3 percent of total estimated payments. We also stated in the FY 2009 final rule (73 FR 46370 at 46385) that we would continue to analyze the estimated outlier payments for subsequent years and adjust the outlier threshold amount as appropriate to maintain the 3 percent target.

To update the IRF outlier threshold amount for FY 2020, we propose to use FY 2018 claims data and the same methodology that we used to set the initial outlier threshold amount in the FY 2002 IRF PPS final rule (66 FR 41316 and 41362 through 41363), which is also the same methodology that we used to update the outlier threshold amounts for FYs 2006 through 2019. The outlier threshold is calculated by simulating aggregate payments and using an iterative process to determine a threshold that results in outlier payments being equal to 3 percent of total payments under the simulation. To determine the outlier threshold for FY 2020, we estimate the amount of FY 2020 IRF PPS aggregate and outlier payments using the most recent claims available (FY 2018) and the proposed FY 2020 standard payment conversion factor, labor-related share, and wage indexes, incorporating any applicable budget-neutrality adjustment factors. The outlier threshold is adjusted either up or down in this simulation until the estimated outlier payments equal 3 percent of the estimated aggregate payments. Based on an analysis of the preliminary data used for the proposed rule, we estimated that IRF outlier payments as a percentage of total estimated payments would be approximately 3.2 percent in FY 2019. Therefore, we propose to update the outlier threshold amount from $9,402 for FY 2019 to $9,935 for FY 2020 to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2020.

We invite public comment on the proposed update to the FY 2020 outlier threshold amount to maintain estimated outlier payments at approximately 3 percent of total estimated IRF payments.

B. Proposed Update to the IRF Cost-to-Charge Ratio Ceiling and Urban/Rural Averages for FY 2020

Cost-to-charge ratios are used to adjust charges from Medicare claims to costs and are computed annually from facility-specific data obtained from Medicare cost reports. IRF specific cost-to-charge ratios are used in the development of the CMG relative weights and the calculation of outlier payments under the IRF prospective payment system. In accordance with the methodology stated in the FY 2004 IRF PPS final rule (68 FR 45674, 45692 through 45694), we propose to apply a ceiling to IRFs' CCRs. Using the methodology described in that final rule, we propose to update the national urban and rural CCRs for IRFs, as well as the national CCR ceiling for FY 2020, based on analysis of the most recent data that is available. We apply the national urban and rural CCRs in the following situations:

- New IRFs that have not yet submitted their first Medicare cost report.
- IRFs whose overall CCR is in excess of the national CCR ceiling for FY 2020, as discussed below in this section.
- Other IRFs for which accurate data to calculate an overall CCR are not available.

Specifically, for FY 2020, we propose to estimate a national average CCR of 0.500 for rural IRFs, which we calculated by taking an average of the CCRs for all rural IRFs using their most recently submitted cost report data. Similarly, we propose to estimate a national average CCR of 0.406 for urban IRFs, which we calculated by taking an average of the CCRs for all urban IRFs using their most recently submitted cost report data. We apply weights to both of these averages using the IRFs' estimated costs, meaning that the CCRs of IRFs with higher total costs factor more heavily into the averages than the CCRs of IRFs with lower total costs. For this proposed rule, we have used the most recent available cost report data (FY 2017). This includes all IRFs whose cost reporting periods begin on or after October 1, 2016, and before October 1, 2017. If, for any IRF, the FY 2017 cost report was missing or had an ''as submitted'' status, we used data from a previous fiscal year's (that is, FY 2004 through FY 2016) settled cost report for that IRF. We do not use cost report data from before FY 2004 for any IRF because changes in IRF utilization since FY 2004 resulting from the 60 percent rule and IRF medical review activities suggest that these older data do not adequately reflect the current cost of care.

In accordance with past practice, we propose to set the national CCR ceiling at 3 standard deviations above the mean CCR. Using this method, we propose a national CCR ceiling of 1.31 for FY 2020. This means that, if an individual IRF's CCR were to exceed this ceiling of 1.31 for FY 2020, we would replace the IRF's CCR with the appropriate proposed national average CCR (either rural or urban, depending on the geographic location of the IRF). We calculated the proposed national CCR ceiling by:

Step 1. Taking the national average CCR (weighted by each IRF's total costs, as previously discussed) of all IRFs for which we have sufficient cost report data (both rural and urban IRFs combined).

Step 2. Estimating the standard deviation of the national average CCR computed in step 1.

Step 3. Multiplying the standard deviation of the national average CCR computed in step 2 by a factor of 3 to compute a statistically significant reliable ceiling.

Step 4. Adding the result from step 3 to the national average CCR of all IRFs for which we have sufficient cost report data, from step 1.

The proposed national average rural and urban CCRs and the proposed national CCR ceiling in this section will be updated in the final rule if more recent data becomes available to use in these analyses.

We invite public comment on the proposed update to the IRF CCR ceiling and the urban/rural averages for FY 2020.

VII. Proposed Amendments to § 412.622 To Clarify the Definition of a Rehabilitation Physician

Under § 412.622(a)(3)(iv), a rehabilitation physician is defined as ''a licensed physician with specialized training and experience in inpatient rehabilitation.'' The term rehabilitation physician is used in several other places in § 412.622, with corresponding references to § 412.622(a)(3)(iv). The definition at § 412.622(a)(3)(iv) does not specify the level or type of training and experience required for a licensed physician to be designated as a rehabilitation physician because we believe that the IRFs are in the best position to make this determination for purposes of § 412.622.

Therefore, we propose to amend the definition of a rehabilitation physician to clarify that the determination as to whether a physician qualifies as a rehabilitation physician (that is, a licensed physician with specialized training and experience in inpatient rehabilitation) is made by the IRF. For clarity, we also propose to remove this definition from § 412.622(a)(3)(iv) and move it to a new paragraph (§ 412.622(c)). We also propose to make corresponding technical corrections elsewhere in § 412.622(a)(3)(iv), (a)(4)(i)(A), (a)(4)(iii)(A), and (a)(5)(i) to remove the references to § 412.622(a)(3)(iv) in those paragraphs,

so as to reflect the new location of the definition.

We invite public comment on the proposal to clarify the definition of a rehabilitation physician, to move the definition from § 412.622(a)(3)(iv) to § 412.622(c), and to make corresponding technical corrections elsewhere in § 412.622 to remove references to the current location of the definition in § 412.622(a)(3)(iv).

VIII. Proposed Revisions and Updates to the IRF Quality Reporting Program (QRP)

A. Background

The Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP) is authorized by section 1886(j)(7) of the Act, and it applies to freestanding IRFs, as well as inpatient rehabilitation units of hospitals or critical access hospitals (CAHs) paid by Medicare under the IRF PPS. Under the IRF QRP, the Secretary must reduce the annual increase factor for discharges occurring during such fiscal year by 2 percentage points for any IRF that does not submit data in accordance with the requirements established by the Secretary. For more information on the background and statutory authority for the IRF QRP, we refer readers to the FY 2012 IRF PPS final rule (76 FR 47873 through 47874), the CY 2013 Hospital Outpatient Prospective Payment System/Ambulatory Surgical Center (OPPS/ASC) Payment Systems and Quality Reporting Programs final rule (77 FR 68500 through 68503), the FY 2014 IRF PPS final rule (78 FR 47902), the FY 2015 IRF PPS final rule (79 FR 45908), the FY 2016 IRF PPS final rule (80 FR 47080 through 47083), the FY 2017 IRF PPS final rule (81 FR 52080 through 52081), the FY 2018 IRF PPS final rule (82 FR 36269 through 36270), and the FY 2019 IRF PPS final rule (83 FR 38555 through 38556).

B. General Considerations Used for the Selection of Measures for the IRF QRP

For a detailed discussion of the considerations we historically used for the selection of IRF QRP quality, resource use, and other measures, we refer readers to the FY 2016 IRF PPS final rule (80 FR 47083 through 47084).

C. Quality Measures Currently Adopted for the FY 2021 IRF QRP

The IRF QRP currently has 15 measures for the FY 2020 program year, which are set out in Table 18.

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TABLE 18: Quality Measures Currently Adopted for the FY 2020 IRF QRP

Short Name	Measure Name & Data Source
IRF-PAI	
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674)
Application of Functional Assessment	Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631)
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues- Post Acute Care (PAC) Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP)
Change in Self-Care	IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633)
Change in Mobility	IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634)
Discharge Self-Care Score	IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635)
Discharge Mobility Score	IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636)
NHSN	
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection Outcome Measure (NQF #0138)
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717)
HCP Influenza Vaccine	Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431)
Claims-Based	
MSPB IRF	Medicare Spending Per Beneficiary (MSPB) –Post Acute Care (PAC) PAC IRF QRP
DTC	Discharge to Community–PAC IRF QRP
PPR 30 day	Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP
PPR Within Stay	Potentially Preventable Within Stay Readmission Measure for IRFs

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D. IRF QRP Quality Measure Proposals Beginning With the FY 2022 IRF QRP

In this proposed rule, we are proposing to adopt two process measures for the IRF QRP that would satisfy section 1899B(c)(1)(E)(ii) of the Act, which requires that the quality measures specified by the Secretary include measures with respect to the

quality measure domain titled ''Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual when the individual transitions from a post-acute care (PAC) provider to another applicable setting, including a different PAC provider, a hospital, a critical access hospital, or the home of the individual.'' Given the length of this domain title, hereafter, we will refer to this quality measure domain as ''Transfer of Health Information.''

The two measures we are proposing to adopt are: (1) Transfer of Health Information to the Provider–Post-Acute Care (PAC); and (2) Transfer of Health Information to the Patient–Post-Acute Care (PAC). Both of these proposed measures support our Meaningful Measures priority of promoting effective communication and coordination of care, specifically the Meaningful Measure area of the transfer of health information and interoperability.

In addition to the two measure proposals, we are proposing to update the specifications for the Discharge to Community–Post Acute Care (PAC) IRF QRP measure to exclude baseline nursing facility (NF) residents from the measure.

We are seeking public comment on each of these proposals.

1. Proposed Transfer of Health Information to the Provider–Post-Acute Care (PAC) Measure

The proposed Transfer of Health Information to the Provider–Post-Acute Care (PAC) Measure is a process-based measure that assesses whether or not a current reconciled medication list is given to the subsequent provider when a patient is discharged or transferred from his or her current PAC setting.

a. Background

In 2013, 22.3 percent of all acute hospital discharges were discharged to PAC settings, including 11 percent who were discharged to home under the care of a home health agency, and nine percent who were discharged to SNFs.[2] The proportion of patients being discharged from an acute care hospital to a PAC setting was greater among beneficiaries enrolled in Medicare fee-for-service (FFS). Among Medicare FFS patients discharged from an acute hospital, 42 percent went directly to PAC settings. Of that 42 percent, 20 percent were discharged to a SNF, 18 percent were discharged to a home health agency (HHA), 3 percent were discharged to an IRF, and one percent were discharged to an LTCH.[3] Of the Medicare FFS beneficiaries with an IRF stay in FYs 2016 and 2017, an estimated 10 percent were discharged or transferred to an acute care hospital, 51 percent discharged home with home health services, 16 percent discharged or transferred to a SNF, and one percent discharged or transferred to another PAC setting (for example, another IRF, a hospice, or an LTCH).[4]

The transfer and/or exchange of health information from one provider to another can be done verbally (for example, clinician-to-clinician communication in-person or by telephone), paper-based (for example, faxed or printed copies of records), and via electronic communication (for example, through a health information exchange network using an electronic health/medical record, and/or secure messaging). Health information, such as medication information, that is incomplete or missing increases the likelihood of a patient or resident safety risk, and is often life-threatening.[5] [6] [7] [8] [9] [10] Poor communication and coordination across health care settings contributes to patient complications, hospital readmissions, emergency department visits, and medication errors.[11] [12] [13] [14] [15] [16] [17] [18] [19] [20] Communication has been cited as the third most frequent root cause in sentinel events, which The Joint Commission defines[21] as a patient safety event that results in death, permanent harm, or severe temporary harm. Failed or ineffective patient handoffs are estimated to play a role in 20 percent of serious preventable adverse events.[22] When care transitions are enhanced through care coordination activities, such as expedited patient information flow, these activities can reduce duplication of care services and costs of care, resolve conflicting care plans, and prevent medical errors.[23] [24] [25] [26] [27]

[2] Tian, W. ''An all-payer view of hospital discharge to post-acute care,'' May 2016. Available at *https://www.hcup-us.ahrq.gov/reports/statbriefs/sb205-Hospital-Discharge-Postacute-Care.jsp.*

[3] Ibid.

[4] RTI International analysis of Medicare claims data for index stays in IRF 2016/2017. (RTI program reference: MM150).

[5] Kwan, J.L., Lo, L., Sampson, M., & Shojania, K.G., ''Medication reconciliation during transitions of care as a patient safety strategy: A systematic review,'' Annals of Internal Medicine, 2013, Vol. 158(5), pp. 397–403.

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[8] Basey, A.J., Krska, J., Kennedy, T.D., & Mackridge, A.J., ''Prescribing errors on admission to hospital and their potential impact: A mixed-methods study,'' BMJ Quality & Safety, 2014, Vol. 23(1), pp. 17–25.

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[10] Boling, P.A., ''Care transitions and home health care,'' Clinical Geriatric Medicine, 2009, Vol.25(1), pp. 135–48.

[11] Barnsteiner, J.H., ''Medication Reconciliation: Transfer of medication information across settings—keeping it free from error,'' The American Journal of Nursing, 2005, Vol. 105(3), pp. 31–36.

[12] Arbaje, A.I., Kansagara, D.L., Salanitro, A.H., Englander, H.L., Kripalani, S., Jencks, S.F., & Lindquist, L.A., ''Regardless of age: Incorporating principles from geriatric medicine to improve care transitions for patients with complex needs,'' Journal of General Internal Medicine, 2014, Vol. 29(6), pp. 932–939.

[13] Jencks, S.F., Williams, M.V., & Coleman, E.A., ''Rehospitalizations among patients in the Medicare fee-for-service program,'' New England Journal of Medicine, 2009, Vol. 360(14), pp. 1418–1428.

[14] Institute of Medicine. ''Preventing medication errors: quality chasm series,'' Washington, DC: The National Academies Press 2007. Available at *https://www.nap.edu/read/11623/chapter/1.*

[15] Kitson, N.A., Price, M., Lau, F.Y., & Showler, G., ''Developing a medication communication framework across continuums of care using the Circle of Care Modeling approach,'' BMC Health Services Research, 2013, Vol. 13(1), pp. 1–10.

[16] Mor, V., Intrator, O., Feng, Z., & Grabowski, D.C., ''The revolving door of rehospitalization from skilled nursing facilities,'' Health Affairs, 2010, Vol. 29(1), pp. 57–64.

[17] Institute of Medicine. ''Preventing medication errors: quality chasm series,'' Washington, DC: The National Academies Press 2007. Available at *https://www.nap.edu/read/11623/chapter/1.*

[18] Kitson, N.A., Price, M., Lau, F.Y., & Showler, G., ''Developing a medication communication framework across continuums of care using the Circle of Care Modeling approach,'' BMC Health Services Research, 2013, Vol. 13(1), pp. 1–10.

[19] Forster, A.J., Murff, H.J., Peterson, J.F., Gandhi, T.K., & Bates, D.W., ''The incidence and severity of adverse events affecting patients after discharge from the hospital.'' Annals of Internal Medicine, 2003,138(3), pp. 161–167.

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[21] The Joint Commission, ''Sentinel Event Policy'' available at *https://www.jointcommission.org/sentinel_event_policy_and_procedures/.*

[22] The Joint Commission. ''Sentinel Event Data Root Causes by Event Type 2004 –2015.'' 2016. Available at *https://www.jointcommission.org/assets/1/23/jconline_Mar_2_2016.pdf.*

[23] Mor, V., Intrator, O., Feng, Z., & Grabowski, D.C., ''The revolving door of rehospitalization from skilled nursing facilities,'' *Health Affairs,* 2010, Vol. 29(1), pp. 57–64.

[24] Institute of Medicine, ''Preventing medication errors: Quality chasm series,'' Washington, DC: The

Care transitions across health care settings have been characterized as complex, costly, and potentially hazardous, and may increase the risk for multiple adverse outcomes. [28] [29] The rising incidence of preventable adverse events, complications, and hospital readmissions have drawn attention to the importance of the timely transfer of health information and care preferences at the time of transition. Failures of care coordination, including poor communication of information, were estimated to cost the U.S. health care system between $25 billion and $45 billion in wasteful spending in 2011.[30] The communication of health information and patient care preferences is critical to ensuring safe and effective transitions from one health care setting to another.[31] [32]

Patients in PAC settings often have complicated medication regimens and require efficient and effective communication and coordination of care between settings, including detailed transfer of medication information.[33] [34] [35] Individuals in PAC settings may be vulnerable to adverse health outcomes due to insufficient medication information on the part of their health care providers, and the higher likelihood for multiple comorbid chronic conditions, polypharmacy, and complicated transitions between care settings.[36] [37] Preventable adverse drug events (ADEs) may occur after hospital discharge in a variety of settings including PAC.[38] A 2014 Office of Inspector General report found that 10 percent of Medicare patients in IRFs experienced adverse events, with most of those events being medication related. Over 45 percent of the adverse events and temporary harm events were clearly or likely preventable.[39] Medication errors and one-fifth of ADEs occur during transitions between settings, including admission to or discharge from a hospital to home or a PAC setting, or transfer between hospitals.[40] [41]

Patients in PAC settings are often taking multiple medications. Consequently, PAC providers regularly are in the position of starting complex new medication regimens with little knowledge of the patients or their medication history upon admission. Furthermore, inter-facility communication barriers delay resolving medication discrepancies during transitions of care.[42] Medication discrepancies are common,[43] and found to occur in 86 percent of all transitions, increasing the likelihood of ADEs.[44] [45] [46] Up to 90 percent of patients experience at least one medication discrepancy in the transition from hospital to home care, and discrepancies occur within all therapeutic classes of medications.[47] [48]

Transfer of a medication list between providers is necessary for medication reconciliation interventions, which have been shown to be a cost-effective way to avoid ADEs by reducing errors,[49] [50] [51]

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especially when medications are reviewed by a pharmacist using electronic medical records.[52]

b. Stakeholder and Technical Expert Panel (TEP) Input

The proposed measure was developed after consideration of feedback we received from stakeholders and four TEPs convened by our contractors. Further, the proposed measure was developed after evaluation of data collected during two pilot tests we conducted in accordance with the CMS Measures Management System Blueprint.

Our measure development contractors constituted a TEP which met on September 27, 2016 [53], January 27, 2017, and August 3, 2017 [54] to provide input on a prior version of this measure. Based on this input, we updated the measure concept in late 2017 to include the transfer of a specific component of health information—medication information. Our measure development contractors reconvened this TEP on April 20, 2018 for the purpose of obtaining expert input on the proposed measure, including the measure's reliability, components of face validity, and feasibility of being implemented across PAC settings. Overall, the TEP was supportive of the proposed measure, affirming that the measure provides an opportunity to improve the transfer of medication information. A summary of the April 20, 2018 TEP proceedings titled ''Transfer of Health Information TEP Meeting 4—June 2018'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Our measure development contractors solicited stakeholder feedback on the proposed measure by requesting comment on the CMS Measures Management System Blueprint website, and accepted comments that were submitted from March 19, 2018 to May 3, 2018. The comments received expressed overall support for the measure. Several commenters suggested ways to improve the measure, primarily related to what types of information should be included at transfer. We incorporated this input into development of the proposed measure. The summary report for the March 19 to May 3, 2018 public comment period titled ''IMPACT Medication Profile Transferred Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

c. Pilot Testing

The proposed measure was tested between June and August 2018 in a pilot test that involved 24 PAC facilities/agencies, including five IRFs, six SNFs, six LTCHs, and seven HHAs. The 24 pilot sites submitted a total of 801 records. Analysis of agreement between coders within each participating facility (266 qualifying pairs) indicated a 93 percent agreement for this measure. Overall, pilot testing enabled us to verify its reliability, components of face validity, and feasibility of being implemented across PAC settings. Further, more than half of the sites that participated in the pilot test stated during the debriefing interviews that the measure could distinguish facilities or agencies with higher quality medication information transfer from those with lower quality medication information transfer at discharge. The pilot test summary report titled ''Transfer of Health Information 2018 Pilot Test Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

d. Measure Applications Partnership (MAP) Review and Related Measures

We included the proposed measure in the IRF QRP section of the 2018 Measures Under Consideration (MUC) list. The MAP conditionally supported this measure pending NQF endorsement, noting that the measure can promote the transfer of important medication information. The MAP also suggested that CMS consider a measure that can be adapted to capture bi-directional information exchange, and recommended that the medication information transferred include important information about supplements and opioids. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/Publications/2019/02/MAP_2019_Considerations_for_Implementing_Measures_Final_Report_-_PAC-LTC.aspx.*

As part of the measure development and selection process, we also identified one NQF-endorsed quality measure similar to the proposed measure, titled Documentation of Current Medications in the Medical Record (NQF #0419, CMS eCQM ID: CMS68v8). This measure was adopted as one of the recommended adult core clinical quality measures for eligible professionals for the EHR Incentive Program beginning in 2014 and was also adopted under the Merit-based Incentive Payment System (MIPS) quality performance category beginning in 2017. The measure is calculated based on the percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all resources immediately available on the date of the encounter.

The proposed Transfer of Health Information to the Provider–Post-Acute Care (PAC) measure addresses the transfer of information whereas the NQF-endorsed measure #0419 assesses the documentation of medications, but not the transfer of such information. This is important as the proposed measure assesses for the transfer of medication information for the proposed measure calculation. Further, the proposed measure utilizes standardized patient assessment data elements (SPADEs), which is a

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of admission medication reconciliation on adverse drug events from admission medication changes,'' Archives of Internal Medicine, 2011, Vol. 171(9), pp. 860–861.

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[52] Agrawal A., Wu WY. ''Reducing medication errors and improving systems reliability using an electronic medication reconciliation system,'' The Joint Commission Journal on Quality and Patient Safety, 2009, Vol. 35(2), pp. 106–114.

[53] Technical Expert Panel Summary Report: Development of two quality measures to satisfy the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) Domain of Transfer of health Information and Care Preferences When an Individual Transitions to Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs), Long Term Care Hospitals (LTCHs) and Home Health Agencies (HHAs). Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-TEP_Summary_Report_Final-June-2017.pdf.*

[54] Technical Expert Panel Summary Report: Development of two quality measures to satisfy the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) Domain of Transfer of health Information and Care Preferences When an Individual Transitions to Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs), Long Term Care Hospitals (LTCHs) and Home Health Agencies (HHAs). Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-TEP-Meetings-2-3-Summary-Report_Final_Feb2018.pdf.*

requirement for measures specified under the Transfer of Health Information measure domain under section 1899B(c)(1)(E) of the Act, whereas NQF #0419 does not.

After review of the NQF-endorsed measure, we determined that the proposed Transfer of Health Information to the Provider–Post-Acute Care (PAC) measure better addresses the Transfer of Health Information measure domain, which requires that at least some of the data used to calculate the measure be collected as standardized patient assessment data through the post-acute care assessment instruments. Section 1886(j)(7)(D)(i) of the Act requires that any measure specified by the Secretary be endorsed by the entity with a contract under section 1890(a) of the Act, which is currently the National Quality Form (NQF). However, when a feasible and practical measure has not been NQF endorsed for a specified area or medical topic determined appropriate by the Secretary, section 1886(j)(7)(D)(ii) of the Act allows the Secretary to specify a measure that is not NQF endorsed as long as due consideration is given to the measures that have been endorsed or adopted by a consensus organization identified by the Secretary. For the reasons discussed previously, we believe that there is currently no feasible NQF-endorsed measure that we could adopt under section 1886(j)(7)(D)(ii) of the Act. However, we note that we intend to submit the proposed measure to the NQF for consideration of endorsement when feasible.

e. Quality Measure Calculation

The proposed Transfer of Health Information to the Provider-Post-Acute Care (PAC) quality measure is calculated as the proportion of patient stays with a discharge assessment indicating that a current reconciled medication list was provided to the subsequent provider at the time of discharge. The proposed measure denominator is the total number of IRF patient stays ending in discharge to a subsequent provider, which is defined as a short-term general acute-care hospital, intermediate care (intellectual and developmental disabilities providers), home under care of an organized home health service organization or hospice, hospice in an institutional facility, a SNF, an LTCH, another IRF, an inpatient psychiatric facility, or a CAH. These health care providers were selected for inclusion in the denominator because they are identified as subsequent providers on the discharge destination item that is currently included on the IRF patient assessment instrument (IRF–PAI). The proposed measure numerator is the number of IRF patient stays with an IRF–PAI discharge assessment indicating a current reconciled medication list was provided to the subsequent provider at the time of discharge. For additional technical information about this proposed measure, we refer readers to the document titled, ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.* The data source for the proposed quality measure is the IRF–PAI assessment instrument for IRF patients.

For more information about the data submission requirements we are proposing for this measure, we refer readers to section VIII.G.3. of this proposed rule.

2. Proposed Transfer of Health Information to the Patient-Post-Acute Care (PAC) Measure

Beginning with the FY 2022 IRF QRP, we are proposing to adopt the Transfer of Health Information to the Patient—Post Acute Care (PAC) measure, a measure that satisfies the IMPACT Act domain of Transfer of Health Information, with data collection for discharges beginning October 1, 2020. This process-based measure assesses whether or not a current reconciled medication list was provided to the patient, family, or caregiver when the patient was discharged from a PAC setting to a private home/apartment, a board and care home, assisted living, a group home, transitional living or home under care of an organized home health service organization, or a hospice.

a. Background

In 2013, 22.3 percent of all acute hospital discharges were discharged to PAC settings, including 11 percent who were discharged to home under the care of a home health agency.[55] Of the Medicare FFS beneficiaries with an IRF stay in fiscal years 2016 and 2017, an estimated 51 percent were discharged home with home health services, 21 percent were discharged home with self-care, and .5 percent were discharged with home hospice services.[56]

The communication of health information, such as a reconciled medication list, is critical to ensuring safe and effective patient transitions from health care settings to home and/or other community settings. Incomplete or missing health information, such as medication information, increases the likelihood of a patient safety risk, often life-threatening.[57] [58] [59] [60] [61] Individuals who use PAC care services are particularly vulnerable to adverse health outcomes due to their higher likelihood of having multiple comorbid chronic conditions, polypharmacy, and complicated transitions between care settings.[62] [63] Upon discharge to home, individuals in PAC settings may be faced with numerous medication changes, new medication regimes, and follow-up details.[64] [65] [66] The efficient

[55] Tian, W. ''An all-payer view of hospital discharge to postacute care,'' May 2016. Available at *https://www.hcup-us.ahrq.gov/reports/statbriefs/sb205-Hospital-Discharge-Postacute-Care.jsp.*

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[64] Brody, A.A., Gibson, B., Tresner-Kirsch, D., Kramer, H., Thraen, I., Coarr, M.E., & Rupper, R. ''High prevalence of medication discrepancies between home health referrals and Centers for Medicare and Medicaid Services home health certification and plan of care and their potential to affect safety of vulnerable elderly adults,'' Journal

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and effective communication and coordination of medication information may be critical to prevent potentially deadly adverse effects. When care coordination activities enhance care transitions, these activities can reduce duplication of care services and costs of care, resolve conflicting care plans, and prevent medical errors.[67] [68]

Finally, the transfer of a patient's discharge medication information to the patient, family, or caregiver is common practice and supported by discharge planning requirements for participation in Medicare and Medicaid programs.[69] [70] Most PAC EHR systems generate a discharge medication list to promote patient participation in medication management, which has been shown to be potentially useful for improving patient outcomes and transitional care.[71]

b. Stakeholder and Technical Expert Panel (TEP) Input

The proposed measure was developed after consideration of feedback we received from stakeholders and four TEPs convened by our contractors. Further, the proposed measure was developed after evaluation of data collected during two pilot tests we conducted in accordance with the CMS Measures Management System Blueprint.

Our measure development contractors constituted a TEP which met on September 27, 2016,[72] January 27, 2017, and August 3, 2017 [73] to provide input on a prior version of this measure. Based on this input, we updated the measure concept in late 2017 to include the transfer of a specific component of health information—medication information. Our measure development contractors reconvened this TEP on April 20, 2018 to seek expert input on the measure. Overall, the TEP members supported the proposed measure, affirming that the measure provides an opportunity to improve the transfer of medication information. Most of the TEP members believed that the measure could improve the transfer of medication information to patients, families, and caregivers. Several TEP members emphasized the importance of transferring information to patients and their caregivers in a clear manner using plain language. A summary of the April 20, 2018 TEP proceedings titled ''Transfer of Health Information TEP Meeting 4—June 2018'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Our measure development contractors solicited stakeholder feedback on the proposed measure by requesting comment on the CMS Measures Management System Blueprint website, and accepted comments that were submitted from March 19, 2018 to May 3, 2018. Several commenters noted the importance of ensuring that the instruction provided to patients and caregivers is clear and understandable to promote transparent access to medical record information and meet the goals of the IMPACT Act. The summary report for the March 19 to May 3, 2018 public comment period titled ''IMPACT-Medication Profile Transferred Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

c. Pilot Testing

Between June and August 2018, we held a pilot test involving 24 PAC facilities/agencies, including five IRFs, six SNFs, six LTCHs, and seven HHAs. The 24 pilot sites submitted a total of 801 assessments. Analysis of agreement between coders within each participating facility (241 qualifying pairs) indicated an 87 percent agreement for this measure. Overall, pilot testing enabled us to verify its reliability, components of face validity, and feasibility of being implemented across PAC settings. Further, more than half of the sites that participated in the pilot test stated, during debriefing interviews, that the measure could distinguish facilities or agencies with higher quality medication information transfer from those with lower quality medication information transfer at discharge. The pilot test summary report titled ''Transfer of Health Information 2018 Pilot Test Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

d. Measure Applications Partnership (MAP) Review and Related Measures

We included the proposed measure in the IRF QRP section of the 2018 MUC list. The MAP conditionally supported this measure pending NQF endorsement, noting that the measure can promote the transfer of important medication information to the patient. The MAP recommended that providers transmit medication information to patients that is easy to understand because health literacy can impact a person's ability to take medication as directed. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/Publications/*

of the American Geriatrics Society, 2016, Vol. 64(11), pp. e166–e170.

[65] Bell, C.M., Brener, S.S., Gunraj, N., Huo, C., Bierman, A.S., Scales, D.C., & Urbach, D.R., ''Association of ICU or hospital admission with unintentional discontinuation of medications for chronic diseases,'' JAMA, 2011, Vol. 306(8), pp. 840–847.

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[67] Mor, V., Intrator, O., Feng, Z., & Grabowski, D.C., ''The revolving door of rehospitalization from skilled nursing facilities,'' Health Affairs, 2010, Vol. 29(1), pp. 57–64.

[68] Starmer, A.J., Sectish, T.C., Simon, D.W., Keohane, C., McSweeney, M.E., Chung, E.Y., Yoon, C.S., Lipsitz, S.R., Wassner, A.J., Harper, M.B., & Landrigan, C.P., ''Rates of medical errors and preventable adverse events among hospitalized children following implementation of a resident handoff bundle,'' JAMA, 2013, Vol. 310(21), pp. 2262–2270.

[69] CMS, ''Revision to state operations manual (SOM), Hospital Appendix A—Interpretive Guidelines for 42 CFR 482.43, Discharge Planning'' May 17, 2013. Available at *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-32.pdf.*

[70] The State Operations Manual Guidance to Surveyors for Long Term Care Facilities (Guidance § 483.21(c)(1) Rev. 11–22–17) for discharge planning process. Available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf.*

[71] Toles, M., Colon-Emeric, C., Naylor, M.D., Asafu-Adjei, J., Hanson, L.C., ''Connect-home: transitional care of skilled nursing facility patients and their caregivers,'' Am Geriatr Soc., 2017, Vol. 65(10), pp. 2322–2328.

[72] Technical Expert Panel Summary Report: Development of two quality measures to satisfy the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) Domain of Transfer of health Information and Care Preferences When an Individual Transitions to Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs), Long Term Care Hospitals (LTCHs) and Home Health Agencies (HHAs). Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-TEP_Summary_Report_Final-June-2017.pdf.*

[73] Technical Expert Panel Summary Report: Development of two quality measures to satisfy the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) Domain of Transfer of health Information and Care Preferences When an Individual Transitions to Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs), Long Term Care Hospitals (LTCHs) and Home Health Agencies (HHAs). Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-TEP-Meetings-2-3-Summary-Report_Final_Feb2018.pdf.*

2019/02/MAP_2019_Considerations_for_Implementing_Measures_Final_Report_-_PAC-LTC.aspx.

Section 1886(j)(7)(D)(i) of the Act, requires that any measure specified by the Secretary be endorsed by the entity with a contract under section 1890(a) of the Act, which is currently the NQF. However, when a feasible and practical measure has not been NQF endorsed for a specified area or medical topic determined appropriate by the Secretary, section 1886(j)(7)(D)(ii) of the Act allows the Secretary to specify a measure that is not NQF endorsed as long as due consideration is given to the measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Therefore, in the absence of any NQF-endorsed measures that address the proposed Transfer of Health Information to the Patient –Post-Acute Care (PAC), which requires that at least some of the data used to calculate the measure be collected as standardized patient assessment data through post-acute care assessment instruments, we believe that there is currently no feasible NQF-endorsed measure that we could adopt under section 1886(j)(7)(D)(ii) of the Act. However, we note that we intend to submit the proposed measure to the NQF for consideration of endorsement when feasible.

e. Quality Measure Calculation

The calculation of the proposed Transfer of Health Information to the Patient–Post-Acute Care (PAC) measure would be based on the proportion of patient stays with a discharge assessment indicating that a current reconciled medication list was provided to the patient, family, or caregiver at the time of discharge.

The proposed measure denominator is the total number of IRF patient stays ending in discharge to a private home/apartment, a board and care home, assisted living, a group home, transitional living or home under care of an organized home health service organization, or a hospice. These locations were selected for inclusion in the denominator because they are identified as home locations on the discharge destination item that is currently included on the IRF–PAI. The proposed measure numerator is the number of IRF patient stays with an IRF–PAI discharge assessment indicating a current reconciled medication list was provided to the patient, family, or caregiver at the time of discharge. For technical information about this proposed measure, we refer readers to the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.* Data for the proposed quality measure would be calculated using data from the IRF–PAI assessment instrument for IRF patients.

For more information about the data submission requirements we are proposing for this measure, we refer readers to section VIII.G.3. of this proposed rule.

3. Proposed Update to the Discharge to Community–Post Acute Care (PAC) Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP) Measure

We are proposing to update the specifications for the Discharge to Community–PAC IRF QRP measure to exclude baseline nursing facility (NF) residents from the measure. This measure reports an IRF's risk-standardized rate of Medicare FFS patients who are discharged to the community following an IRF stay, do not have an unplanned readmission to an acute care hospital or LTCH in the 31 days following discharge to community, and who remain alive during the 31 days following discharge to community. We adopted this measure in the FY 2017 IRF PPS final rule (81 FR 52095 through 52103).

In the FY 2017 IRF PPS final rule (81 FR 52099), we addressed public comments recommending exclusion of IRF patients who were baseline NF residents, as these patients lived in a NF prior to their IRF stay, as these patients may not be expected to return to the community following their IRF stay. In the FY 2018 IRF PPS final rule (82 FR 36285), we addressed public comments expressing support for a potential future modification of the measure that would exclude baseline NF residents; commenters stated that the exclusion would result in the measure more accurately portraying quality of care provided by IRFs, while controlling for factors outside of IRF control.

We assessed the impact of excluding baseline NF residents from the measure using CY 2015 and Cy 2016 data, and found that this exclusion impacted both patient- and facility-level discharge to community rates. We defined baseline NF residents as IRF patients who had a long-term NF stay in the 180 days preceding their hospitalization and IRF stay, with no intervening community discharge between the NF stay and qualifying hospitalization for measure inclusion. Baseline NF residents represented 0.3 percent of the measure population after all measure exclusions were applied. Observed patient-level discharge to community rates were significantly lower for baseline NF residents (20.82 percent) compared with non-NF residents (64.52 percent). The national observed patient-level discharge to community rate was 64.41 percent when baseline NF residents were included in the measure, increasing to 64.52 percent when they were excluded from the measure. After excluding baseline NF residents, 26.9 percent of IRFs had an increase in their risk-standardized discharge to community rate that exceeded the increase in the national observed patient-level discharge to community rate.

Based on public comments received and our impact analysis, we are proposing to exclude baseline NF residents from the Discharge to Community–PAC IRF QRP measure beginning with the FY 2020 IRF QRP, with baseline NF residents defined as IRF patients who had a long-term NF stay in the 180 days preceding their hospitalization and IRF stay, with no intervening community discharge between the NF stay and hospitalization.

For additional technical information regarding the Discharge to Community–PAC IRF QRP measure, including technical information about the proposed exclusion, we refer readers to the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We invite public comment on this proposal.

E. IRF QRP Quality Measures, Measure Concepts, and Standardized Patient Assessment Data Elements Under Consideration for Future Years: Request for Information

We are seeking input on the importance, relevance, appropriateness, and applicability of each of the measures, standardized patient assessment data elements (SPADEs), and concepts under consideration listed in the Table 19 for future years in the IRF QRP.

TABLE 19—FUTURE MEASURES, MEASURE CONCEPTS, AND STANDARDIZED PATIENT ASSESSMENT DATA ELEMENTS (SPADES) UNDER CONSIDERATION FOR THE IRF QRP

Quality Measures and Measure Concepts
Opioid use and frequency.
Exchange of Electronic Health Information and Interoperability.
Standardized Patient Assessment Data Elements (SPADEs)
Cognitive complexity, such as executive function and memory.
Dementia.
Bladder and bowel continence including appliance use and episodes of incontinence.
Care preferences, advance care directives, and goals of care.
Caregiver Status.
Veteran Status.
Health disparities and risk factors, including education, sex and gender identity, and sexual orientation.

While we will not be responding to specific comments submitted in response to this Request for Information in the FY 2020 IRF PPS final rule, we intend to use this input to inform our future measure and SPADE development efforts.

F. Proposed Standardized Patient Assessment Data Reporting Beginning With the FY 2022 IRF QRP

Section 1886(j)(7)(F)(ii) of the Act requires that, for fiscal years 2019 and each subsequent year, IRFs must report standardized patient assessment data (SPADE), required under section 1899B(b)(1) of the Act. Section 1899B(a)(1)(C) of the Act requires, in part, the Secretary to modify the PAC assessment instruments in order for PAC providers, including IRFs, to submit SPADEs under the Medicare program. Section 1899B(b)(1)(A) of the Act requires PAC providers to submit SPADEs under applicable reporting provisions (which, for IRFs, is the IRF QRP) with respect to the admission and discharge of an individual (and more frequently as the Secretary deems appropriate), and section 1899B(b)(1)(B) of the Act defines standardized patient assessment data as data required for at least the quality measures described in section 1899B(c)(1) and that is with respect to the following categories: (1) Functional status, such as mobility and self-care at admission to a PAC provider and before discharge from a PAC provider; (2) cognitive function, such as ability to express ideas and to understand, and mental status, such as depression and dementia; (3) special services, treatments, and interventions, such as need for ventilator use, dialysis, chemotherapy, central line placement, and total parenteral nutrition; (4) medical conditions and comorbidities, such as diabetes, congestive heart failure, and pressure ulcers; (5) impairments, such as incontinence and an impaired ability to hear, see, or swallow, and (6) other categories deemed necessary and appropriate by the Secretary.

In the FY 2018 IRF PPS proposed rule (82 FR 20722 through 20739), we proposed to adopt SPADEs that would satisfy the first five categories. In the FY 2018 IRF PPS final rule (82 FR 36287 through 36289), we summarized comments that supported our adoption of SPADEs, including support for our broader standardization goal and support for the clinical usefulness of specific proposed SPADEs. However, we did not finalize the majority of our SPADE proposals in recognition of the concern raised by many commenters that we were moving too fast to adopt the SPADEs and modify our assessment instruments in light of all of the other requirements we were also adopting under the IMPACT Act at that time (82 FR 36292 through 36294). In addition, commenters expressed that we should conduct further testing of the data elements we have proposed (82 FR 36288).

However, we finalized the adoption of SPADEs for two of the categories described in section 1899B(b)(1)(B) of the Act: (1) Functional status: Data elements currently reported by IRFs to calculate the measure Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631); and (2) Medical conditions and comorbidities: The data elements used to calculate the pressure ulcer measures, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) and the replacement measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. We stated that these data elements were important for care planning, known to be valid and reliable, and already being reported by IRFs for the calculation of quality measures.

Since we issued the FY 2018 IRF PPS final rule, IRFs have had an opportunity to familiarize themselves with other new reporting requirements that we have adopted under the IMPACT Act. We have also conducted further testing of the SPADEs, as described more fully below, and believe that this testing supports the use of the SPADEs in our PAC assessment instruments. Therefore, we are now proposing to adopt many of the same SPADEs that we previously proposed to adopt, along with other SPADEs.

We are proposing that IRFs would be required to report these SPADEs beginning with the FY 2022 IRF QRP. If finalized as proposed, IRFs would be required to report these data with respect to admission and discharge for patients discharged between October 1, 2020, and December 31, 2020 for the FY 2022 IRF QRP. Beginning with the FY 2023 IRF QRP, we propose that IRFs must report data with respect to admissions and discharges that occur during the subsequent calendar year (for example, CY 2021 for the FY 2023 IRF QRP, CY 2022 for the FY 2024 IRF QRP).

We are also proposing that IRFs that submit the Hearing, Vision, Race, and Ethnicity SPADEs with respect to admission only will be deemed to have submitted those SPADEs with respect to both admission and discharge, because it is unlikely that the assessment of those SPADEs at admission will differ from the assessment of the same SPADEs at discharge.

In selecting the proposed SPADEs below, we considered the burden of assessment-based data collection and aimed to minimize additional burden by evaluating whether any data that is currently collected through one or more PAC assessment instruments could be collected as SPADE. In selecting the

proposed SPADEs below, we also took into consideration the following factors with respect to each data element:

(1) Overall clinical relevance;

(2) Interoperable exchange to facilitate care coordination during transitions in care;

(3) Ability to capture medical complexity and risk factors that can inform both payment and quality; and

(4) Scientific reliability and validity, general consensus agreement for its usability.

In identifying the SPADEs proposed below, we additionally drew on input from several sources, including TEPs held by our data element contractor, public input, and the results of a recent National Beta Test of candidate data elements conducted by our data element contractor (hereafter ''National Beta Test'').

The National Beta Test collected data from 3,121 patients and residents across 143 LTCHs, SNFs, IRFs, and HHAs from November 2017 to August 2018 to evaluate the feasibility, reliability, and validity of the candidate data elements across PAC settings. The National Beta Test also gathered feedback on the candidate data elements from staff who administered the test protocol in order to understand usability and workflow of the candidate data elements. More information on the methods, analysis plan, and results for the National Beta Test can be found in the document titled, ''Development and Evaluation of Candidate Standardized Patient Assessment Data Elements: Findings from the National Beta Test (Volume 2),'' available in the document titled, ''Development and Evaluation of Candidate Standardized Patient Assessment Data Elements: Findings from the National Beta Test (Volume 2),'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Further, to inform the proposed SPADEs, we took into account feedback from stakeholders, as well as from technical and clinical experts, including feedback on whether the candidate data elements would support the factors described above. Where relevant, we also took into account the results of the Post-Acute Care Payment Reform Demonstration (PAC PRD) that took place from 2006 to 2012.

G. Proposed Standardized Patient Assessment Data by Category

1. Cognitive Function and Mental Status Data

A number of underlying conditions, including dementia, stroke, traumatic brain injury, side effects of medication, metabolic and/or endocrine imbalances, delirium, and depression, can affect cognitive function and mental status in PAC patient and resident populations.[74] The assessment of cognitive function and mental status by PAC providers is important because of the high percentage of patients and residents with these conditions,[75] and because these assessments provide opportunity for improving quality of care.

Symptoms of dementia may improve with pharmacotherapy, occupational therapy, or physical activity,[76] [77] [78] and promising treatments for severe traumatic brain injury are currently being tested.[79] For older patients and residents diagnosed with depression, treatment options to reduce symptoms and improve quality of life include antidepressant medication and psychotherapy,[80] [81] [82] [83] and targeted services, such as therapeutic recreation, exercise, and restorative nursing, to increase opportunities for psychosocial interaction.[84]

In alignment with our Meaningful Measures Initiative, accurate assessment of cognitive function and mental status of patients and residents in PAC is expected to make care safer by reducing harm caused in the delivery of care; promote effective prevention and treatment of chronic disease; strengthen person and family engagement as partners in their care; and promote effective communication and coordination of care. For example, standardized assessment of cognitive function and mental status of patients and residents in PAC will support establishing a baseline for identifying changes in cognitive function and mental status (for example, delirium), anticipating the patient's or resident's ability to understand and participate in treatments during a PAC stay, ensuring patient and resident safety (for example, risk of falls), and identifying appropriate support needs at the time of discharge or transfer. Standardized patient assessment data elements will enable or support clinical decision-making and early clinical intervention; person-centered, high quality care through facilitating better care continuity and coordination; better data exchange and interoperability between settings; and longitudinal outcome analysis. Therefore, reliable standardized patient assessment data elements assessing cognitive function and mental status are needed to initiate a management program that can optimize a patient's or resident's prognosis and reduce the possibility of adverse events.

The data elements related to cognitive function and mental status were first proposed as standardized patient assessment data elements in the FY 2018 IRF PPS proposed rule (82 FR 20723 through 20726). In response to our proposals, a few commenters noted that the proposed data elements did not capture some dimensions of cognitive function and mental status, such as functional cognition, communication, attention, concentration, and agitation. One commenter also suggested that other cognitive assessments should be considered for standardization. Another commenter stated support for the standardized assessment of cognitive function and mental status, because it could support appropriate use of skilled therapy for beneficiaries with

[74] National Institute on Aging. (2014). Assessing Cognitive Impairment in Older Patients. A Quick Guide for Primary Care Physicians. Retrieved from: *https://www.nia.nih.gov/alzheimers/publication/assessing-cognitive-impairment-older-patients.*

[75] Gage B., Morley M., Smith L., et al. (2012). Post-Acute Care Payment Reform Demonstration (Final report, Volume 4 of 4). Research Triangle Park, NC: RTI International.

[76] Casey D.A., Antimisiaris D., O'Brien J. (2010). Drugs for Alzheimer's Disease: Are They Effective? *Pharmacology & Therapeutics,* 35, 208–11.

[77] Graff M.J., Vernooij-Dassen M.J., Thijssen M., Dekker J., Hoefnagels W.H., Rikkert M.G.O. (2006). Community Based Occupational Therapy for Patients with Dementia and their Care Givers: Randomised Controlled Trial. BMJ, 333(7580): 1196.

[78] Bherer L., Erickson K.I., Liu-Ambrose T. (2013). A Review of the Effects of Physical Activity and Exercise on Cognitive and Brain Functions in Older Adults. Journal of Aging Research, 657508.

[79] Giacino J.T., Whyte J., Bagiella E., et al. (2012). Placebo-controlled trial of amantadine for severe traumatic brain injury. New England Journal of Medicine, 366(9), 819–826.

[80] Alexopoulos G.S., Katz I.R., Reynolds C.F. 3rd, Carpenter D., Docherty J.P., Ross R.W. (2001). Pharmacotherapy of depression in older patients: a summary of the expert consensus guidelines. *Journal of Psychiatric Practice,* 7(6), 361–376.

[81] Arean P.A., Cook B.L. (2002). Psychotherapy and combined psychotherapy/pharmacotherapy for late life depression. *Biological Psychiatry,* 52(3), 293–303.

[82] Hollon S.D., Jarrett R.B., Nierenberg A.A., Thase M.E., Trivedi M., Rush A.J. (2005). Psychotherapy and medication in the treatment of adult and geriatric depression: which monotherapy or combined treatment? *Journal of Clinical Psychiatry,* 66(4), 455–468.

[83] Wagenaar D, Colenda CC, Kreft M, Sawade J, Gardiner J, Poverejan E. (2003). Treating depression in nursing homes: practice guidelines in the real world. *J Am Osteopath Assoc.* 103(10), 465–469.

[84] Crespy SD, Van Haitsma K, Kleban M, Hann CJ. Reducing Depressive Symptoms in Nursing Home Residents: Evaluation of the Pennsylvania Depression Collaborative Quality Improvement Program. J Healthc Qual. 2016. Vol. 38, No. 6, pp. e76–e88.

degenerative conditions, such as dementia, and appropriate use of medications for behavioral and psychological symptoms of dementia.

We are inviting comment on our proposals to collect as standardized patient assessment data the following data with respect to cognitive function and mental status.

- Brief Interview for Mental Status (BIMS)

We are proposing that the data elements that comprise the BIMS meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act.

As described in the FY 2018 IRF PPS Proposed Rule (82 FR 20723 through 20724), dementia and cognitive impairment are associated with long-term functional dependence and, consequently, poor quality of life and increased healthcare costs and mortality.[85] This makes assessment of mental status and early detection of cognitive decline or impairment critical in the PAC setting. The intensity of routine nursing care is higher for patients and residents with cognitive impairment than those without, and dementia is a significant variable in predicting readmission after discharge to the community from PAC providers.[86]

The BIMS is a performance-based cognitive assessment screening tool that assesses repetition, recall with and without prompting, and temporal orientation. The data elements that make up the BIMS are seven questions on the repetition of three words, temporal orientation, and recall that result in a cognitive function score. The BIMS was developed to be a brief, objective screening tool, with a focus on learning and memory. As a brief screener, the BIMS was not designed to diagnose dementia or cognitive impairment, but rather to be a relatively quick and easy to score assessment that could identify cognitively impaired patients as well as those who may be at risk for cognitive decline and require further assessment. It is currently in use in two of the PAC assessments: The MDS used by SNFs and the IRF–PAI used by IRFs. For more information on the BIMS, we refer readers to the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The data elements that comprise the BIMS were first proposed as standardized patient assessment data elements in the FY 2018 IRF PPS proposed rule (82 FR 20723 through 20724). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016, expressed support for use of the BIMS, noting that it is reliable, feasible to use across settings, and will provide useful information about patients and residents. We also stated that the data collected through the BIMS will provide a clearer picture of patient or resident complexity, help with the care planning process, and be useful during care transitions and when coordinating across providers. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 IRF PPS proposed rule, we received public comments in support of the use of the BIMS, especially in its capacity to inform care transitions, but other commenters were critical, noting the limitations of the BIMS to assess mild cognitive impairment and ''functional'' cognition, and that the BIMS cannot be completed by patients and residents who are unable to communicate. They also stated that other cognitive assessments available in the public domain should be considered for standardization. One commenter suggested that CMS require use of the BIMS with respect to discharge as well as admission.

Subsequent to receiving comments on the FY 2018 IRF PPS rule, the BIMS was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the BIMS to be feasible and reliable for use with PAC patients and residents. More information about the performance of the BIMS in the National Beta Test can be found in the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements and the TEP supported the assessment of patient or resident cognitive status with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Some commenters also expressed concern that the BIMS, if used alone, may not be sensitive enough to capture the range of cognitive impairments, including mild cognitive impairment. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We understand the concerns raised by stakeholders that BIMS, if used alone, may not be sensitive enough to capture the range of cognitive impairments, including functional cognition and MCI, but note that the purpose of the BIMS

[85] Agüero-Torres, H., Fratiglioni, L., Guo, Z., Viitanen, M., von Strauss, E., & Winblad, B. (1998). ''Dementia is the major cause of functional dependence in the elderly: 3-year follow-up data from a population-based study.'' Am J of Public Health 88(10): 1452–1456.

[86] RTI International. Proposed Measure Specifications for Measures Proposed in the FY 2017 IRF QRP NPRM. Research Triangle Park, NC. 2016.

data elements as SPADEs is to screen for cognitive impairment in a broad population. We also acknowledge that further cognitive tests may be required based on a patient's condition and will take this feedback into consideration in the development of future standardized assessment data elements. However, taking together the importance of assessing for cognitive status, stakeholder input, and strong test results, we are proposing that the BIMS data elements meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act and to adopt the BIMS data elements as standardized patient assessment data for use in the IRF QRP.

- Confusion Assessment Method (CAM)

In this proposed rule, we are proposing that the data elements that comprise the Confusion Assessment Method (CAM) meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act.

As described in the FY 2018 IRF PPS proposed rule (82 FR 20724), the CAM was developed to identify the signs and symptoms of delirium. It results in a score that suggests whether a patient or resident should be assigned a diagnosis of delirium. Because patients and residents with multiple comorbidities receive services from PAC providers, it is important to assess delirium, which is associated with a high mortality rate and prolonged duration of stay in hospitalized older adults.[87] Assessing these signs and symptoms of delirium is clinically relevant for care planning by PAC providers.

The CAM is a patient assessment that screens for overall cognitive impairment, as well as distinguishes delirium or reversible confusion from other types of cognitive impairment. The CAM is currently in use in two of the PAC assessments: A four-item version of the CAM is used in the MDS in SNFs; and a six-item version of the CAM is used in the LTCH CARE Data Set (LCDS) in LTCHs. We are proposing the four-item version of the CAM that assesses acute change in mental status, inattention, disorganized thinking, and altered level of consciousness. For more information on the CAM, we refer readers to the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The data elements that comprise the CAM were first proposed as standardized patient assessment data elements in the FY 2018 IRF PPS proposed rule (82 FR 20724). In that proposed rule, we stated that the proposal was informed by public input we received on the CAM through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed support for use of the CAM, noting that it would provide important information for care planning and care coordination, and therefore, contribute to quality improvement. We also stated that those commenters had noted the CAM is particularly helpful in distinguishing delirium and reversible confusion from other types of cognitive impairment. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 IRF PPS proposed rule, one commenter supported use of the CAM for standardized patient assessment data. However, some commenters expressed concerns that the CAM data elements assess: The presence of behavioral symptoms, but not the cause; the possibility of a false positive for delirium due to patient cognitive or communication impairments; and the lack of specificity of the assessment specifications. In addition, other commenters noted that the CAM is not necessary because: Delirium is easily diagnosed without a tool; the CAM and BIMS assessments are redundant; and some CAM response options are not meaningful.

Subsequent to receiving comments on the FY 2018 IRF PPS rule, the CAM was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the CAM to be feasible and reliable for use with PAC patients and residents. More information about the performance of the CAM in the National Beta Test can be found in the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although they did not specifically discuss the CAM data elements, the TEP supported the assessment of patient or resident cognitive status with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for delirium, stakeholder input, and strong test results, we are proposing that the CAM data elements meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act and to adopt the CAM data elements as standardized patient assessment data for use in the IRF QRP.

[87] Fick, D.M., Steis, M.R., Waller, J.L., & Inouye, S.K. (2013). ''Delirium superimposed on dementia is associated with prolonged length of stay and poor outcomes in hospitalized older adults.'' *J of Hospital Med* 8(9): 500–505.

• Patient Health Questionnaire—2 to 9 (PHQ–2 to 9)

In this proposed rule, we are proposing that the Patient Health Questionnaire-2 to 9 (PHQ–2 to 9) data elements meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act. The proposed data elements are based on the PHQ–2 mood interview, which focuses on only the two cardinal symptoms of depression, and the longer PHQ–9 mood interview, which assesses presence and frequency of nine signs and symptoms of depression. The name of the data element, the PHQ–2 to 9, refers to an embedded skip pattern that transitions patients with a threshold level of symptoms in the PHQ–2 to the longer assessment of the PHQ–9. The skip pattern is described further below. As described in the FY 2018 IRF PPS proposed rule (82 FR 20725 through 20726), depression is a common and under-recognized mental health condition. Assessments of depression help PAC providers better understand the needs of their patients and residents by: Prompting further evaluation after establishing a diagnosis of depression; elucidating the patient's or resident's ability to participate in therapies for conditions other than depression during their stay; and identifying appropriate ongoing treatment and support needs at the time of discharge.

The proposed PHQ–2 to 9 is based on the PHQ–9 mood interview. The PHQ–2 consists of questions about only the first two symptoms addressed in the PHQ–9: depressed mood and anhedonia (inability to feel pleasure), which are the cardinal symptoms of depression. The PHQ–2 has performed well as both a screening tool for identifying depression, to assess depression severity, and to monitor patient mood over time.[88] [89] If a patient demonstrates signs of depressed mood and anhedonia under the PHQ–2, then the patient is administered the lengthier PHQ–9. This skip pattern (also referred to as a gateway) is designed to reduce the length of the interview assessment for patients who fail to report the cardinal symptoms of depression. The design of the PHQ–2 to 9 reduces the burden that would be associated with requiring the full PHQ–9, while ensuring that patients and residents with indications of depressive symptoms based on the PHQ–2 receive the longer assessment.

Components of the proposed data elements are currently used in the OASIS for HHAs (PHQ–2) and the MDS for SNFs (PHQ–9). For more information on the PHQ–2 to 9, we refer readers to the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We proposed the PHQ–2 data elements as SPADEs in the FY 2018 IRF proposed rule (82 FR 20725 through 20726). In that proposed rule, we stated that the proposal was informed by input we received from the TEP convened by our data element contractor on April 6 and 7, 2016. The TEP members particularly noted that the brevity of the PHQ–2 made it feasible to administer with low burden for both assessors and PAC patients or residents. A summary of the April 6 and 7, 2016 TEP meeting titled ''SPADE Technical Expert Panel Summary (First Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

That rule proposal was also informed by public input that we received through a call for input published on the CMS Measures Management System Blueprint website. Input was submitted from August 12 to September 12, 2016 on three versions of the PHQ depression screener: The PHQ–2; the PHQ–9; and the PHQ–2 to 9 with the skip pattern design. Many commenters were supportive of the standardized assessment of mood in PAC settings, given the role that depression plays in well-being. Several commenters expressed support for an approach that would use PHQ–2 as a gateway to the longer PHQ–9 while still potentially reducing burden on most patients and residents, as well as test administrators, and ensuring the administration of the PHQ–9, which exhibits higher specificity,[90] for patients and residents who showed signs and symptoms of depression on the PHQ–2. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In response to our proposal to use the PHQ–2 in the FY 2018 IRF PPS proposed rule (82 FR 20725 through 20726), we received comments agreeing to the importance of a standardized assessment of depression in patients and residents receiving PAC services. Commenters also raised concerns about the ability of the PHQ–2 to correctly identify all patients and residents with signs and symptoms of depression. One commenter supported using the PHQ–2 as a gateway assessment and conducting a more thorough evaluation of depression symptoms with the PHQ–9 if the PHQ–2 is positive. Another commenter expressed concern that standardized assessment of signs and symptoms of depression via the PHQ–2 is not appropriate in the IRF setting, as patients may have recently experienced acute illness or injury, and routine screening may lead to overprescribing of antidepressant medications. Another commenter expressed concern about potential conflicts between the results of screening assessments and documented diagnoses based on the expertise of physicians and other clinicians. In response to these comments, we carried out additional testing, and we provide our findings below.

Subsequent to receiving comments on the FY 2018 IRF PPS rule, the PHQ–2 to 9 was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the PHQ–2 to 9 to be feasible and reliable for use with PAC patients and residents. More information about the performance of the PHQ–2 to 9 in the National Beta Test can be found in the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of

[88] Li, C., Friedman, B., Conwell, Y., & Fiscella, K. (2007). ''Validity of the Patient Health Questionnaire 2 (PHQ-2) in identifying major depression in older people.'' *J of the A Geriatrics Society,* 55(4): 596–602.

[89] Löwe, B., Kroenke, K., & Gräfe, K. (2005). ''Detecting and monitoring depression with a two-item questionnaire (PHQ–2).'' *J of Psychosomatic Research,* 58(2): 163–171.

[90] Arroll B, Goodyear-Smith F, Crengle S, Gunn J, Kerse N, Fishman T, et al. Validation of PHQ–2 and PHQ–9 to screen for major depression in the primary care population. *Annals of family medicine.* 2010;8(4):348–53. doi: 10.1370/afm.1139 pmid:20644190; PubMed Central PMCID: PMC2906530.

soliciting input on the PHQ–2 to 9. The TEP was supportive of the PHQ–2 to 9 data element set as a screener for signs and symptoms of depression. The TEP's discussion noted that symptoms evaluated by the full PHQ–9 (for example, concentration, sleep, appetite) had relevance to care planning and the overall well-being of the patient or resident, but that the gateway approach of the PHQ–2 to 9 would be appropriate as a depression screening assessment, as it depends on the well-validated PHQ–2 and focuses on the cardinal symptoms of depression. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for depression, stakeholder input, and test results, we are proposing that the PHQ–2 to 9 data elements meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act and to adopt the PHQ–2 to 9 data elements as standardized patient assessment data for use in the IRF QRP.

2. Special Services, Treatments, and Interventions Data

Special services, treatments, and interventions performed in PAC can have a major effect on an individual's health status, self-image, and quality of life. The assessment of these special services, treatments, and interventions in PAC is important to ensure the continuing appropriateness of care for the patients and residents receiving them, and to support care transitions from one PAC provider to another, an acute care hospital, or discharge. In alignment with our Meaningful Measures Initiative, accurate assessment of special services, treatments, and interventions of patients and residents served by PAC providers is expected to make care safer by reducing harm caused in the delivery of care; promote effective prevention and treatment of chronic disease; strengthen person and family engagement as partners in their care; and promote effective communication and coordination of care.

For example, standardized assessment of special services, treatments, and interventions used in PAC can promote patient and resident safety through appropriate care planning (for example, mitigating risks such as infection or pulmonary embolism associated with central intravenous access), and identifying life-sustaining treatments that must be continued, such as mechanical ventilation, dialysis, suctioning, and chemotherapy, at the time of discharge or transfer. Standardized assessment of these data elements will enable or support: Clinical decision-making and early clinical intervention; person-centered, high quality care through, for example, facilitating better care continuity and coordination; better data exchange and interoperability between settings; and longitudinal outcome analysis. Therefore, reliable data elements assessing special services, treatments, and interventions are needed to initiate a management program that can optimize a patient's or resident's prognosis and reduce the possibility of adverse events.

A TEP convened by our data element contractor provided input on the proposed data elements for special services, treatments, and interventions. In a meeting held on January 5 and 6, 2017, this TEP found that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice, and that the collection of these data by means of a list and checkbox format would conform with common workflow for PAC providers. A summary of the January 5 and 6, 2017 TEP meeting titled ''SPADE Technical Expert Panel Summary (Second Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Comments on the category of special services, treatments, and interventions were also submitted by stakeholders during the FY 2018 IRF PPS proposed rule (82 FR 20726 through 20736) public comment period. One commenter supported adding the SPADEs for special services, treatments and interventions. Others stated labor costs and staff burden would increase for data collection. The Medicare Payment Advisory Commission (MedPAC) suggested that a few other high-cost services, such as cardiac monitoring and specialty bed/surfaces, may warrant consideration for inclusion in future collection efforts. One commenter believed that the low frequency of the special services, treatments, and interventions in the IRF setting makes them not worth assessing for patients given the cost of data collection and reporting. A few commenters noted that that many of these data elements should be obtainable from administrative data (that is, coding and Medicare claims), and therefore, assessing them through patient record review would be duplicated effort.

Information on data element performance in the National Beta Test, which collected data between November 2017 and August 2018, is reported within each data element proposal below. Clinical staff who participated in the National Beta Test supported these data elements because of their importance in conveying patient or resident significant health care needs, complexity, and progress. However, clinical staff also noted that, despite the simple ''check box'' format of these data element, they sometimes needed to consult multiple information sources to determine a patient's or resident's treatments.

We are inviting comment on our proposals to collect as standardized patient assessment data the following data with respect to special services, treatments, and interventions.

- Cancer Treatment: Chemotherapy (IV, Oral, Other)

We are proposing that the Chemotherapy (IV, Oral, Other) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IRF PPS proposed rule (82 FR 20726 through 20727), chemotherapy is a type of cancer treatment that uses drugs to destroy cancer cells. It is sometimes used when a patient has a malignancy (cancer), which is a serious, often life-threatening or life-limiting condition. Both intravenous (IV) and oral chemotherapy have serious side effects, including nausea/vomiting, extreme fatigue, risk of infection due to a suppressed immune system, anemia, and an increased risk of bleeding due to low platelet counts. Oral chemotherapy can be as potent as chemotherapy given by IV and can be significantly more convenient and less resource-intensive to administer. Because of the toxicity of these agents, special care must be exercised in handling and transporting chemotherapy drugs. IV chemotherapy is administered either peripherally, or more commonly, given via an indwelling central line, which raises the risk of bloodstream infections. Given the significant burden of malignancy, the resource intensity of administering chemotherapy, and the side effects and potential complications of these highly-toxic medications, assessing the receipt of chemotherapy is important in the PAC setting for care planning and determining resource use. The need for chemotherapy predicts resource intensity, both because of the complexity of administering these potent, toxic drug combinations under specific protocols, and because of what the need for chemotherapy signals about the patient's underlying medical condition. Furthermore, the resource intensity of IV chemotherapy is higher than for oral chemotherapy, as the protocols for administration and the care of the central line (if present) for IV chemotherapy require significant resources.

The Chemotherapy (IV, Oral, Other) data element consists of a principal data element (Chemotherapy) and three response option sub-elements: IV chemotherapy, which is generally resource-intensive; Oral chemotherapy, which is less invasive and generally requires less intensive administration protocols; and a third category, Other, provided to enable the capture of other less common chemotherapeutic approaches. This third category is potentially associated with higher risks and is more resource intensive due to delivery by other routes (for example, intraventricular or intrathecal). If the assessor indicates that the patient is receiving chemotherapy on the principal Chemotherapy data element, the assessor would then indicate by which route or routes (for example, IV, Oral, Other) the chemotherapy is administered.

A single Chemotherapy data element that does not include the proposed three sub-elements is currently in use in the MDS in SNFs. For more information on the Chemotherapy (IV, Oral, Other) data element, we refer readers to the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The Chemotherapy data element was first proposed as a standardized patient assessment data element in the FY 2018 IRF PPS proposed rule (82 FR 20726 through 20727). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed support for the IV Chemotherapy data element and suggested it be included as standardized patient assessment data. We also stated that those commenters had noted that assessing the use of chemotherapy services is relevant to share across the care continuum to facilitate care coordination and care transitions and noted the validity of the data element. Commenters also noted the importance of capturing all types of chemotherapy, regardless of route, and stated that collecting data only on patients and residents who received chemotherapy by IV would limit the usefulness of this standardized data element. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In response to our proposal in the FY 2018 IRF PPS proposed rule, we received public comments in support of the special services, treatments, and interventions data elements in general; no additional comments were received that were specific to the Chemotherapy data element.

Subsequent to receiving comments on the FY 2018 IRF PPS rule, the Chemotherapy data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Chemotherapy data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Chemotherapy data element in the National Beta Test can be found in the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP members did not specifically discuss the Chemotherapy data element, the TEP members supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

Taking together the importance of assessing for chemotherapy, stakeholder input, and strong test results, we are proposing that the Chemotherapy (IV, Oral, Other) data element with a principal data element and three sub-elements meet the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Chemotherapy (IV, Oral, Other) data element as standardized patient assessment data for use in the IRF QRP.

• Cancer Treatment: Radiation

We are proposing that the Radiation data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IRF PPS proposed rule (82 FR 20727 through 20728), radiation is a type of cancer treatment that uses high-energy radioactivity to stop cancer by damaging cancer cell DNA, but it can also damage normal cells. Radiation is an important therapy for particular types of cancer, and the resource utilization is high, with frequent radiation sessions required, often daily for a period of several weeks. Assessing whether a patient or resident is receiving radiation therapy is important to determine resource utilization because PAC patients and residents will need to be transported to and from radiation treatments, and monitored and treated for side effects after receiving this intervention. Therefore, assessing the receipt of radiation therapy, which would compete with other care processes given the time burden, would be important for care planning and care coordination by PAC providers.

The proposed data element consists of the single Radiation data element. The Radiation data element is currently in use in the MDS in SNFs. For more information on the Radiation data element, we refer readers to the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The Radiation data element was first proposed as a standardized patient assessment data element in the FY 2018 IRF PPS proposed rule (82 FR 20727 through 20728). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed support for the Radiation data element, noting its importance and clinical usefulness for patients and residents in PAC settings, due to the side effects and consequences of radiation treatment on patients and residents that need to be considered in care planning and care transitions, the feasibility of the item, and the potential for it to improve quality. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In response to our proposal in the FY 2018 IRF PPS proposed rule, we received public comments in support of the special services, treatments, and interventions data elements in general; no additional comments were received that were specific to the Radiation data element.

Subsequent to receiving comments on the FY 2018 IRF PPS rule, the Radiation data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Radiation data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Radiation data element in the National Beta Test can be found in the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP members did not specifically discuss the Radiation data element, the TEP members supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

Taking together the importance of assessing for radiation, stakeholder input, and strong test results, we are proposing that the Radiation data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Radiation data element as standardized patient assessment data for use in the IRF QRP.

• Respiratory Treatment: Oxygen Therapy (Intermittent, Continuous, High-concentration Oxygen Delivery System)

We are proposing that the Oxygen Therapy (Intermittent, Continuous, High-concentration Oxygen Delivery System) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IRF PPS proposed rule (82 FR 20728), we proposed a similar data element related to oxygen therapy. Oxygen therapy provides a patient or resident with extra oxygen when medical conditions such as chronic obstructive pulmonary

disease, pneumonia, or severe asthma prevent the patient or resident from getting enough oxygen from breathing. Oxygen administration is a resource-intensive intervention, as it requires specialized equipment such as a source of oxygen, delivery systems (for example, oxygen concentrator, liquid oxygen containers, and high-pressure systems), the patient interface (for example, nasal cannula or mask), and other accessories (for example, regulators, filters, tubing). The data element proposed here captures patient or resident use of three types of oxygen therapy (intermittent, continuous, and high-concentration oxygen delivery system), which reflects the intensity of care needed, including the level of monitoring and bedside care required. Assessing the receipt of this service is important for care planning and resource use for PAC providers.

The proposed data element, Oxygen Therapy, consists of the principal Oxygen Therapy data element and three response option sub-elements: Continuous (whether the oxygen was delivered continuously, typically defined as > =14 hours per day); Intermittent; or High-concentration Oxygen Delivery System. Based on public comments and input from expert advisors about the importance and clinical usefulness of documenting the extent of oxygen use, we added a third sub-element, high-concentration oxygen delivery system, to the sub-elements, which previously included only intermittent and continuous. If the assessor indicates that the patient is receiving oxygen therapy on the principal oxygen therapy data element, the assessor then would indicate the type of oxygen the patient receives (for example, Intermittent, Continuous, High-concentration oxygen delivery system).

These three proposed sub-elements were developed based on similar data elements that assess oxygen therapy, currently in use in the MDS in SNFs (''Oxygen Therapy''), previously used in the OASIS (''Oxygen (intermittent or continuous)''), and a data element tested in the PAC PRD that focused on intensive oxygen therapy (''High O2 Concentration Delivery System with FiO2 > 40 percent''). For more information on the proposed Oxygen Therapy (Continuous, Intermittent, High-concentration oxygen delivery system) data element, we refer readers to the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The Oxygen Therapy (Intermittent, Continuous) data element was first proposed as standardized patient assessment data in the FY 2018 IRF PPS proposed rule (82 FR 20728). In that proposed rule, we stated that the proposal was informed by input we received on the single data element, Oxygen (inclusive of intermittent and continuous oxygen use), through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016, expressed the importance of the Oxygen data element, noting feasibility of this item in PAC, and the relevance of it to facilitating care coordination and supporting care transitions, but suggesting that the extent of oxygen use be documented. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In response to our proposal in the FY 2018 IRF PPS proposed rule, we received public comments in support of the special services, treatments, and interventions data elements in general; no additional comments were received that were specific to the Oxygen Therapy (Intermittent, Continuous) data element.

Subsequent to receiving comments on the FY 2018 IRF PPS rule, the Oxygen Therapy data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Oxygen Therapy data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Oxygen Therapy data element in the National Beta Test can be found in the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Oxygen Therapy data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

Taking together the importance of assessing oxygen therapy, stakeholder input, and strong test results, we are proposing that the Oxygen Therapy (Intermittent, Continuous, High-concentration Oxygen Delivery System) data element with a principal data element and three sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Oxygen Therapy (Intermittent, Continuous, High-concentration Oxygen Delivery System) data element as standardized patient assessment data for use in the IRF QRP.

- Respiratory Treatment: Suctioning (Scheduled, as Needed)

We are proposing that the Suctioning (Scheduled, As needed) data element meets the definition of standardized

patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IRF PPS proposed rule (82 FR 20728 through 20729), suctioning is a process used to clear secretions from the airway when a person cannot clear those secretions on his or her own. It is done by aspirating secretions through a catheter connected to a suction source. Types of suctioning include oropharyngeal and nasopharyngeal suctioning, nasotracheal suctioning, and suctioning through an artificial airway such as a tracheostomy tube. Oropharyngeal and nasopharyngeal suctioning are a key part of many patients' or residents' care plans, both to prevent the accumulation of secretions than can lead to aspiration pneumonias (a common condition in patients and residents with inadequate gag reflexes), and to relieve obstructions from mucus plugging during an acute or chronic respiratory infection, which often lead to desaturations and increased respiratory effort. Suctioning can be done on a scheduled basis if the patient is judged to clinically benefit from regular interventions, or can be done as needed when secretions become so prominent that gurgling or choking is noted, or a sudden desaturation occurs from a mucus plug. As suctioning is generally performed by a care provider rather than independently, this intervention can be quite resource intensive if it occurs every hour, for example, rather than once a shift. It also signifies an underlying medical condition that prevents the patient from clearing his/her secretions effectively (such as after a stroke, or during an acute respiratory infection). Generally, suctioning is necessary to ensure that the airway is clear of secretions which can inhibit successful oxygenation of the individual. The intent of suctioning is to maintain a patent airway, the loss of which can lead to death or complications associated with hypoxia.

The Suctioning (Scheduled, As needed) data element consists of a principal data element, and two sub-elements: Scheduled and As needed. These sub-elements capture two types of suctioning. Scheduled indicates suctioning based on a specific frequency, such as every hour. As needed means suctioning only when indicated. If the assessor indicates that the patient is receiving suctioning on the principal Suctioning data element, the assessor would then indicate the frequency (for example, Scheduled, As needed). The proposed data element is based on an item currently in use in the MDS in SNFs which does not include our proposed two sub-elements, as well as data elements tested in the PAC PRD that focused on the frequency of suctioning required for patients and residents with tracheostomies (''Trach Tube with Suctioning: Specify most intensive frequency of suctioning during stay [Every __hours]''). For more information on the Suctioning data element, we refer readers to the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The Suctioning data element was first proposed as standardized patient assessment data elements in the FY 2018 IRF PPS proposed rule (82 FR 20728 through 20729). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed support for the Suctioning data element. The input noted the feasibility of this item in PAC, and the relevance of this data element to facilitating care coordination and supporting care transitions.

We also stated that those commenters had suggested that we examine the frequency of suctioning to better understand the use of staff time, the impact on a patient or resident's capacity to speak and swallow, and intensity of care required. Based on these comments, we decided to add two sub-elements (Scheduled and As needed) to the suctioning element. The proposed Suctioning data element includes both the principal Suctioning data element that is included on the MDS in SNFs and two sub-elements, Scheduled and As needed. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In response to our proposal in the FY 2018 IRF PPS proposed rule, we received public comments in support of the special services, treatments, and interventions data elements in general; no additional comments were received that were specific to the Suctioning data element.

Subsequent to receiving comments on the FY 2018 IRF PPS rule, the Suctioning data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Suctioning data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Suctioning data element in the National Beta Test can be found in the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Suctioning data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicited additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-*

Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

Taking together the importance of assessing for suctioning, stakeholder input, and strong test results, we are proposing that the Suctioning (Scheduled, As needed) data element with a principal data element and two sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Suctioning (Scheduled, As needed) data element as standardized patient assessment data for use in the IRF QRP.

• Respiratory Treatment: Tracheostomy Care

We are proposing that the Tracheostomy Care data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IRF PPS proposed rule (82 FR 20729 through 20730), a tracheostomy provides an air passage to help a patient or resident breathe when the usual route for breathing is obstructed or impaired. Generally, in all of these cases, suctioning is necessary to ensure that the tracheostomy is clear of secretions, which can inhibit successful oxygenation of the individual. Often, individuals with tracheostomies are also receiving supplemental oxygenation. The presence of a tracheostomy, albeit permanent or temporary, warrants careful monitoring and immediate intervention if the tracheostomy becomes occluded or if the device used becomes dislodged. While in rare cases the presence of a tracheostomy is not associated with increased care demands (and in some of those instances, the care of the ostomy is performed by the patient) in general the presence of such as device is associated with increased patient risk, and clinical care services will necessarily include close monitoring to ensure that no life-threatening events occur as a result of the tracheostomy. In addition, tracheostomy care, which primarily consists of cleansing, dressing changes, and replacement of the tracheostomy cannula (tube), is a critical part of the care plan. Regular cleansing is important to prevent infection, such as pneumonia, and to prevent any occlusions with which there are risks for inadequate oxygenation.

The proposed data element consists of the single Tracheostomy Care data element. The proposed data element is currently in use in the MDS in SNFs (''Tracheostomy care''). For more information on the Tracheostomy Care data element, we refer readers to the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Tracheostomy Care data element was first proposed as a standardized patient assessment data element in the FY 2018 IRF PPS proposed rule (82 FR 20729 through 20730). In that proposed rule, we stated that the proposal was informed by input we received on the Tracheostomy Care data element through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed support for this data element, noting the feasibility of this item in PAC, and the relevance of this data element to facilitating care coordination and supporting care transitions. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 IRF PPS proposed rule, we received public comments in support of the special services, treatments, and interventions data elements in general; no additional comments were received that were specific to the Tracheostomy Care data element.

Subsequent to receiving comments on the FY 2018 IRF PPS rule, the Tracheostomy Care data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Tracheostomy Care data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Tracheostomy Care data element in the National Beta Test can be found in the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Tracheostomy Care data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for tracheostomy care, stakeholder input, and strong test results, we are proposing that the Tracheostomy Care data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Tracheostomy Care data element as standardized patient assessment data for use in the IRF QRP.

• Respiratory Treatment: Non-Invasive Mechanical Ventilator (BiPAP, CPAP)

We are proposing that the Non-invasive Mechanical Ventilator (Bilevel Positive Airway Pressure [BiPAP], Continuous Positive Airway Pressure [CPAP]) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IRF PPS proposed rule (82 FR 20730), BiPAP and CPAP are respiratory support devices that prevent the airways from closing by delivering slightly pressurized air via electronic cycling throughout the breathing cycle (BiPAP) or through a mask continuously (CPAP). Assessment of non-invasive mechanical ventilation is important in care planning, as both CPAP and BiPAP are resource-intensive (although less so than invasive mechanical ventilation) and signify underlying medical conditions about the patient or resident who requires the use of this intervention. Particularly when used in settings of acute illness or progressive respiratory decline, additional staff (for example, respiratory therapists) are required to monitor and adjust the CPAP and BiPAP settings and the patient or resident may require more nursing resources.

The proposed data element, Non-invasive Mechanical Ventilator (BIPAP, CPAP), consists of the principal Non-invasive Mechanical Ventilator data element and two response option sub-elements: BiPAP and CPAP. If the assessor indicates that the patient is receiving non-invasive mechanical ventilation on the principal Non-invasive Mechanical Ventilator data element, the assessor would then indicate which type (for example, BIPAP, CPAP). Data elements that assess non-invasive mechanical ventilation are currently included on LCDS for the LTCH setting (''Non-invasive Ventilator (BIPAP, CPAP)''), and the MDS for the SNF setting (''Non-invasive Mechanical Ventilator (BiPAP/CPAP)''). For more information on the Non-invasive Mechanical Ventilator (BIPAP, CPAP) data element, we refer readers to the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Non-invasive Mechanical Ventilator data element was first proposed as standardized patient assessment data elements in the FY 2018 IRF PPS proposed rule (82 FR 20730). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 on a single data element, BiPAP/CPAP, that captures equivalent clinical information but uses a different label than the data element currently used in the MDS in SNFs and LCDS, expressed support for this data element, noting the feasibility of these items in PAC, and the relevance of this data element for facilitating care coordination and supporting care transitions. In addition, we also stated that some commenters supported separating out BiPAP and CPAP as distinct sub-elements, as they are therapies used for different types of patients and residents. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 IRF PPS proposed rule, we received public comments in support of the special services, treatments, and interventions data elements in general. One commenter noted appreciation of the revisions to the Non-invasive Mechanical Ventilator data element in response to comments submitted during a public input period held from August 12 to September 12, 2016.

Subsequent to receiving comments on the FY 2018 IRF PPS rule, the Non-invasive Mechanical Ventilator data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Non-invasive Mechanical Ventilator data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Non-invasive Mechanical Ventilator data element in the National Beta Test can be found in the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Non-invasive Mechanical Ventilator data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for non-invasive mechanical ventilation, stakeholder input, and strong test results, we are proposing that the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data element with a principal data element and two sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data element as standardized patient assessment data for use in the IRF QRP.

• Respiratory Treatment: Invasive Mechanical Ventilator

We are proposing that the Invasive Mechanical Ventilator data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IRF PPS proposed rule (82 FR 20730 through 20731), invasive mechanical ventilation includes ventilators and respirators that ventilate the patient through a tube that extends via the oral airway into the pulmonary region or through a surgical opening directly into the trachea. Thus, assessment of invasive mechanical ventilation is important in care planning and risk mitigation. Ventilation in this manner is a resource-intensive therapy associated with life-threatening conditions without which the patient or resident would not survive. However, ventilator use has inherent risks requiring close monitoring. Failure to adequately care for the patient or resident who is ventilator dependent can lead to iatrogenic events such as death, pneumonia, and sepsis. Mechanical ventilation further signifies the complexity of the patient's underlying medical or surgical condition. Of note, invasive mechanical ventilation is associated with high daily and aggregate costs.[91]

The proposed data element, Invasive Mechanical Ventilator, consists of a single data element. Data elements that capture invasive mechanical ventilation are currently in use in the MDS in SNFs and LCDS in LTCHs. For more information on the Invasive Mechanical Ventilator data element, we refer readers to the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Invasive Mechanical Ventilator data element was first proposed as a standardized patient assessment data element in the FY 2018 IRF PPS proposed rule (82 FR 20730 through 20731). In that proposed rule, we stated that the proposal was informed by input we received on data elements that assess invasive ventilator use and weaning status that were tested in the PAC PRD (''Ventilator—Weaning'' and ''Ventilator—Non-Weaning'') through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016, expressed support for this data element, highlighting the importance of this information in supporting care coordination and care transitions. We also stated that some commenters had expressed concern about the appropriateness for standardization given: The prevalence of ventilator weaning across PAC providers; the timing of administration; how weaning is defined; and how weaning status in particular relates to quality of care. These public comments guided our decision to propose a single data element focused on current use of invasive mechanical ventilation only, which does not attempt to capture weaning status. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' we received is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 IRF PPS proposed rule, we received public comments in support of the special services, treatments, and interventions data elements in general. Two commenters noted their appreciation of the revisions to the Invasive Mechanical Ventilator data element in response to comments submitted during a public input period held from August 12 to September 12, 2016.

Subsequent to receiving comments on the FY 2018 IRF PPS rule, the Invasive Mechanical Ventilator data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Invasive Mechanical Ventilator data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Invasive Mechanical Ventilator data element in the National Beta Test can be found in the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data element. Although the TEP did not specifically discuss the Invasive Mechanical Ventilator data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for invasive mechanical ventilation, stakeholder input, and strong test results, we are proposing that the Invasive Mechanical Ventilator data element that assesses the use of an invasive mechanical ventilator meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Invasive Mechanical Ventilator data element as standardized patient assessment data for use in the IRF QRP.

[91] Wunsch, H., Linde-Zwirble, W.T., Angus, D.C., Hartman, M.E., Milbrandt, E.B., & Kahn, J.M. (2010). ''The epidemiology of mechanical ventilation use in the United States.'' *Critical Care Med* 38(10): 1947–1953.

• Intravenous (IV) Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other)

We are proposing that the IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IRF PPS proposed rule (82 FR 20731 through 20732), when we proposed a similar data element related to IV medications, IV medications are solutions of a specific medication (for example, antibiotics, anticoagulants) administered directly into the venous circulation via a syringe or intravenous catheter. IV medications are administered via intravenous push, single, intermittent, or continuous infusion through a catheter placed into the vein. Further, IV medications are more resource intensive to administer than oral medications, and signify a higher patient complexity (and often higher severity of illness).

The clinical indications for each of the sub-elements of the IV Medications data element (Antibiotics, Anticoagulants, Vasoactive Medications, and Other) are very different. IV antibiotics are used for severe infections when the bioavailability of the oral form of the medication would be inadequate to kill the pathogen or an oral form of the medication does not exist. IV anticoagulants refer to anti-clotting medications (that is, ''blood thinners''). IV anticoagulants are commonly used for hospitalized patients who have deep venous thrombosis, pulmonary embolism, or myocardial infarction, as well as those undergoing interventional cardiac procedures. Vasoactive medications refer to the IV administration of vasoactive drugs, including vasopressors, vasodilators, and continuous medication for pulmonary edema, which increase or decrease blood pressure or heart rate. The indications, risks, and benefits of each of these classes of IV medications are distinct, making it important to assess each separately in PAC. Knowing whether or not patients and residents are receiving IV medication and the type of medication provided by each PAC provider will improve quality of care.

The IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, and Other) data element we are proposing consists of a principal data element (IV Medications) and four response option sub-elements: Antibiotics, Anticoagulants, Vasoactive Medications, and Other. The Vasoactive Medications sub-element was not proposed in the FY 2018 IRF PPS proposed rule (82 FR 20731 through 20732). We added the Vasoactive Medications sub-element to our proposal in order to harmonize the proposed IV Mediciations element with the data currently collected in the LCDS.

If the assessor indicates that the patient is receiving IV medications on the principal IV Medications data element, the assessor would then indicate which types of medications (for example, Antibiotics, Anticoagulants, Vasoactive Medications, Other). An IV Medications data element is currently in use on the MDS in SNFs and there is a related data element in OASIS that collects information on Intravenous and Infusion Therapies. For more information on the IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other) data element, we refer readers to the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

An IV Medications data element was first proposed as standardized patient assessment data element in the FY 2018 IRF PPS proposed rule (82 FR 20731 through 20732). In that proposed rule, we stated that the proposal was informed by input we received on Vasoactive Medications through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 supported this data element with one noting the importance of this data element in supporting care transitions. We also stated that those commenters had criticized the need for collecting specifically Vasoactive Medications, giving feedback that the data element was too narrowly focused. In addition, public comment received indicated that the clinical significance of vasoactive medications administration alone was not high enough in PAC to merit mandated assessment, noting that related and more useful information could be captured in an item that assessed all IV medication use. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 IRF PPS proposed rule, we received public comments in support of the special services, treatments, and interventions data elements in general; no additional comments were received that were specific to the IV Medications data element.

Subsequent to receiving comments on the FY 2018 IRF PPS rule, the IV Medications data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the IV Medications data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the IV Medications data element in the National Beta Test can be found in the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the IV Medications data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received

from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for IV medications, stakeholder input, and strong test results, we are proposing that the IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other) data element with a principal data element and four sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other) data element as standardized patient assessment data for use in the IRF QRP.

- Transfusions

We are proposing that the Transfusions data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IRF PPS proposed rule (82 FR 20732), transfusion refers to introducing blood or blood products into the circulatory system of a person. Blood transfusions are based on specific protocols, with multiple safety checks and monitoring required during and after the infusion in case of adverse events. Coordination with the provider's blood bank is necessary, as well as documentation by clinical staff to ensure compliance with regulatory requirements. In addition, the need for transfusions signifies underlying patient complexity that is likely to require care coordination and patient monitoring, and impacts planning for transitions of care, as transfusions are not performed by all PAC providers.

The proposed data element consists of the single Transfusions data element. A data element on transfusion is currently in use in the MDS in SNFs (''Transfusions'') and a data element tested in the PAC PRD (''Blood Transfusions'') was found feasible for use in each of the four PAC settings. For more information on the Transfusions data element, we refer readers to the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Transfusions data element was first proposed as a standardized patient assessment data element in the FY 2018 IRF PPS proposed rule (82 FR 20732). In response to our proposal in the FY 2018 IRF PPS proposed rule, we received public comments in support of the special services, treatments, and interventions data elements in general; no additional comments were received that were specific to the Transfusions data element.

Subsequent to receiving comments on the FY 2018 IRF PPS rule, the Transfusions data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Transfusions data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Transfusions data element in the National Beta Test can be found in the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Transfusions data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for transfusions, stakeholder input, and strong test results, we are proposing that the Transfusions data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Transfusions data element as standardized patient assessment data for use in the IRF QRP.

- Dialysis (Hemodialysis, Peritoneal Dialysis)

We are proposing that the Dialysis (Hemodialysis, Peritoneal dialysis) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IRF PPS proposed rule (82 FR 20732 through 20733), dialysis is a treatment primarily used to provide replacement for lost kidney function. Both forms of dialysis (hemodialysis and peritoneal dialysis) are resource intensive, not only during the actual dialysis process but before, during, and following. Patients and residents who need and undergo dialysis procedures are at high risk for physiologic and hemodynamic instability from fluid shifts and electrolyte disturbances, as well as infections that can lead to sepsis. Further, patients or residents receiving hemodialysis are often transported to a different facility, or at a minimum, to a different location in the same facility for treatment. Close monitoring for fluid

shifts, blood pressure abnormalities, and other adverse effects is required prior to, during, and following each dialysis session. Nursing staff typically perform peritoneal dialysis at the bedside, and as with hemodialysis, close monitoring is required.

The proposed data element, Dialysis (Hemodialysis, Peritoneal dialysis) consists of the principal Dialysis data element and two response option sub-elements: Hemodialysis and Peritoneal dialysis. If the assessor indicates that the patient is receiving dialysis on the principal Dialysis data element, the assessor would then indicate which type (Hemodialysis or Peritoneal dialysis). The principal Dialysis data element is currently included on the MDS in SNFs and the LCDS for LTCHs and assesses the overall use of dialysis.

As the result public feedback described below, in this proposed rule, we are proposing a data element that includes the principal Dialysis data element and two sub-elements (Hemodialysis and Peritoneal dialysis). For more information on the Dialysis data element, we refer readers to the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Dialysis data element was first proposed as standardized patient assessment data in the FY 2018 IRF PPS proposed rule (82 FR 20732 through 20733). In that proposed rule, we stated that the proposal was informed by input we received on a singular Hemodialysis data element through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 supported the assessment of hemodialysis and recommended that the data element be expanded to include peritoneal dialysis. We also stated that those commenters had supported the singular Hemodialysis data element, noting the relevance of this information for sharing across the care continuum to facilitate care coordination and care transitions, the potential for this data element to be used to improve quality, and the feasibility for use in PAC. In addition, we received comments that the item would be useful in improving patient and resident transitions of care. We also noted that several commenters had stated that peritoneal dialysis should be included in a standardized data element on dialysis and recommended collecting information on peritoneal dialysis in addition to hemodialysis. The rationale for including peritoneal dialysis from commenters included the fact that patients and residents receiving peritoneal dialysis will have different needs at post-acute discharge compared to those receiving hemodialysis or not having any dialysis. Based on these comments, the Hemodialysis data element was expanded to include a principal Dialysis data element and two sub-elements, Hemodialysis and Peritoneal dialysis. We are proposing the version of the Dialysis element that includes two types of dialysis. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 IRF PPS proposed rule, we received comments in support of the special services, treatments, and interventions data elements in general. One commenter noted that they appreciated the revisions to the Dialysis data element in response to comments submitted during a public input period held from August 12 to September 12, 2016.

Subsequent to receiving comments on the FY 2018 IRF PPS rule, the Dialysis data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Dialysis data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Dialysis data element in the National Beta Test can be found in the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although they did not specifically discuss the Dialysis data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for dialysis, stakeholder input, and strong test results, we are proposing that the Dialysis (Hemodialysis, Peritoneal dialysis) data element with a principal data element and two sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Dialysis (Hemodialysis, Peritoneal dialysis) data element as standardized patient assessment data for use in the IRF QRP.

- Intravenous (IV) Access (Peripheral IV, Midline, Central line)

We are proposing that the IV Access (Peripheral IV, Midline, Central line) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IRF PPS proposed rule (82 FR 20733 through 20734), patients or residents with central lines, including those peripherally inserted or who have

subcutaneous central line ''port'' access, always require vigilant nursing care to keep patency of the lines and ensure that such invasive lines remain free from any potentially life-threatening events such as infection, air embolism, or bleeding from an open lumen. Clinically complex patients and residents are likely to be receiving medications or nutrition intravenously. The sub-elements included in the IV Access data elements distinguish between peripheral access and different types of central access. The rationale for distinguishing between a peripheral IV and central IV access is that central lines confer higher risks associated with life-threatening events such as pulmonary embolism, infection, and bleeding.

The proposed data element, IV Access (Peripheral IV, Midline, Central line), consists of the principal IV Access data element and three response option sub-elements: Peripheral IV, Midline, and Central line. The proposed IV Access data element is not currently included on any of the PAC assessment instruments. For more information on the IV Access data element, we refer readers to the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The IV Access data element was first proposed as standardized patient assessment data elements in the FY 2018 IRF PPS proposed rule (82 FR 20733 through 20734). In that proposed rule, we stated that the proposal was informed by input we received on one of the PAC PRD data elements, Central Line Management, through a call for input published on the CMS Measures Management System Blueprint website. A central line is a type of IV access. Input submitted from August 12 to September 12, 2016 supported the assessment of central line management and recommended that the data element be broadened to also include other types of IV access. Several commenters noted feasibility and importance for facilitating care coordination and care transitions. However, a few commenters recommended that the definition of this data element be broadened to include peripherally inserted central catheters (''PICC lines'') and midline IVs. Based on public comment feedback and in consultation with expert input, described below, we created an overarching IV Access data element with sub-elements for other types of IV access in addition to central lines (that is, peripheral IV and midline). This expanded version of IV Access is the data element being proposed. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 IRF PPS proposed rule, we received public comments in support of the special services, treatments, and interventions data elements in general. One commenter noted appreciation of the revisions to the IV Access data element in response to comments submitted during a public input period held from August 12 to September 12, 2016.

Subsequent to receiving comments on the FY 2018 IRF PPS rule, the IV Access data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the IV Access data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the IV Access data element in the National Beta Test can be found in the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the IV Access data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for IV access, stakeholder input, and strong test results, we are proposing that the IV access (Peripheral IV, Midline, Central line) data element with a principal data element and three sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the IV Access (Peripheral IV, Midline, Central line) data element as standardized patient assessment data for use in the IRF QRP.

• Nutritional Approach: Parenteral/IV Feeding

We are proposing that the Parenteral/IV Feeding data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IRF PPS proposed rule (82 FR 20734), parenteral nutrition/IV feeding refers to a patient or resident being fed intravenously using an infusion pump, bypassing the usual process of eating and digestion. The need for IV/parenteral feeding indicates a clinical complexity that prevents the patient or resident from meeting his or her nutritional needs enterally, and is more resource intensive than other forms of nutrition, as it often requires monitoring of blood chemistries and the maintenance of a central line. Therefore, assessing a patient's or resident's need for parenteral feeding is important for care

planning and resource use. In addition to the risks associated with central and peripheral intravenous access, total parenteral nutrition is associated with significant risks, such as air embolism and sepsis.

The proposed data element consists of the single Parenteral/IV Feeding data element. The proposed Parenteral/IV Feeding data element is currently in use in the MDS in SNFs, and equivalent or related data elements are in use in the LCDS, IRF–PAI, and OASIS. We are proposing to rename the existing Tube/Parenteral feeding item in the IRF–PAI to be the Parenteral/IV Feeding data element. For more information on the Parenteral/IV Feeding data element, we refer readers to the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Parenteral/IV Feeding data element was first proposed as a standardized patient assessment data element in the FY 2018 IRF PPS proposed rule (82 FR 20734). In that proposed rule, we stated that the proposal was informed by input we received on Total Parenteral Nutrition (an item with nearly the same meaning as the proposed data element, but with the label used in the PAC PRD), through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 supported this data element, noting its relevance to facilitating care coordination and supporting care transitions. After the public comment period, the Total Parenteral Nutrition data element was renamed Parenteral/IV Feeding, to be consistent with how this data element is referred to in the MDS in SNFs. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 IRF PPS proposed rule, we received comments in support of the special services, treatments, and interventions data elements in general; no additional comments were received that were specific to the Parenteral/IV Feeding data element.

Subsequent to receiving comments on the FY 2018 IRF PPS rule, the Parenteral/IV Feeding data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Parenteral/IV Feeding data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Parenteral/IV Feeding data element in the National Beta Test can be found in the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Parenteral/IV Feeding data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for parenteral/IV feeding, stakeholder input, and strong test results, we are proposing that the Parenteral/IV Feeding data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Parenteral/IV Feeding data element as standardized patient assessment data for use in the IRF QRP.

- Nutritional Approach: Feeding Tube

We are proposing that the Feeding Tube data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IRF PPS proposed rule (82 FR 20734 through 20735), the majority of patients admitted to acute care hospitals experience deterioration of their nutritional status during their hospital stay, making assessment of nutritional status and method of feeding if unable to eat orally very important in PAC. A feeding tube can be inserted through the nose or the skin on the abdomen to deliver liquid nutrition into the stomach or small intestine. Feeding tubes are resource intensive, and therefore, are important to assess for care planning and resource use. Patients with severe malnutrition are at higher risk for a variety of complications.[92] In PAC settings, there are a variety of reasons that patients and residents may not be able to eat orally (including clinical or cognitive status).

The proposed data element consists of the single Feeding Tube data element. The Feeding Tube data element is currently included in the MDS for SNFs, and in the OASIS for HHAs, where it is labeled Enteral Nutrition. A related data element, collected in the IRF–PAI for IRFs (Tube/Parenteral Feeding), assesses use of both feeding tubes and parenteral nutrition. We are proposing to rename the existing Tube/Parenteral feeding item in the IRF–PAI to the Feeding Tube data element. For more information on the Feeding Tube data element, we refer readers to the document titled

[92] Dempsey, D.T., Mullen, J.L., & Buzby, G.P. (1988). ''The link between nutritional status and clinical outcome: Can nutritional intervention modify it?'' Am J of Clinical Nutrition, 47(2): 352–356.

''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Feeding Tube data element was first proposed as a standardized patient assessment data element in the FY 2018 IRF PPS proposed rule (82 FR 20734 through 20735). In that proposed rule, we stated that the proposal was informed by input we received on an Enteral Nutrition data element (the Enteral Nutrition data item is the same as the data element we are proposing in this proposed rule, but is used in the OASIS under a different name) through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 supported the data element, noting the importance of assessing enteral nutrition status for facilitating care coordination and care transitions. After the public comment period, the Enteral Nutrition data element used in public comment was renamed Feeding Tube, indicating the presence of an assistive device. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 IRF PPS proposed rule, we received public comments in support of the special services, treatments, and interventions data elements in general. In addition, a commenter recommended that the term ''enteral feeding'' be used instead of ''feeding tube''.

Subsequent to receiving comments on the FY 2018 IRF PPS rule, the Feeding Tube data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Feeding Tube data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Feeding Tube data element in the National Beta Test can be found in the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Feeding Tube data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for feeding tubes, stakeholder input, and strong test results, we are proposing that the Feeding Tube data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Feeding Tube data element as standardized patient assessment data for use in the IRF QRP.

• Nutritional Approach: Mechanically Altered Diet

We are proposing that the Mechanically Altered Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IRF PPS proposed rule (82 FR 20735 through 20736), the Mechanically Altered Diet data element refers to food that has been altered to make it easier for the patient or resident to chew and swallow, and this type of diet is used for patients and residents who have difficulty performing these functions. Patients with severe malnutrition are at higher risk for a variety of complications.[93]

In PAC settings, there are a variety of reasons that patients and residents may have impairments related to oral feedings, including clinical or cognitive status. The provision of a mechanically altered diet may be resource intensive, and can signal difficulties associated with swallowing/eating safety, including dysphagia. In other cases, it signifies the type of altered food source, such as ground or puree that will enable the safe and thorough ingestion of nutritional substances and ensure safe and adequate delivery of nourishment to the patient. Often, patients and residents on mechanically altered diets also require additional nursing support, such as individual feeding or direct observation, to ensure the safe consumption of the food product. Therefore, assessing whether a patient or resident requires a mechanically altered diet is important for care planning and resource identification.

The proposed data element consists of the single Mechanically Altered Diet data element. The proposed data element is currently included on the MDS for SNFs. A related data element (''Modified food consistency/supervision'') is currently included on the IRF–PAI for IRFs. Another related data element is included in the OASIS for HHAs that collects information about independent eating that requires ''a liquid, pureed or ground meat diet.'' We are proposing to replace the existing Modified food consistency/supervision data element in the IRF–PAI to the Mechanically Altered Diet data element. For more information on the Mechanically Altered Diet data element, we refer readers to the document titled

[93] Dempsey, D.T., Mullen, J.L., & Buzby, G.P. (1988). ''The link between nutritional status and clinical outcome: Can nutritional intervention modify it?'' Am J of Clinical Nutrition, 47(2): 352–356.

''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Mechanically Altered Diet data element was first proposed as a standardized patient assessment data element in the FY 2018 IRF PPS proposed rule (82 FR 20735 through 20736). In response to our proposal in the FY 2018 IRF PPS proposed rule, we received public comments in support of the special services, treatments, and interventions data elements in general; no additional comments were received that were specific to the Mechanically Altered Diet data element.

Subsequent to receiving comments on the FY 2018 IRF PPS rule, the Mechanically Altered Diet data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Mechanically Altered Diet data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Mechanically Altered Diet data element in the National Beta Test can be found in the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Mechanically Altered Diet data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for mechanically altered diet, stakeholder input, and strong test results, we are proposing that the Mechanically Altered Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Mechanically Altered Diet data element as standardized patient assessment data for use in the IRF QRP.

• Nutritional Approach: Therapeutic Diet

We are proposing that the Therapeutic Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 IRF PPS proposed rule (82 FR 20736), a therapeutic diet refers to meals planned to increase, decrease, or eliminate specific foods or nutrients in a patient's or resident's diet, such as a low-salt diet, for the purpose of treating a medical condition. The use of therapeutic diets among patients and residents in PAC provides insight on the clinical complexity of these patients and residents and their multiple comorbidities. Therapeutic diets are less resource intensive from the bedside nursing perspective, but do signify one or more underlying clinical conditions that preclude the patient from eating a regular diet. The communication among PAC providers about whether a patient is receiving a particular therapeutic diet is critical to ensure safe transitions of care.

The proposed data element consists of the single Therapeutic Diet data element. This data element is currently in use in the MDS in SNFs. For more information on the Therapeutic Diet data element, we refer readers to the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Therapeutic Diet data element was first proposed as a standardized patient assessment data element in the FY 2018 IRF PPS proposed rule (82 FR 20736). In response to our proposal in the FY 2018 IRF PPS proposed rule, we received public comments in support of the special services, treatments, and interventions data elements in general. One commenter recommended that the definition of Therapeutic Diet be aligned with the Academy of Nutrition and Dietetics' definition and that ''medically altered diet'' be added to the list of nutritional approaches.

Subsequent to receiving comments on the FY 2018 IRF PPS rule, the Therapeutic Diet data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Therapeutic Diet data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Therapeutic Diet data element in the National Beta Test can be found in the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Therapeutic Diet data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP

meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for therapeutic diet, stakeholder input, and strong test results, we are proposing that the Therapeutic Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Therapeutic Diet data element as standardized patient assessment data for use in the IRF QRP.

• High-Risk Drug Classes: Use and Indication

We are proposing that the High-Risk Drug Classes: Use and Indication data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

Most patients and residents receiving PAC services depend on short- and long-term medications to manage their medical conditions. However, as a treatment, medications are not without risk; medications are, in fact, a leading cause of adverse events. A study by the U.S. Department of Health and Human Services found that 31 percent of adverse events that occurred in 2008 among hospitalized Medicare beneficiaries were related to medication.[94] Moreover, changes in a patient's condition, medications, and transitions between care settings put patients at risk of medication errors and adverse drug events (ADEs). ADEs may be caused by medication errors such as drug omissions, errors in dosage, and errors in dosing frequency.[95]

ADEs are known to occur across different types of healthcare settings. For example, the incidence of ADEs in the outpatient setting has been estimated at 1.15 ADEs per 100 person-months,[96] while the rate of ADEs in the long-term care setting is approximately 9.80 ADEs per 100 resident-months.[97] In the hospital setting, the incidence has been estimated at 15 ADEs per 100 admissions.[98] In addition, approximately half of all hospital-related medication errors and 20 percent of ADEs occur during transitions within, admission to, transfer to, or discharge from a hospital.[99] [100] [101] ADEs are more common among older adults, who make up most patients receiving PAC services. The rate of emergency department visits for ADEs is three times higher among adults 65 years of age and older compared to that among those younger than age 65.[102]

Understanding the types of medication a patient is taking, and the reason for its use, are key facets of a patient's treatment with respect to medication. Some classes of drugs are associated with more risk than others.[103] We are proposing one High-Risk Drug Class data element with six sub-elements. The six medication classes response options are: Anticoagulants, antiplatelets, hypoglycemics (including insulin), opioids, antipsychotics, and antibiotics. These drug classes are high-risk due to the adverse effects that may result from use. In particular, bleeding risk is associated with anticoagulants and antiplatelets; [104] [105] fluid retention, heart failure, and lactic acidosis are associated with hypoglycemics; [106] misuse is associated with opioids; [107] fractures and strokes are associated with antipsychotics; [108] [109] and various adverse events, such as central nervous systems effects and gastrointestinal intolerance, are associated with antimicrobials,[110] the larger category of medications that include antibiotics. Moreover, some medications in five of the six drug classes included in this data element are included in the 2019 Updated Beers Criteria® list as potentially inappropriate medications for use in older adults.[111] Finally, although a complete medication list should record several important attributes of each medication (for example, dosage, route, stop date),

[94] U.S. Department of Health and Human Services. Office of Inspector General. Daniel R. Levinson. Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries. OEI–06–09–00090. November 2010.

[95] Boockvar KS, Liu S, Goldstein N, Nebeker J, Siu A, Fried T. Prescribing discrepancies likely to cause adverse drug events after patient transfer. Qual Saf Health Care. 2009;18(1):32–6.

[96] Gandhi TK, Seger AC, Overhage JM, et al. Outpatient adverse drug events identified by screening electronic health records. *J Patient Saf* 2010;6:91–6.doi:10.1097/PTS.0b013e3181dcae06.

[97] Gurwitz JH, Field TS, Judge J, Rochon P, Harrold LR, Cadoret C, et al. The incidence of adverse drug events in two large academic long-term care facilities. *Am J Med.* 2005; 118(3):251±8. Epub 2005/03/05. *https://doi.org/10.1016/j.amjmed.2004.09.018* PMID: 15745723.

[98] Hug BL, Witkowski DJ, Sox CM, Keohane CA, Seger DL, Yoon C, Matheny ME, Bates DW. Occurrence of adverse, often preventable, events in community hospitals involving nephrotoxic drugs or those excreted by the kidney. Kidney Int. 2009; 76:1192–1198. [PubMed: 19759525].

[99] Barnsteiner JH. Medication reconciliation: transfer of medication information across settings-keeping it free from error. J Infus Nurs. 2005;28(2 Suppl):31–36.

[100] Rozich J, Roger, R. Medication safety: one organization's approach to the challenge. *Journal of Clinical Outcomes Management.* 2001(8):27–34.

[101] Gleason KM, Groszek JM, Sullivan C, Rooney D, Barnard C, Noskin GA. Reconciliation of discrepancies in medication histories and admission orders of newly hospitalized patients. Am J Health Syst Pharm. 2004;61(16):1689–1695.

[102] Shehab N, Lovegrove MC, Geller AI, Rose KO, Weidle NJ, Budnitz DS. US emergency department visits for outpatient adverse drug events, 2013–2014. *JAMA.* doi: 10.1001/jama.2016.16201.

[103] Ibid.

[104] Shoeb M, Fang MC. Assessing bleeding risk in patients taking anticoagulants. *J Thromb Thrombolysis.* 2013;35(3):312–319. doi: 10.1007/s11239–013–0899–7.

[105] Melkonian M, Jarzebowski W, Pautas E. Bleeding risk of antiplatelet drugs compared with oral anticoagulants in older patients with atrial fibrillation: a systematic review and meta-analysis. *J Thromb Haemost.* 2017;15:1500–1510. DOI: 10.1111/jth.13697.

[106] Hamnvik OP, McMahon GT. Balancing Risk and Benefit with Oral Hypoglycemic Drugs. *The Mount Sinai journal of medicine,* New York. 2009; 76:234–243.

[107] Naples JG, Gellad WF, Hanlon JT. The Role of Opioid Analgesics in Geriatric Pain Management. *Clin Geriatr Med.* 2016;32(4):725–735.

[108] Rigler SK, Shireman TI, Cook-Wiens GJ, Ellerbeck EF, Whittle JC, Mehr DR, Mahnken JD. Fracture risk in nursing home residents initiating antipsychotic medications. *J Am Geriatr Soc.* 2013; 61(5):715–722. [PubMed: 23590366].

[109] Wang S, Linkletter C, Dore D et al. Age, antipsychotics, and the risk of ischemic stroke in the Veterans Health Administration. *Stroke* 2012;43:28–31. doi:10.1161/STROKEAHA.111.617191.

[110] Faulkner CM, Cox HL, Williamson JC. Unique aspects of antimicrobial use in older adults. *Clin Infect Dis.* 2005;40(7):997–1004.

[111] American Geriatrics Society 2019 Beers Criteria Update Expert Panel. American Geriatrics Society 2019 Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. *J Am Geriatr Soc* 2019; 00:1–21.

recording an indication for the drug is of crucial importance.[112]

The High-Risk Drug Classes: Use and Indication data element requires an assessor to record whether or not a patient is taking any medications within six the drug classes. The six response options for this data element are high-risk drug classes with particular relevance to PAC patients and residents, as identified by our data element contractor. The six data element response options are Anticoagulants, Antiplatelets, Hypoglycemics, Opioids, Antipsychotics, and Antibiotics. For each drug class, the assessor is asked to indicate if the patient is taking any medications within the class, and, for drug classes in which medications were being taken, whether indications for all drugs in the class are noted in the medical record. For example, for the response option Anticoagulants, if the assessor indicates that the patient has received anticoagulant medication, the assessor would then indicate if an indication is recorded in the medication record for the anticoagulant(s).

The High-Risk Drug Classes: Use and Indication data element that is being proposed as a SPADE was developed as part of a larger set of data elements to assess medication reconciliation, the process of obtaining a patient's multiple medication lists and reconciling any discrepancies. For more information on the High-Risk Drug Classes: Use and Indication data element, we refer readers to the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We sought public input on the relevance of conducting assessments on medication reconciliation and specifically on the proposed High-Risk Drug Classes: Use and Indication data element. Our data element contractor presented data elements related to medication reconciliation to the TEP convened on April 6 and 7, 2016. The TEP supported a focus on high-risk drugs, because of higher potential for harm to patients and residents, and were in favor of a data element to capture whether or not indications for medications were recorded in the medical record. A summary of the April 6 and 7, 2016 TEP meeting titled ''SPADE Technical Expert Panel Summary (First Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.* Medication reconciliation data elements were also discussed at a second TEP meeting on January 5 and 6, 2017, convened by our data element contractor. At this meeting, the TEP agreed about the importance of evaluating the medication reconciliation process, but disagreed about how this could be accomplished through standardized assessment. The TEP also disagreed about the usability and appropriateness of using the Beers Criteria to identify high-risk medications.[113] A summary of the January 5 and 6, 2017 TEP meeting titled ''SPADE Technical Expert Panel Summary (Second Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also solicited public input on data elements related to medication reconciliation during a public input period from April 26 to June 26, 2017. Several commenters expressed support for the medication reconciliation data elements that were put on display, noting the importance of medication reconciliation in preventing medication errors and stated that the items seemed feasible and clinically useful. A few commenters were critical of the choice of 10 drug classes posted during that comment period, arguing that ADEs are not limited to high-risk drugs, and raised issues related to training assessors to correctly complete a valid assessment of medication reconciliation. A summary report for the April 26 to June 26, 2017 public comment period titled ''SPADE May–June 2017 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The High-Risk Drug Classes: Use and Indication data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the High-Risk Drug Classes: Use and Indication data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the High-Risk Drug Classes: Use and Indication data element in the National Beta Test can be found in the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. The TEP acknowledged the challenges of assessing medication safety, but were supportive of some of the data elements focused on medication reconciliation that were tested in the National Beta Test. The TEP was especially supportive of the focus on the six high-risk drug classes and using these classes to assess whether the indication for a drug is recorded. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. These activities provided updates on the field-testing work and solicited feedback on data elements considered for standardization, including the High-Risk Drug Classes: Use and Indication data element. One stakeholder group was critical of the six drug classes included as response options in the High-Risk Drug Classes: Use and Indication data element, noting that potentially risky medications (for example, muscle relaxants) are not included in this list; that there may be important differences between drugs within classes (for example, more recent versus older style antidepressants); and that drug allergy information is not captured. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders

[112] Li Y, Salmasian H, Harpaz R, Chase H, Friedman C. Determining the reasons for medication prescriptions in the EHR using knowledge and natural language processing. AMIA Annu Symp Proc. 2011;2011:768–76.

[113] American Geriatrics Society 2015 Beers Criteria Update Expert Panel. American Geriatrics Society. Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. *J Am Geriatr Soc* 2015; 63:2227–2246.

to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Additionally, one commenter questioned whether the time to complete the High-Risk Drug Classes: Use and Indication data element would differ across settings. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing high-risk drugs and for whether or not indications are noted for high-risk drugs, stakeholder input, and strong test results, we are proposing that the High-Risk Drug Classes: Use and Indication data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the High-Risk Drug Classes: Use and Indication data element as standardized patient assessment data for use in the IRF QRP.

3. Medical Condition and Comorbidity Data

Assessing medical conditions and comorbidities is critically important for care planning and safety for patients and residents receiving PAC services, and the standardized assessment of selected medical conditions and comorbidities across PAC providers is important for managing care transitions and understanding medical complexity.

Below we discuss our proposals for data elements related to the medical condition of pain as standardized patient assessment data. Appropriate pain management begins with a standardized assessment, and thereafter establishing and implementing an overall plan of care that is person-centered, multi-modal, and includes the treatment team and the patient. Assessing and documenting the effect of pain on sleep, participation in therapy, and other activities may provide information on undiagnosed conditions and comorbidities and the level of care required, and do so more objectively than subjective numerical scores. With that, we assess that taken separately and together, these proposed data elements are essential for care planning, consistency across transitions of care, and identifying medical complexities including undiagnosed conditions. We also conclude that it is the standard of care to always consider the risks and benefits associated with a personalized care plan, including the risks of any pharmacological therapy, especially opioids.[114] We also conclude that in addition to assessing and appropriately treating pain through the optimum mix of pharmacologic, non-pharmacologic, and alternative therapies, while being cognizant of current prescribing guidelines, clinicians in partnership with patients are best able to mitigate factors that contribute to the current opioid crisis.[115] [116] [117]

In alignment with our Meaningful Measures Initiative, accurate assessment of medical conditions and comorbidities of patients and residents in PAC is expected to make care safer by reducing harm caused in the delivery of care; promote effective prevention and treatment of chronic disease; strengthen person and family engagement as partners in their care; and promote effective communication and coordination of care. The SPADEs will enable or support: Clinical decision-making and early clinical intervention; person-centered, high quality care through: Facilitating better care continuity and coordination; better data exchange and interoperability between settings; and longitudinal outcome analysis. Therefore, reliable data elements assessing medical conditions and comorbidities are needed to initiate a management program that can optimize a patient's or resident's prognosis and reduce the possibility of adverse events.

We are inviting comment that applies specifically to the standardized patient assessment data for the category of medical conditions and co-morbidities, specifically on:

- Pain Interference (Pain Effect on Sleep, Pain Interference With Therapy Activities, and Pain Interference With Day-to-Day Activities)

In acknowledgement of the opioid crisis, we specifically are seeking comment on whether or not we should add these pain items in light of those concerns. Commenters should address to what extent the collection of the SPADES described below through patient queries might encourage providers to prescribe opioids.

We are proposing that a set of three data elements on the topic of Pain Interference (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities) meet the definition of standardized patient assessment data with respect to medical condition and comorbidity data under section 1899B(b)(1)(B)(iv) of the Act.

The practice of pain management began to undergo significant changes in the 1990s because the inadequate, non-standardized, non-evidence-based assessment and treatment of pain became a public health issue.[118] In pain management, a critical part of providing comprehensive care is performance of a thorough initial evaluation, including assessment of both the medical and any biopsychosocial factors causing or contributing to the pain, with a treatment plan to address the causes of pain and to manage pain that persists over time.[119] Quality pain management, based on current guidelines and evidence-based practices, can minimize unnecessary opioid prescribing both by offering alternatives or supplemental treatment to opioids and by clearly stating when they may be appropriate, and how to utilize risk-benefit analysis for opioid and non-opioid treatment modalities.[120]

[114] Department of Health and Human Services: Pain Management Best Practices Inter-Agency Task Force. *Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations.* Accessed April 1, 2019. *https://www.hhs.gov/sites/default/files/final-pmtf-draft-report-on-pain-management%20-best-practices-2018-12-12-html-ready-clean.pdf.*

[115] Department of Health and Human Services: Pain Management Best Practices Inter-Agency Task Force. *Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations.* Accessed April 1, 2019. *https://www.hhs.gov/sites/default/files/final-pmtf-draft-report-on-pain-management%20-best-practices-2018-12-12-html-ready-clean.pdf.*

[116] Fishman SM, Carr DB, Hogans B, et al. Scope and Nature of Pain- and Analgesia-Related Content of the United States Medical Licensing Examination (USMLE). *Pain Med Malden Mass.* 2018;19(3):449–459. doi:10.1093/pm/pnx336.

[117] Fishman SM, Young HM, Lucas Arwood E, et al. Core competencies for pain management: results of an interprofessional consensus summit. *Pain Med Malden Mass.* 2013;14(7):971–981. doi:10.1111/pme.12107.

[118] Institute of Medicine. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research.* Washington (DC): National Academies Press (U.S.); 2011. *http://www.ncbi.nlm.nih.gov/books/NBK91497/.*

[119] Department of Health and Human Services: Pain Management Best Practices Inter-Agency Task Force. *Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations.* Accessed April 1, 2019. *https://www.hhs.gov/sites/default/files/final-pmtf-draft-report-on-pain-management%20-best-practices-2018-12-12-html-ready-clean.pdf.*

[120] National Academies. *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use.* Washington, DC National Academies of Sciences, Engineering, and Medicine,; 2017.

Pain is not a surprising symptom in PAC patients and residents, where healing, recovery, and rehabilitation often require regaining mobility and other functions after an acute event. Standardized assessment of pain that interferes with function is an important first step towards appropriate pain management in PAC settings. The National Pain Strategy called for refined assessment items on the topic of pain, and describes the need for these improved measures to be implemented in PAC assessments.[121] Further, the focus on pain *interference,* as opposed to pain intensity or pain frequency, was supported by the TEP convened by our data element contractor as an appropriate and actionable metric for assessing pain. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We appreciate the important concerns related to the misuse and overuse of opioids in the treatment of pain and to that end we note that in this proposed rule we have also proposed a SPADE that assess for the use of, as well as importantly the indication for that use of, high risk drugs, including opioids. Further, in the FY 2017 IRF PPS final rule (81 FR 52111) we adopted the Drug Regimen Review Conducted With Follow-Up for Identified Issues—Post Acute Care (PAC) IRF QRP measure which assesses whether PAC providers were responsive to potential or actual clinically significant medication issue(s), which includes issues associated with use and misuse of opioids for pain management, when such issues were identified.

We also note that the proposed SPADE related to pain assessment are not associated with any particular approach to management. Since the use of opioids is associated with serious complications, particularly in the elderly,[122] [123] [124] an array of successful non-pharmacologic and non-opioid approaches to pain management may be considered. PAC providers have historically used a range of pain management strategies, including non-steroidal anti-inflammatory drugs, ice, transcutaneous electrical nerve stimulation (TENS) therapy, supportive devices, acupuncture, and the like. In addition, non-pharmacological interventions for pain management include, but are not limited to, biofeedback, application of heat/cold, massage, physical therapy, nerve block, stretching and strengthening exercises, chiropractic, electrical stimulation, radiotherapy, and ultrasound.[125] [126] [127]

We believe that standardized assessment of pain interference will support PAC clinicians in applying best-practices in pain management for chronic and acute pain, consistent with current clinical guidelines. For example, the standardized assessment of both opioids and pain interference would support providers in successfully tapering patients/residents who arrive in the PAC setting with long-term opioid use off of opioids onto non-pharmacologic treatments and non-opioid medications, as recommended by the Society for Post-Acute and Long-Term Care Medicine,[128] and consistent with HHS's 5-Point Strategy To Combat the Opioid Crisis [129] which includes ''Better Pain Management.''

The Pain Interference data elements consist of three data elements: Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities. Pain Effect on Sleep assesses the frequency with which pain effects a resident's sleep. Pain Interference with Therapy Activities assesses the frequency with which pain interferes with a resident's ability to participate in therapies. The Pain Interference with Day-to-Day Activities assesses the extent to which pain interferes with a resident's ability to participate in day-to-day activities excluding therapy.

A similar data element on the effect of pain on activities is currently included in the OASIS. A similar data element on the effect on sleep is currently included in the MDS instrument. For more information on the Pain Interference data elements, we refer readers to the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We sought public input on the relevance of conducting assessments on pain and specifically on the larger set of Pain Interview data elements included in the National Beta Test. The proposed data elements were supported by comments from the TEP meeting held by our data element contractor on April 7 to 8, 2016. The TEP affirmed the feasibility and clinical utility of pain as a concept in a standardized assessment. The TEP agreed that data elements on pain interference with ability to participate in therapies versus other activities should be addressed. Further, during a more recent convening of the same TEP on September 17, 2018, the TEP supported the interview-based pain data elements included in the National Beta Test. The TEP members were particularly supportive of the items that focused on how pain interferes with activities (that is, Pain Interference data elements), because understanding the extent to which pain interferes with function would enable clinicians to determine the need for appropriate pain treatment. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We held a public input period in 2016 to solicit feedback on the standardization of pain and several other items that were under development in prior efforts. From the prior public comment period, we included several pain data elements (Pain Effect on Sleep; Pain Interference—Therapy Activities; Pain Interference—Other Activities) in a second call for public input, open from April 26 to June 26, 2017. The items we sought comment on were modified from

[121] National Pain Strategy: A Comprehensive Population-Health Level Strategy for Pain. *https://iprcc.nih.gov/sites/default/files/HHSNational_Pain_Strategy_508C.pdf.*

[122] Chau, D.L., Walker, V., Pai, L., & Cho, L.M. (2008). Opiates and elderly: use and side effects. *Clinical interventions in aging, 3*(2), 273–8.

[123] Fine, P.G. (2009). Chronic Pain Management in Older Adults: Special Considerations. *Journal of Pain and Symptom Management,* 38(2): S4–S14.

[124] Solomon, D.H., Rassen, J.A., Glynn, R.J., Garneau, K., Levin, R., Lee, J., & Schneeweiss, S. (2010). *Archives Internal Medicine,* 170(22):1979–1986.

[125] Byrd L. Managing chronic pain in older adults: a long-term care perspective. *Annals of Long-Term Care: Clinical Care and Aging.* 2013;21(12):34–40.

[126] Kligler, B., Bair, M.J., Banerjea, R. et al. (2018). Clinical Policy Recommendations from the VHA State-of-the-Art Conference on Non-Pharmacological Approaches to Chronic Musculoskeletal Pain. *Journal of General Internal Medicine, 33*(Suppl 1): 16. *https://doi.org/10.1007/s11606-018-4323-z.*

[127] Chou, R., Deyo, R., Friedly, J., et al. (2017). Nonpharmacologic Therapies for Low Back Pain: A Systematic Review for an American College of Physicians Clinical Practice Guideline. *Annals of Internal Medicine, 166*(7):493–505.

[128] Society for Post-Acute and Long-Term Care Medicine (AMDA). (2018). Opioids in Nursing Homes: Position Statement. *https://paltc.org/opioids%20in%20nursing%20homes.*

[129] *https://www.hhs.gov/opioids/about-the-epidemic/hhs-response/index.html.*

all stakeholder and test efforts. Commenters provided general comments about pain assessment in general in addition to feedback on the specific pain items. A few commenters shared their support for assessing pain, the potential for pain assessment to improve the quality of care, and for the validity and reliability of the data elements. Commenters affirmed that the item of pain and the effect on sleep would be suitable for PAC settings. Commenters' main concerns included redundancy with existing data elements, feasibility and utility for cross-setting use, and the applicability of interview-based items to patients and residents with cognitive or communication impairments, and deficits. A summary report for the April 26 to June 26, 2017 public comment period titled ''SPADE May-June 2017 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Pain Interference data elements were included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Pain Interference data elements to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Pain Interference data elements in the National Beta Test can be found in the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the standardized patient assessment data elements. The TEP supported the interview-based pain data elements included in the National Beta Test. The TEP members were particularly supportive of the items that focused on how pain interferes with activities (that is, Pain Interference data elements), because understanding the extent to which pain interferes with function would enable clinicians to determine the need for pain treatment. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Additionally, one commenter expressed strong support for the Pain data elements and was encouraged by the fact that this portion of the assessment goes beyond merely measuring the presence of pain. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for the effect of pain on function, stakeholder input, and strong test results, we are proposing that the three Pain Interference data elements (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities) meet the definition of standardized patient assessment data with respect to medical conditions and comorbidities under section 1899B(b)(1)(B)(iv) of the Act and to adopt the Pain Interference data elements (Pain Effect on Sleep; Pain Interference with Therapy Activities; and Pain Interference with Day-to-Day Activities) as standardized patient assessment data for use in the IRF QRP.

4. Impairment Data

Hearing and vision impairments are conditions that, if unaddressed, affect activities of daily living, communication, physical functioning, rehabilitation outcomes, and overall quality of life. Sensory limitations can lead to confusion in new settings, increase isolation, contribute to mood disorders, and impede accurate assessment of other medical conditions. Failure to appropriately assess, accommodate, and treat these conditions increases the likelihood that patients and residents will require more intensive and prolonged treatment. Onset of these conditions can be gradual, so individualized assessment with accurate screening tools and follow-up evaluations are essential to determining which patients and residents need hearing- or vision-specific medical attention or assistive devices and accommodations, including auxiliary aids and/or services, and to ensure that person-directed care plans are developed to accommodate a patient's or resident's needs. Accurate diagnosis and management of hearing or vision impairment would likely improve rehabilitation outcomes and care transitions, including transition from institutional-based care to the community. Accurate assessment of hearing and vision impairment would be expected to lead to appropriate treatment, accommodations, including the provision of auxiliary aids and services during the stay, and ensure that patients and residents continue to have their vision and hearing needs met when they leave the facility.

In alignment with our Meaningful Measures Initiative, we expect accurate and individualized assessment, treatment, and accommodation of hearing and vision impairments of patients and residents in PAC to make care safer by reducing harm caused in the delivery of care; promote effective prevention and treatment of chronic disease; strengthen person and family engagement as partners in their care; and promote effective communication and coordination of care. For example, standardized assessment of hearing and vision impairments used in PAC will support ensuring patient safety (for example, risk of falls), identifying accommodations needed during the stay, and appropriate support needs at the time of discharge or transfer. Standardized assessment of these data elements will: Enable or support clinical decision-making and early clinical intervention; person-centered, high quality care (for example, facilitating better care continuity and coordination); better data exchange and interoperability between settings; and longitudinal outcome analysis. Therefore, reliable data elements assessing hearing and vision impairments are needed to initiate a management program that can optimize a patient's or resident's prognosis and reduce the possibility of adverse events.

Comments on the category of impairments were also submitted by

stakeholders during the FY 2018 IRF PPS proposed rule (82 FR 20737 through 20739) public comment period. A commenter stated hearing and vision assessments should be administered at the beginning of the assessment process to provide evidence about any sensory deficits that may affect the patient's ability to participate in the assessment and to allow the assessor to offer an assistive device.

We are inviting comment on our proposals to collect as standardized patient assessment data the following data with respect to impairments.

- Hearing

We are proposing that the Hearing data element meets the definition of standardized patient assessment data with respect to impairments under section 1899B(b)(1)(B)(v) of the Act.

As described in the FY 2018 IRF PPS proposed rule (82 FR 20737 through 20738), accurate assessment of hearing impairment is important in the PAC setting for care planning and resource use. Hearing impairment has been associated with lower quality of life, including poorer physical, mental, social functioning, and emotional health.[130] [131] Treatment and accommodation of hearing impairment led to improved health outcomes including, but not limited to, quality of life.[132] For example, hearing loss in elderly individuals has been associated with depression and cognitive impairment,[133] [134] [135] higher rates of incident cognitive impairment and cognitive decline,[136] and less time in occupational therapy.[137] Accurate assessment of hearing impairment is important in the PAC setting for care planning and defining resource use.

The proposed data element consists of the single Hearing data element. This data consists of one question that assesses level of hearing impairment. This data element is currently in use in the MDS in SNFs. For more information on the Hearing data element, we refer readers to the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Hearing data element was first proposed as a standardized patient assessment data element in the FY 2018 IRF PPS proposed rule (82 FR 20737 through 20738). In that proposed rule, we stated that the proposal was informed by input we received on the PAC PRD form of the data element (''Ability to Hear'') through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 recommended that hearing, vision, and communication assessments be administered at the beginning of patient assessment process. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 IRF PPS proposed rule, we received public comments in support of adopting the Hearing data element for standardized cross-setting use, noting that it would help address the needs of patient and residents with disabilities and that failing to identify impairments during the initial assessment can result in inaccurate diagnoses of impaired language or cognition and can invalidate other information obtained from patient assessment.

Subsequent to receiving comments on the FY 2018 IRF PPS rule, the Hearing data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Hearing data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Hearing data element in the National Beta Test can be found in the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on January 5 and 6, 2017 for the purpose of soliciting input on all the SPADEs, including the Hearing data element. The TEP affirmed the importance of standardized assessment of hearing impairment in PAC patients and residents. A summary of the January 5 and 6, 2017 TEP meeting titled ''SPADE Technical Expert Panel Summary (Second Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Additionally, a commenter expressed support for the Hearing data element and suggested administration at the beginning of the patient assessment to maximize utility. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Due to the relatively stable nature of hearing impairment, it is unlikely that a

[130] Dalton DS, Cruickshanks KJ, Klein BE, Klein R, Wiley TL, Nondahl DM. The impact of hearing loss on quality of life in older adults. *Gerontologist.* 2003;43(5):661–668.

[131] Hawkins K, Bottone FG, Jr., Ozminkowski RJ, et al. The prevalence of hearing impairment and its burden on the quality of life among adults with Medicare Supplement Insurance. *Qual Life Res.* 2012;21(7):1135–1147.

[132] Horn KL, McMahon NB, McMahon DC, Lewis JS, Barker M, Gherini S. Functional use of the Nucleus 22-channel cochlear implant in the elderly. *The Laryngoscope.* 1991;101(3):284–288.

[133] Sprinzl GM, Riechelmann H. Current trends in treating hearing loss in elderly people: a review of the technology and treatment options—a mini-review. *Gerontology.* 2010;56(3):351–358.

[134] Lin FR, Thorpe R, Gordon-Salant S, Ferrucci L. Hearing Loss Prevalence and Risk Factors Among Older Adults in the United States. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences.* 2011;66A(5):582–590.

[135] Hawkins K, Bottone FG, Jr., Ozminkowski RJ, et al. The prevalence of hearing impairment and its burden on the quality of life among adults with Medicare Supplement Insurance. *Qual Life Res.* 2012;21(7):1135–1147.

[136] Lin FR, Metter EJ, O'Brien RJ, Resnick SM, Zonderman AB, Ferrucci L. Hearing Loss and Incident Dementia. *Arch Neurol.* 2011;68(2):214–220.

[137] Cimarolli VR, Jung S. Intensity of Occupational Therapy Utilization in Nursing Home Residents: The Role of Sensory Impairments. *J Am Med Dir Assoc.* 2016;17(10):939–942.

patient's score on this assessment would change between the start and end of the IRF stay. Therefore, we are proposing that IRFs that submit the Hearing data element with respect to admission will be considered to have submitted with respect to discharge as well.

Taking together the importance of assessing for hearing, stakeholder input, and strong test results, we are proposing that the Hearing data element meets the definition of standardized patient assessment data with respect to impairments under section 1899B(b)(1)(B)(v) of the Act and to adopt the Hearing data element as standardized patient assessment data for use in the IRF QRP.

• Vision

We are proposing that the Vision data element meets the definition of standardized patient assessment data with respect to impairments under section 1899B(b)(1)(B)(v) of the Act.

As described in the FY 2018 IRF PPS proposed rule (82 FR 20738 through 20739), evaluation of an individual's ability to see is important for assessing for risks such as falls and provides opportunities for improvement through treatment and the provision of accommodations, including auxiliary aids and services, which can safeguard patients and residents and improve their overall quality of life. Further, vision impairment is often a treatable risk factor associated with adverse events and poor quality of life. For example, individuals with visual impairment are more likely to experience falls and hip fracture, have less mobility, and report depressive symptoms.[138] [139] [140] [141] [142] [143] [144] Individualized initial screening can lead to life-improving interventions such as accommodations, including the provision of auxiliary aids and services, during the stay and/or treatments that can improve vision and prevent or slow further vision loss. In addition, vision impairment is often a treatable risk factor associated with adverse events which can be prevented and accommodated during the stay. Accurate assessment of vision impairment is important in the IRF setting for care planning and defining resource use.

The proposed data element consists of the single Vision data element (Ability To See in Adequate Light) that consists of one question with five response categories. The Vision data element that we are proposing for standardization was tested as part of the development of the MDS and is currently in use in that assessment in SNFs. Similar data elements, but with different wording and fewer response option categories, are in use in the OASIS. For more information on the Vision data element, we refer readers to the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Vision data element was first proposed as a standardized patient assessment data element in the FY 2018 IRF PPS proposed rule (82 FR 20738 through 20739).

In that proposed rule, we stated that the proposal was informed by input we received on the Ability to See in Adequate Light data element (version tested in the PAC PRD with three response categories) through a call for input published on the CMS Measures Management System Blueprint website. Although the data element in public comment differed from the proposed data element, input submitted from August 12 to September 12, 2016 supported assessing vision in PAC settings and the useful information a vision data element would provide. We also stated that commenters had noted that the Ability to See item would provide important information that would facilitate care coordination and care planning, and consequently improve the quality of care. Other commenters suggested it would be helpful as an indicator of resource use and noted that the item would provide useful information about the abilities of patients and residents to care for themselves. Additional commenters noted that the item could feasibly be implemented across PAC providers and that its kappa scores from the PAC PRD support its validity. Some commenters noted a preference for MDS version of the Vision data element in SNFs over the form put forward in public comment, citing the widespread use of this data element. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 IRF PPS proposed rule, we received a comment supporting having a standardized patient assessment data element for vision across PAC settings, but it stated the proposed data element captures only basic information for risk adjustment, and more detailed information would need to be collected to use it as an outcome measure.

Subsequent to receiving comments on the FY 2018 IRF PPS rule, the Vision data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Vision data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Vision data element in the National Beta Test can be found in the document titled ''Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on January 5 and 6, 2017 for the purpose of soliciting input on all the SPADEs including the Vision data element. The TEP affirmed the importance of standardized assessment of vision impairment in PAC patients and residents. A summary of the January 5 and 6, 2017 TEP meeting titled ''SPADE Technical Expert Panel Summary (Second Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

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[138] Colon-Emeric CS, Biggs DP, Schenck AP, Lyles KW. Risk factors for hip fracture in skilled nursing facilities: Who should be evaluated? *Osteoporos Int.* 2003;14(6):484–489.

[139] Freeman EE, Munoz B, Rubin G, West SK. Visual field loss increases the risk of falls in older adults: The Salisbury eye evaluation. *Invest Ophthalmol Vis Sci.* 2007;48(10):4445–4450.

[140] Keepnews D, Capitman JA, Rosati RJ. Measuring patient-level clinical outcomes of home health care. *J Nurs Scholarsh.* 2004;36(1):79–85.

[141] Nguyen HT, Black SA, Ray LA, Espino DV, Markides KS. Predictors of decline in MMSE scores among older Mexican Americans. *J Gerontol A Biol Sci Med Sci.* 2002;57(3):M181–185.

[142] Prager AJ, Liebmann JM, Cioffi GA, Blumberg DM. Self-reported Function, Health Resource Use, and Total Health Care Costs Among Medicare Beneficiaries With Glaucoma. *JAMA ophthalmology.* 2016;134(4):357–365.

[143] Rovner BW, Ganguli M. Depression and disability associated with impaired vision: The MoVies Project. *J Am Geriatr Soc.* 1998;46(5):617–619.

[144] Tinetti ME, Ginter SF. The nursing home life-space diameter. A measure of extent and frequency of mobility among nursing home residents. *J Am Geriatr Soc.* 1990;38(12):1311–1315.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Additionally, a commenter expressed support for the Vision data element and suggested administration at the beginning of the patient assessment to maximize utility. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Due to the relatively stable nature of vision impairment, it is unlikely that a patient's score on this assessment would change between the start and end of the IRF stay. Therefore, we are proposing that IRFs that submit the Vision data element with respect to admission will be considered to have submitted with respect to discharge as well.

Taking together the importance of assessing for vision, stakeholder input, and strong test results, we are proposing that the Vision data element meets the definition of standardized patient assessment data with respect to impairments under section 1899B(b)(1)(B)(v) of the Act and to adopt the Vision data element as standardized patient assessment data for use in the IRF QRP.

4. Proposed New Category: Social Determinants of Health

a. Proposed Social Determinants of Health Data Collection To Inform Measures and Other Purposes

Subparagraph (A) of section 2(d)(2) of the IMPACT Act requires CMS to assess appropriate adjustments to quality measures, resource measures and other measures, and to assess and implement appropriate adjustments to payment under Medicare, based on those measures, after taking into account studies conducted by ASPE on social risk factors (described below) and other information, and based on an individual's health status and other factors. Subparagraph (C) of section 2(d)(2) of the IMPACT Act further requires the Secretary to carry out periodic analyses, at least every three years, based on the factors referred to in subparagraph (A) so as to monitor changes in possible relationships. Subparagraph (B) of section 2(d)(2) of the IMPACT Act requires CMS to collect or otherwise obtain access to data necessary to carry out the requirement of the paragraph (both assessing adjustments described above in such subparagraph (A) and for periodic analyses in such subparagraph (C)). Accordingly we are proposing to use our authority under subparagraph (B) of section 2(d)(2) of the IMPACT Act to establish a new data source for information to meet the requirements of subparagraphs (A) and (C) of section 2(d)(2) of the IMPACT Act. In this rule, we are proposing to collect and access data about social determinants of health (SDOH) in order to perform CMS' responsibilities under subparagraphs (A) and (C) of section 2(d)(2) of the IMPACT Act, as explained in more detail below. Social determinants of health, also known as social risk factors, or health-related social needs, are the socioeconomic, cultural and environmental circumstances in which individuals live that impact their health. We are proposing to collect information on seven proposed SDOH SPADE data elements relating to race, ethnicity, preferred language, interpreter services, health literacy, transportation, and social isolation; a detailed discussion of each of the proposed SDOH data elements is found in section VII.G.5.b. of this proposed rule.

We are also proposing to use the assessment instrument for the IRF QRP, the IRF–PAI, described as a PAC assessment instrument under section 1899B(a)(2)(B) of the Act, to collect these data via an existing data collection mechanism. We believe this approach will provide CMS with access to data with respect to the requirements of section 2(d)(2) of the IMPACT Act, while minimizing the reporting burden on PAC health care providers by relying on a data reporting mechanism already used and an existing system to which PAC health care providers are already accustomed.

The IMPACT Act includes several requirements applicable to the Secretary, in addition to those imposing new data reporting obligations on certain PAC providers as discussed in VII.G.5.b. of this proposed rule. Subparagraphs (A) and (B) of sections 2(d)(1) of the IMPACT Act require the Secretary, acting through the Office of the Assistant Secretary for Planning and Evaluation (ASPE), to conduct two studies that examine the effect of risk factors, including individuals' socioeconomic status, on quality, resource use and other measures under the Medicare program. The first ASPE study was completed in December 2016 and is discussed below, and the second study is to be completed in the fall of 2019. We recognize that ASPE, in its studies, is considering a broader range of social risk factors than the SDOH data elements in this proposal, and address both PAC and non-PAC settings. We acknowledge that other data elements may be useful to understand, and that some of those elements may be of particular interest in non-PAC settings. For example, for beneficiaries receiving care in the community, as opposed to an in-patient facility, housing stability and food insecurity may be more relevant. We will continue to take into account the findings from both of ASPE's reports in future policy making.

One of the ASPE's first actions under the IMPACT Act was to commission the National Academies of Sciences, Engineering, and Medicine (NASEM) to define and conceptualize socioeconomic status for the purposes of ASPE's two studies under section 2(d)(1) of the IMPACT Act. The NASEM convened a panel of experts in the field and conducted an extensive literature review. Based on the information collected, the 2016 NASEM panel report titled, ''Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors'', concluded that the best way to assess how social processes and social relationships influence key health-related outcomes in Medicare beneficiaries is through a framework of social risk factors instead of socioeconomic status. Social risk factors discussed in the NASEM report include socioeconomic position, race, ethnicity, gender, social context, and community context. These factors are discussed at length in chapter 2 of the NASEM report, titled ''Social Risk Factors.'' [145] Consequently NASEM framed the results of its report in terms of ''social risk factors'' rather than ''socioeconomic status'' or ''sociodemographic status.'' The full text of the ''Social Risk Factors'' NASEM report is available for reading on the website at *https://www.nap.edu/read/21858/chapter/1.*

[145] National Academies of Sciences, Engineering, and Medicine. 2016. *Accounting for social risk factors in Medicare payment: Identifying social risk factors.* Chapter 2. Washington, DC: The National Academies Press.

Each of the data elements we are proposing to collect and access under our authority under section 2(d)(2)(B) of the IMPACT Act is identified in the 2016 NASEM report as a social risk factor that has been shown to impact care use, cost and outcomes for Medicare beneficiaries. CMS uses the term social determinants of health (SDOH) to denote social risk factors, which is consistent with the objectives of Healthy People 2020.[146]

ASPE issued its first Report to Congress, titled ''Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs,'' under section 2(d)(1)(A) of the IMPACT Act on December 21, 2016.[147] Using NASEM's social risk factors framework, ASPE focused on the following social risk factors, in addition to disability: (1) Dual enrollment in Medicare and Medicaid as a marker for low income, (2) residence in a low-income area, (3) Black race, (4) Hispanic ethnicity; and (5) residence in a rural area. ASPE acknowledged that the social risk factors examined in its report were limited due to data availability. The report also noted that the data necessary to meaningfully attempt to reduce disparities and identify and reward improved outcomes for beneficiaries with social risk factors have not been collected consistently on a national level in post-acute care settings. Where these data have been collected, the collection frequently involves lengthy questionnaires. More information on the Report to Congress on Social Risk Factors and Performance under Medicare's Value-Based Purchasing Programs, including the full report, is available on the website at *https://aspe.hhs.gov/social-risk-factors-and-medicares-value-based-purchasing-programs-reports.*

Section 2(d)(2) of the IMPACT Act relates to CMS activities and imposes several responsibilities on the Secretary relating to quality, resource use, and other measures under Medicare. As mentioned previously, under subparagraph (A) of section 2(d)(2) of the IMPACT Act, the Secretary is required, on an ongoing basis, taking into account the ASPE studies and other information, and based on an individual's health status and other factors, to assess appropriate adjustments to quality, resource use, and other measures, and to assess and implement appropriate adjustments to Medicare payments based on those measures. Section 2(d)(2)(A)(i) of the IMPACT Act applies to measures adopted under subsections (c) and (d) of section 1899B of the Act and to other measures under Medicare. However, CMS' ability to perform these analyses, and assess and make appropriate adjustments is hindered by limits of existing data collections on SDOH data elements for Medicare beneficiaries. In its first study in 2016, in discussing the second study, ASPE noted that information relating to many of the specific factors listed in the IMPACT Act, such as health literacy, limited English proficiency, and Medicare beneficiary activation, are not available in Medicare data.

Subparagraph 2(d)(2)(A) of the IMPACT Act specifically requires the Secretary to take the studies and considerations from ASPE's reports to Congress, as well as other information as appropriate, into account in assessing and implementing adjustments to measures and related payments based on measures in Medicare. The results of the ASPE's first study demonstrated that Medicare beneficiaries with social risk factors tended to have worse outcomes on many quality measures, and providers who treated a disproportionate share of beneficiaries with social risk factors tended to have worse performance on quality measures. As a result of these findings, ASPE suggested a three-pronged strategy to guide the development of value-based payment programs under which all Medicare beneficiaries receive the highest quality healthcare services possible. The three components of this strategy are to: (1) Measure and report quality of care for beneficiaries with social risk factors; (2) set high, fair quality standards for care provided to all beneficiaries; and (3) reward and support better outcomes for beneficiaries with social risk factors. In discussing how measuring and reporting quality for beneficiaries with social risk factors can be applied to Medicare quality payment programs, the report offered nine considerations across the three-pronged strategy, including enhancing data collection and developing statistical techniques to allow measurement and reporting of performance for beneficiaries with social risk factors on key quality and resource use measures.

Congress, in section 2(d)(2)(B) of the IMPACT Act, required the Secretary to collect or otherwise obtain access to the data necessary to carry out the provisions of paragraph (2) of section 2(d) of the IMPACT Act through both new and existing data sources. Taking into consideration NASEM's conceptual framework for social risk factors discussed above, ASPE's study, and considerations under section 2(d)(1)(A) of the IMPACT Act, as well as the current data constraints of ASPE's first study and its suggested considerations, we are proposing to collect and access data about SDOH under section 2(d)(2) of the IMPACT Act. Our collection and use of the SDOH data described in section VII.G.5.b.(1) of this proposed rule, under section 2(d)(2) of the IMPACT Act would be independent of our proposal below (in section VII.G.5.b.(2) of this proposed rule) and our authority to require submission of that data for use as SPADE under section 1899B(a)(1)(B) of the Act.

Accessing standardized data relating to the SDOH data elements on a national level is necessary to permit CMS to conduct periodic analyses, to assess appropriate adjustments to quality measures, resource use measures, and other measures, and to assess and implement appropriate adjustments to Medicare payments based on those measures. We agree with ASPE's observations, in the value-based purchasing context, that the ability to measure and track quality, outcomes, and costs for beneficiaries with social risk factors over time is critical as policymakers and providers seek to reduce disparities and improve care for these groups. Collecting the data as proposed will provide the basis for our periodic analyses of the relationship between an individual's health status and other factors and quality, resource use, and other measures, as required by section 2(d)(2) of the IMPACT Act, and to assess appropriate adjustments. These data will also permit us to develop the statistical tools necessary to maximize the value of Medicare data, reduce costs and improve the quality of care for all beneficiaries. Collecting and accessing SDOH data in this way also supports the three-part strategy put forth in the first ASPE report, specifically ASPE's consideration to enhance data collection and develop statistical techniques to allow measurement and reporting of performance for beneficiaries with social risk factors on key quality and resource use measures.

For the reasons discussed above, we are proposing under section 2(d)(2) of the IMPACT Act, to collect the data on the following SDOH: (1) Race, as described in section VII.G.5.b.(1) of this proposed rule; (2) Ethnicity, as described in section VII.G5.b.(1) of this

[146] Social Determinants of Health. Healthy People 2020. *https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health.* (February 2019).

[147] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. 2016. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Payment Programs. Washington, DC.

proposed rule; (3) Preferred Language, as described in section VII.G.5.b.(2) of this proposed rule; (4) Interpreter Services, as described in section VII.G.5.b.(2) of this proposed rule; (5) Health Literacy, as described in section VII.G.5.b.(3) of this proposed rule; (6) Transportation, as described in section VII.G.5.b.(4) of this proposed rule; and (7) Social Isolation, as described in section VII.G.5.b.(5) of this proposed rule. These data elements are discussed in more detail below in section VII.G.5.b of this proposed rule. We welcome comment on this proposal.

b. Standardized Patient Assessment Data

Section 1899B(b)(1)(B)(vi) of the Act authorizes the Secretary to collect SPADEs with respect to other categories deemed necessary and appropriate. Below we are proposing to create a Social Determinants of Health SPADE category under section 1899B(b)(1)(B)(vi) of the Act. In addition to collecting SDOH data for the purposes outlined above under section 2(d)(2)(B), we are also proposing to collect as SPADE these same data elements (race, ethnicity, preferred language, interpreter services, health literacy, transportation, and social isolation) under section 1899B(b)(1)(B)(vi) of the Act. We believe that this proposed new category of Social Determinants of Health will inform provider understanding of individual patient risk factors and treatment preferences, facilitate coordinated care and care planning, and improve patient outcomes. We are proposing to deem this category necessary and appropriate, for the purposes of SPADE, because using common standards and definitions for PAC data elements is important in ensuring interoperable exchange of longitudinal information between PAC providers and other providers to facilitate coordinated care, continuity in care planning, and the discharge planning process from post-acute care settings.

All of the Social Determinants of Health data elements we are proposing under section 1899B(b)(1)(B)(vi) of the Act have the capacity to take into account treatment preferences and care goals of patients, and to inform our understanding of patient complexity and risk factors that may affect care outcomes. While acknowledging the existence and importance of additional social determinants of health, we are proposing to assess some of the factors relevant for patients receiving post-acute care that PAC settings are in a position to impact through the provision of services and supports, such as connecting patients with identified needs with transportation programs, certified interpreters, or social support programs.

As previously mentioned, and described in more detail below, we are proposing to adopt the following seven data elements as SPADE under the proposed Social Determinants of Health category: Race, ethnicity, preferred language, interpreter services, health literacy, transportation, and social isolation. To select these data elements, we reviewed the research literature, a number of validated assessment tools and frameworks for addressing SDOH currently in use (for example, Health Leads, NASEM, Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE), and ICD–10), and we engaged in discussions with stakeholders. We also prioritized balancing the reporting burden for PAC providers with our policy objective to collect SPADEs that will inform care planning and coordination and quality improvement across care settings. Furthermore, incorporating SDOH data elements into care planning has the potential to reduce readmissions and help beneficiaries achieve and maintain their health goals.

We also considered feedback received during a listening session that we held on December 13, 2018. The purpose of the listening session was to solicit feedback from health systems, research organizations, advocacy organizations and state agencies and other members of the public on collecting patient-level data on SDOH across care settings, including consideration of race, ethnicity, spoken language, health literacy, social isolation, transportation, sex, gender identity, and sexual orientation. We also gave participants an option to submit written comments. A full summary of the listening session, titled ''Listening Session on Social Determinants of Health Data Elements: Summary of Findings,'' includes a list of participating stakeholders and their affiliations, and is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

(1) Race and Ethnicity

The persistence of racial and ethnic disparities in health and health care is widely documented including in PAC settings.[148] [149] [150] [151] [152] Despite the trend toward overall improvements in quality of care and health outcomes, the Agency for Healthcare Research and Quality, in its National Healthcare Quality and Disparities Reports, consistently indicates that racial and ethnic disparities persist, even after controlling for factors such as income, geography, and insurance.[153] For example, racial and ethnic minorities tend to have higher rates of infant mortality, diabetes and other chronic conditions, and visits to the emergency department, and lower rates of having a usual source of care and receiving immunizations such as the flu vaccine.[154] Studies have also shown that African Americans are significantly more likely than white Americans to die prematurely from heart disease and stroke.[155] However, our ability to identify and address racial and ethnic health disparities has historically been constrained by data limitations, particularly for smaller populations groups such as Asians, American Indians and Alaska Natives, and Native Hawaiians and other Pacific Islanders.[156]

The ability to improve understanding of and address racial and ethnic disparities in PAC outcomes requires

[148] 2017 National Healthcare Quality and Disparities Report. Rockville, MD: Agency for Healthcare Research and Quality; September 2018. AHRQ Pub. No. 18–0033–EF.

[149] Fiscella, K. and Sanders, M.R. Racial and Ethnic Disparities in the Quality of Health Care. (2016). Annual Review of Public Health. 37:375–394.

[150] 2018 National Impact Assessment of the Centers for Medicare & Medicaid Services (CMS) Quality Measures Reports. Baltimore, MD: U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services; February 28, 2018.

[151] Smedley, B.D., Stith, A.Y., & Nelson, A.R. (2003). Unequal treatment: confronting racial and ethnic disparities in health care. Washington, DC, National Academy Press.

[152] Chase, J., Huang, L. and Russell, D. (2017). Racial/ethnic disparities in disability outcomes among post-acute home care patients. J of Aging and Health. 30(9):1406–1426.

[153] National Healthcare Quality and Disparities Reports. (December 2018). Agency for Healthcare Research and Quality, Rockville, MD. *http://www.ahrq.gov/research/findings/nhqrdr/index.html.*

[154] National Center for Health Statistics. Health, United States, 2017: With special feature on mortality. Hyattsville, Maryland. 2018.

[155] HHS. Heart disease and African Americans. 2016b. (October 24, 2016). *http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=19.*

[156] National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice; Committee on Community-Based Solutions to Promote Health Equity in the United States; Baciu A, Negussie Y, Geller A, et al., editors. Communities in Action: Pathways to Health Equity. Washington (DC): National Academies Press (US); 2017 Jan 11. 2, The State of Health Disparities in the United States. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK425844/.*

the availability of better data. There is currently a Race and Ethnicity data element, collected in the MDS, LCDS, IRF–PAI, and OASIS, that consists of a single question, which aligns with the 1997 Office of Management and Budget (OMB) minimum data standards for federal data collection efforts.[157] The 1997 OMB Standard lists five minimum categories of race: (1) American Indian or Alaska Native; (2) Asian; (3) Black or African American; (4) Native Hawaiian or Other Pacific Islander; (5) and White. The 1997 OMB Standard also lists two minimum categories of ethnicity: (1) Hispanic or Latino and (2) Not Hispanic or Latino. The 2011 HHS Data Standards requires a two-question format when self-identification is used to collect data on race and ethnicity. Large federal surveys such as the National Health Interview Survey, Behavioral Risk Factor Surveillance System, and the National Survey on Drug Use and Health, have implemented the 2011 HHS race and ethnicity data standards. CMS has similarly updated the Medicare Current Beneficiary Survey, Medicare Health Outcomes Survey, and the Health Insurance Marketplace Application for Health Coverage with the 2011 HHS data standards. More information about the HHS Race and Ethnicity Data Standards are available on the website at *https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=54.*

We are proposing to revise the current Race and Ethnicity data element for purposes of this proposal to conform to the 2011 HHS Data Standards for person-level data collection, while also meeting the 1997 OMB minimum data standards for race and ethnicity. Rather than one data element that assesses both race and ethnicity, we are proposing two separate data elements: One for Race and one for Ethnicity, that would conform with the 2011 HHS Data Standards and the 1997 OMB Standard. In accordance with the 2011 HHS Data Standards a two-question format would be used for the proposed race and ethnicity data elements.

The proposed Race data element asks, ''What is your race? We are proposing to include fourteen response options under the race data element: (1) White; (2) Black or African American; (3) American Indian or Alaska Native; (4) Asian Indian; (5) Chinese; (6) Filipino; (7) Japanese; (8) Korean; (9) Vietnamese; (10) Other Asian; (11) Native Hawaiian; (12) Guamanian or Chamorro; (13) Samoan; and, (14) Other Pacific Islander.

The proposed Ethnicity data element asks, ''Are you Hispanic, Latino/a, or Spanish origin?'' We are proposing to include five response options under the ethnicity data element: (1) Not of Hispanic, Latino/a, or Spanish origin; (2) Mexican, Mexican American, Chicano/a; (3) Puerto Rican; (4) Cuban; and, (5) Another Hispanic, Latino, or Spanish Origin.

We believe that the two proposed data elements for race and ethnicity conform to the 2011 HHS Data Standards for person-level data collection, while also meeting the 1997 OMB minimum data standards for race and ethnicity, because under those standards, more detailed information on population groups can be collected if those additional categories can be aggregated into the OMB minimum standard set of categories.

In addition, we received stakeholder feedback during the December 13, 2018 SDOH listening session on the importance of improving response options for race and ethnicity as a component of health care assessments and for monitoring disparities. Some stakeholders emphasized the importance of allowing for self-identification of race and ethnicity for more categories than are included in the 2011 HHS Standard to better reflect state and local diversity, while acknowledging the burden of coding an open-ended health care assessment question across different settings.

We believe that the proposed modified race and ethnicity data elements more accurately reflect the diversity of the U.S. population than the current race/ethnicity data element included in MDS, LCDS, IRF–PAI, and OASIS.[158] [159] [160] [161] We believe, and research consistently shows, that improving how race and ethnicity data are collected is an important first step in improving quality of care and health outcomes. Addressing disparities in access to care, quality of care, and health outcomes for Medicare beneficiaries begins with identifying and analyzing how SDOH, such as race and ethnicity, align with disparities in these areas.[162] Standardizing self-reported data collection for race and ethnicity allows for the equal comparison of data across multiple healthcare entities.[163] By collecting and analyzing these data, CMS and other healthcare entities will be able to identify challenges and monitor progress. The growing diversity of the US population and knowledge of racial and ethnic disparities within and across population groups supports the collection of more granular data beyond the 1997 OMB minimum standard for reporting categories. The 2011 HHS race and ethnicity data standard includes additional detail that may be used by PAC providers to target quality improvement efforts for racial and ethnic groups experiencing disparate outcomes. For more information on the Race and Ethnicity data elements, we refer readers to the document titled ''Proposed Specifications for IRF QRP Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In an effort to standardize the submission of race and ethnicity data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we are proposing to adopt the Race and Ethnicity data elements described above as SPADEs with respect to the proposed Social Determinants of Health category.

Specifically, we are proposing to replace the current Race/Ethnicity data element with the proposed Race and Ethnicity data elements on the IRF–PAI. We are also proposing that IRFs that submit the Race and Ethnicity data

[157] ''Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity (Notice of Decision)''. **Federal Register** 62:210 (October 30, 1997) pp. 58782–58790. Available from: *https://www.govinfo.gov/content/pkg/FR-1997-10-30/pdf/97-28653.pdf.*

[158] Penman-Aguilar, A., Talih, M., Huang, D., Moonesinghe, R., Bouye, K., Beckles, G. (2016). Measurement of Health Disparities, Health Inequities, and Social Determinants of Health to Support the Advancement of Health Equity. J Public Health Manag Pract. 22 Suppl 1: S33–42.

[159] Ramos, R., Davis, J.L., Ross, T., Grant, C.G., Green, B.L. (2012). Measuring health disparities and health inequities: do you have REGAL data? Qual Manag Health Care. 21(3):176–87.

[160] IOM (Institute of Medicine). 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

[161] ''Revision of Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity: Proposals From Federal Interagency Working Group (Notice and Request for Comments).'' **Federal Register** 82: 39 (March 1, 2017) p. 12242.

[162] National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice; Committee on Community-Based Solutions to Promote Health Equity in the United States; Baciu A, Negussie Y, Geller A, et al., editors. Communities in Action: Pathways to Health Equity. Washington (DC): National Academies Press (US); 2017 Jan 11. 2, The State of Health Disparities in the United States. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK425844/.*

[163] IOM (Institute of Medicine). 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

elements with respect to admission will be considered to have submitted with respect to discharge as well, because it is unlikely that the results of these assessment findings will change between the start and end of the IRF stay, making the information submitted with respect to a patient's admission the same with respect to a patient's discharge.

(2) Preferred Language and Interpreter Services

More than 64 million Americans speak a language other than English at home, and nearly 40 million of those individuals have limited English proficiency (LEP).[164] Individuals with LEP have been shown to receive worse care and have poorer health outcomes, including higher readmission rates.[165] [166] [167] Communication with individuals with LEP is an important component of high quality health care, which starts by understanding the population in need of language services. Unaddressed language barriers between a patient and provider care team negatively affects the ability to identify and address individual medical and non-medical care needs, to convey and understand clinical information, as well as discharge and follow up instructions, all of which are necessary for providing high quality care. Understanding the communication assistance needs of patients with LEP, including individuals who are Deaf or hard of hearing, is critical for ensuring good outcomes.

Presently, the preferred language of patients and residents and need for interpreter services are assessed in two PAC assessment tools. The LCDS and the MDS use the same two data elements to assess preferred language and whether a patient or resident needs or wants an interpreter to communicate with health care staff. The MDS initially implemented preferred language and interpreter services data elements to assess the needs of SNF residents and patients and inform care planning. For alignment purposes, the LCDS later adopted the same data elements for LTCHs. The 2009 NASEM (formerly Institute of Medicine) report on standardizing data for health care quality improvement emphasizes that language and communication needs should be assessed as a standard part of health care delivery and quality improvement strategies.[168]

In developing our proposal for a standardized language data element across PAC settings, we considered the current preferred language and interpreter services data elements that are in LCDS and MDS. We also considered the 2011 HHS Primary Language Data Standard and peer-reviewed research. The current preferred language data element in LCDS and MDS asks, ''What is your preferred language?'' Because the preferred language data element is open-ended, the patient or resident is able to identify their preferred language, including American Sign Language (ASL). Finally, we considered the recommendations from the 2009 NASEM (formerly Institute of Medicine) report, ''Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement.'' In it, the committee recommended that organizations evaluating a patient's language and communication needs for health care purposes, should collect data on the preferred spoken language and on an individual's assessment of his/her level of English proficiency.

A second language data element in LCDS and MDS asks, ''Do you want or need an interpreter to communicate with a doctor or health care staff?'' and includes yes or no response options. In contrast, the 2011 HHS Primary Language Data Standard recommends either a single question to assess how well someone speaks English or, if more granular information is needed, a two-part question to assess whether a language other than English is spoken at home and if so, identify that language. However, neither option allows for a direct assessment of a patient's or resident's preferred spoken or written language nor whether they want or need interpreter services for communication with a doctor or care team, both of which are an important part of assessing patient/resident needs and the care planning process. More information about the HHS Data Standard for Primary Language is available on the website at *https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=54.*

Research consistently recommends collecting information about an individual's preferred spoken language and evaluating those responses for purposes of determining language access needs in health care.[169] However, using ''preferred spoken language'' as the metric does not adequately account for people whose preferred language is ASL, which would necessitate adopting an additional data element to identify visual language. The need to improve the assessment of language preferences and communication needs across PAC settings should be balanced with the burden associated with data collection on the provider and patient. Therefore we are proposing to retain the Preferred Language and Interpreter Services data elements currently in use on the MDS and LCDS on the IRF–PAI.

In addition, we received feedback during the December 13, 2018 listening session on the importance of evaluating and acting on language preferences early to facilitate communication and allowing for patient self-identification of preferred language. Although the discussion about language was focused on preferred spoken language, there was general consensus among participants that stated language preferences may or may not accurately indicate the need for interpreter services, which supports collecting and evaluating data to determine language preference, as well as the need for interpreter services. An alternate suggestion was made to inquire about preferred language specifically for discussing health or health care needs. While this suggestion does allow for ASL as a response option, we do not have data indicating how useful this question might be for assessing the desired information and thus we are not including this question in our proposal.

Improving how preferred language and need for interpreter services data are collected is an important component of improving quality by helping PAC providers and other providers understand patient needs and develop plans to address them. For more information on the Preferred Language and Interpreter Services data elements, we refer readers to the document titled ''Proposed Specifications for IRF QRP

[164] U.S. Census Bureau, 2013–2017 American Community Survey 5-Year Estimates.

[165] Karliner LS, Kim SE, Meltzer DO, Auerbach AD. Influence of language barriers on outcomes of hospital care for general medicine inpatients. *J Hosp Med*. 2010 May–Jun;5(5):276–82. doi: 10.1002/jhm.658.

[166] Kim EJ, Kim T, Paasche-Orlow MK, et al. Disparities in Hypertension Associated with Limited English Proficiency. *J Gen Intern Med*. 2017 Jun;32(6):632–639. doi: 10.1007/s11606–017–3999–9.

[167] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for social risk factors in Medicare payment: Identifying social risk factors. Washington, DC: The National Academies Press.

[168] IOM (Institute of Medicine). 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

[169] Guerino, P. and James, C. Race, Ethnicity, and Language Preference in the Health Insurance Marketplaces 2017 Open Enrollment Period. Centers for Medicare & Medicaid Services, Office of Minority Health. Data Highlight: Volume 7—April 2017. Available at *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Highlight-Race-Ethnicity-and-Language-Preference-Marketplace.pdf.*

Measures and Standardized Patient Assessment Data Elements,'' available on the website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In an effort to standardize the submission of language data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we are proposing to adopt the Preferred Language and Interpreter Services data elements currently used on the MDS and LCDS, and described above, as SPADEs with respect to the Social Determinants of Health category. We are proposing to add the current Preferred Language and Interpreter Services data elements from the MDS and LCDS to the IRF–PAI.

(3) Health Literacy

The Department of Health and Human Services defines health literacy as ''the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.'' [170] Similar to language barriers, low health literacy can interfere with communication between the provider and patient and the ability for patients or their caregivers to understand and follow treatment plans, including medication management. Poor health literacy is linked to lower levels of knowledge about health, worse health outcomes, and the receipt of fewer preventive services, but higher medical costs and rates of emergency department use.[171]

Health literacy is prioritized by Healthy People 2020 as an SDOH.[172] Healthy People 2020 is a long-term, evidence-based effort led by the Department of Health and Human Services that aims to identify nationwide health improvement priorities and improve the health of all Americans. Although not designated as a social risk factor in NASEM's 2016 report on accounting for social risk factors in Medicare payment, the NASEM noted that health literacy is impacted by other social risk factors and can affect access to care as well as quality of care and health outcomes.[173] Assessing for health literacy across PAC settings would facilitate better care coordination and discharge planning. A significant challenge in assessing the health literacy of individuals is avoiding excessive burden on patients and health care providers. The majority of existing, validated health literacy assessment tools use multiple screening items, generally with no fewer than four, which would make them burdensome if adopted in MDS, LCDS, IRF–PAI, and OASIS. The Single Item Literacy Screener (SILS) question asks, ''How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?'' Possible response options are: (1) Never; (2) Rarely; (3) Sometimes; (4) Often; and (5) Always. The SILS question, which assesses reading ability, (a primary component of health literacy), tested reasonably well against the 36 item Short Test of Functional Health Literacy in Adults (S–TOFHLA), a thoroughly vetted and widely adopted health literacy test, in assessing the likelihood of low health literacy in an adult sample from primary care practices participating in the Vermont Diabetes Information System.[174] [175] The S–TOFHLA is a more complex assessment instrument developed using actual hospital related materials such as prescription bottle labels and appointment slips, and often considered the instrument of choice for a detailed evaluation of health literacy.[176] Furthermore, the S–TOFHLA instrument is proprietary and subject to purchase for individual entities or users.[177] Given that SILS is publicly available, shorter and easier to administer than the full health literacy screen, and research found that a positive result on the SILS demonstrates an increased likelihood that an individual has low health literacy, we are proposing to use the single-item reading question for health literacy in the standardized data collection across PAC settings. We believe that use of this data element will provide sufficient information about the health literacy of IRF patients to facilitate appropriate care planning, care coordination, and interoperable data exchange across PAC settings.

In addition, we received feedback during the December 13, 2018 SDOH listening session on the importance of recognizing health literacy as more than understanding written materials and filling out forms, as it is also important to evaluate whether patients understand their conditions. However, the NASEM recently recommended that health care providers implement health literacy universal precautions instead of taking steps to ensure care is provided at an appropriate literacy level based on individualized assessment of health literacy.[178] Given the dearth of Medicare data on health literacy and gaps in addressing health literacy in practice, we recommend the addition of a health literacy data element.

The proposed Health Literacy data element is consistent with considerations raised by NASEM and other stakeholders and research on health literacy, which demonstrates an impact on health care use, cost, and outcomes.[179] For more information on the proposed Health Literacy data element, we refer readers to the document titled ''Proposed Specifications for IRF QRP Measures and Standardized Patient Assessment Data Elements,'' available on the website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-*

[170] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. National action plan to improve health literacy. Washington (DC): Author; 2010.

[171] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for social risk factors in Medicare payment: Identifying social risk factors. Washington, DC: The National Academies Press.

[172] Social Determinants of Health. Healthy People 2020. *https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health.* (February 2019).

[173] U.S. Department of Health & Human Services, Office of the Assistant Secretary for Planning and Evaluation. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.* Washington, DC: 2016.

[174] Morris, N.S., MacLean, C.D., Chew, L.D., & Littenberg, B. (2006). The Single Item Literacy Screener: evaluation of a brief instrument to identify limited reading ability. BMC family practice, 7, 21. doi:10.1186/1471–2296–7–21.

[175] Brice, J.H., Foster, M.B., Principe, S., Moss, C., Shofer, F.S., Falk, R.J., Ferris, M.E., DeWalt, D.A. (2013). Single-item or two-item literacy screener to predict the S–TOFHLA among adult hemodialysis patients. Patient Educ Couns. 94(1):71–5.

[176] University of Miami, School of Nursing & Health Studies, Center of Excellence for Health Disparities Research. Test of Functional Health Literacy in Adults (TOFHLA). (March 2019). Available from: *https://elcentro.sonhs.miami.edu/research/measures-library/tofhla/index.html.*

[177] Nurss, J.R., Parker, R.M., Williams, M.V., &Baker, D.W. David W. (2001). TOFHLA. Peppercorn Books & Press. Available from: *http://www.peppercornbooks.com/catalog/information.php?info_id=5.*

[178] Hudson, S., Rikard, R.V., Staiculescu, I. & Edison, K. (2017). Improving health and the bottom line: The case for health literacy. In Building the case for health literacy: Proceedings of a workshop. Washington, DC: The National Academies Press.

[179] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: The National Academies Press.

2014/IMPACT-Act-Downloads-and-Videos.html.

In an effort to standardize the submission of health literacy data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we are proposing to adopt SILS question described above for the Health Literacy data element as SPADE under the Social Determinants of Health Category. We are proposing to add the Health Literacy data element to the IRF–PAI.

(4) Transportation

Transportation barriers commonly affect access to necessary health care, causing missed appointments, delayed care, and unfilled prescriptions, all of which can have a negative impact on health outcomes.[180] Access to transportation for ongoing health care and medication access needs, particularly for those with chronic diseases, is essential to successful chronic disease management. Adopting a data element to collect and analyze information regarding transportation needs across PAC settings would facilitate the connection to programs that can address identified needs. We are therefore proposing to adopt as SPADE a single transportation data element that is from the Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE) assessment tool and currently part of the Accountable Health Communities (AHC) Screening Tool.

The proposed Transportation data element from the PRAPARE tool asks, ''Has lack of transportation kept you from medical appointments, meetings, work, or from getting things needed for daily living?'' The three response options are: (1) Yes, it has kept me from medical appointments or from getting my medications; (2) Yes, it has kept me from non-medical meetings, appointments, work, or from getting things that I need; and (3) No. The patient would be given the option to select all responses that apply. We are proposing to use the transportation data element from the PRAPARE Tool, with permission from National Association of Community Health Centers (NACHC), after considering research on the importance of addressing transportation needs as a critical SDOH.[181]

The proposed data element is responsive to research on the importance of addressing transportation needs as a critical SDOH and would adopt the Transportation item from the PRAPARE tool.[182] This data element comes from the national PRAPARE social determinants of health assessment protocol, developed and owned by NACHC, in partnership with the Association of Asian Pacific Community Health Organization, the Oregon Primary Care Association, and the Institute for Alternative Futures. Similarly the Transportation data element used in the AHC Screening Tool was adapted from the PRAPARE tool. The AHC screening tool was implemented by the Center for Medicare and Medicaid Innovation's AHC Model and developed by a panel of interdisciplinary experts that looked at evidence-based ways to measure SDOH, including transportation. While the transportation access data element in the AHC screening tool serves the same purposes as our proposed SPADE collection about transportation barriers, the AHC tool has binary yes or no response options that do not differentiate between challenges for medical versus non-medical appointments and activities. We believe that this is an important nuance for informing PAC discharge planning to a community setting, as transportation needs for non-medical activities may differ than for medical activities and should be taken into account.[183] We believe that use of this data element will provide sufficient information about transportation barriers to medical and non-medical care for IRF patients to facilitate appropriate discharge planning and care coordination across PAC settings. As such, we are proposing to adopt the Transportation data element from PRAPARE. More information about development of the PRAPARE tool is available on the website at *https://protect2.fireeye.com/url?k=7cb6eb44-20e2f238-7cb6da7b-0cc47adc5fa2-1751cb986c8c2f8c&u=http://www.nachc.org/prapare*.

In addition, we received stakeholder feedback during the December 13, 2018 SDOH listening session on the impact of transportation barriers on unmet care needs. While recognizing that there is no consensus in the field about whether providers should have responsibility for resolving patient transportation needs, discussion focused on the importance of assessing transportation barriers to facilitate connections with available community resources.

Adding a Transportation data element to the collection of SPADE would be an important step to identifying and addressing SDOH that impact health outcomes and patient experience for Medicare beneficiaries. For more information on the Transportation data element, we refer readers to the document titled ''Proposed Specifications for IRF QRP Measures and Standardized Patient Assessment Data Elements,'' available on the website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In an effort to standardize the submission of transportation data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we are proposing to adopt the Transportation data element described above as SPADE with respect to the proposed Social Determinants of Health category. If finalized as proposed, we would add the Transportation data element to the IRF–PAI.

(5) Social Isolation

Distinct from loneliness, social isolation refers to an actual or perceived lack of contact with other people, such as living alone or residing in a remote area.[184] [185] Social isolation tends to increase with age, is a risk factor for physical and mental illness, and a predictor of mortality.[186] [187] [188] Post-

[180] Syed, S.T., Gerber, B.S., and Sharp, L.K. (2013). Traveling Towards Disease: Transportation Barriers to Health Care Access. *J Community Health*. 38(5): 976–993.

[181] Health Research & Educational Trust. (2017, November). Social determinants of health series: Transportation and the role of hospitals. Chicago, IL. Available at *www.aha.org/transportation.www.aha.org/transportation*.

[182] Health Research & Educational Trust. (2017, November). Social determinants of health series: Transportation and the role of hospitals. Chicago, IL. Available at *www.aha.org/transportation*.

[183] Northwestern University. (2017). PROMIS Item Bank v. 1.0—Emotional Distress—Anger—Short Form 1.

[184] Tomaka, J., Thompson, S., and Palacios, R. (2006). The Relation of Social Isolation, Loneliness, and Social Support to Disease Outcomes Among the Elderly. J of Aging and Health. 18(3): 359–384.

[185] Social Connectedness and Engagement Technology for Long-Term and Post-Acute Care: A Primer and Provider Selection Guide. (2019). Leading Age. Available at *https://www.leadingage.org/white-papers/social-connectedness-and-engagement-technology-long-term-and-post-acute-care-primer-and#1.1*.

[186] Landeiro, F., Barrows, P., Nuttall Musson, E., Gray, A.M., and Leal, J. (2017). Reducing Social Loneliness in Older People: A Systematic Review Protocol. BMJ Open. 7(5): e013778.

[187] Ong, A.D., Uchino, B.N., and Wethington, E. (2016). Loneliness and Health in Older Adults: A Mini-Review and Synthesis. *Gerontology*. 62:443–449.

[188] Leigh-Hunt, N., Bagguley, D., Bash, K., Turner, V., Turnbull, S., Valtorta, N., and Caan, W. (2017). An overview of systematic reviews on the public health consequences of social isolation and loneliness. *Public Health*. 152:157–171.

acute care providers are well-suited to design and implement programs to increase social engagement of patients, while also taking into account individual needs and preferences. Adopting a data element to collect and analyze information about social isolation in IRFs and across PAC settings would facilitate the identification of patients who are socially isolated and who may benefit from engagement efforts.

We are proposing to adopt as SPADE a single social isolation data element that is currently part of the AHC Screening Tool. The AHC item was selected from the Patient-Reported Outcomes Measurement Information System (PROMIS®) Item Bank on Emotional Distress and asks, ''How often do you feel lonely or isolated from those around you?'' The five response options are: (1) Never; (2) Rarely; (3) Sometimes; (4) Often; and (5) Always.[189] The AHC Screening Tool was developed by a panel of interdisciplinary experts that looked at evidence-based ways to measure SDOH, including social isolation. More information about the AHC Screening Tool is available on the website at *https://innovation.cms.gov/Files/worksheets/ahcm-screeningtool.pdf*.

In addition, we received stakeholder feedback during the December 13, 2018 SDOH listening session on the value of receiving information on social isolation for purposes of care planning. Some stakeholders also recommended assessing social isolation as an SDOH as opposed to social support.

The proposed Social Isolation data element is consistent with NASEM considerations about social isolation as a function of social relationships that impacts health outcomes and increases mortality risk, as well as the current work of a NASEM committee examining how social isolation and loneliness impact health outcomes in adults 50 years and older. We believe that adding a Social Isolation data element would be an important component of better understanding patient complexity and the care goals of patients, thereby facilitating care coordination and continuity in care planning across PAC settings. For more information on the Social Isolation data element, we refer readers to the document titled ''Proposed Specifications for IRF QRP Measures and Standardized Patient Assessment Data Elements,'' available on the website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In an effort to standardize the submission of social isolation data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we are proposing to adopt the Social Isolation data element described above as SPADE with respect to the proposed Social Determinants of Health category. We are proposing to add the Social Isolation data element to the IRF–PAI.

We are soliciting comment on this proposal.

H. Form, Manner, and Timing of Data Submission Under the IRF QRP

1. Background

We refer readers to § 412.634(b) for information regarding the current policies for reporting IRF QRP data.

2. Update to the CMS System for Reporting Quality Measures and Standardized Patient Assessment Data and Associated Procedural Proposals

IRFs are currently required to submit IRF–PAI data to CMS using the Quality Improvement and Evaluation System (QIES) Assessment and Submission Processing (ASAP) system. We will be migrating to a new internet Quality Improvement and Evaluation System (iQIES) that will enable real-time upgrades, and we are proposing to designate that system as the data submission system for the IRF QRP beginning October 1, 2019. We are proposing to revise § 412.634(a)(1) by replacing ''Certification and Survey Provider Enhanced Reports (CASPER)'' with ''CMS designated data submission''. We are proposing to revise § 412.634(d)(1) by replacing the reference to ''Quality Improvement and Evaluation System Assessment Submission and Processing (QIES ASAP) system'' with ''CMS designated data submission system''. We are proposing to revise § 412.634(d)(5) by replacing reference to the ''QIES ASAP'' with ''CMS designated data submission''. We are also proposing to revise § 412.634(f)(1) by replacing ''QIES'' with ''CMS designated data submission system''. In addition, we are proposing to notify the public of any future changes to the CMS designated system using subregulatory mechanisms, such as website postings, listserv messaging, and webinars.

We invite public comment on our proposals.

3. Proposed Schedule for Reporting the Transfer of Health Information Quality Measures Beginning With the FY 2022 IRF QRP

As discussed in section VIII.D. of this proposed rule, we are proposing to adopt the Transfer of Health Information to the Provider–Post-Acute Care (PAC) and Transfer of Health Information to the Patient–Post-Acute Care (PAC) quality measures beginning with the FY 2022 IRF QRP. We also are proposing that IRFs would report the data on those measures using the IRF–PAI. IRFs would be required to collect data on both measures for patients beginning with patients discharged on or after October 1, 2020. We refer readers to the FY 2018 IRF PPS final rule (82 FR 36291 through 36292) for the data collection and submission timeframes that we finalized for the IRF QRP.

We invite public comment on this proposal.

4. Proposed Schedule for Reporting Standardized Patient Assessment Data Elements Beginning With the FY 2022 IRF QRP

As discussed in section IV.F. of this proposed rule, we are proposing to adopt SPADEs beginning with the FY 2022 IRF QRP. We are proposing that IRFs would report the data using the IRF–PAI. Similar to the proposed schedule for reporting the Transfer of Health Information to the Provider–Post-Acute Care (PAC) and Transfer of Health Information to the Patient–Post-Acute Care (PAC) quality measures, IRFs would be required to collect the SPADEs for all patients discharged on or after October 1, 2020, at both admission and discharge. IRFs that submit data with respect to admission for the Hearing, Vision, Race, and Ethnicity SPADEs would be considered to have submitted data with respect to discharges. We refer readers to the FY 2018 IRF PPS final rule (82 FR 36291 through 36292) for the data collection and submission timeframes that we finalized for the IRF QRP.

We invite public comment on this proposal.

5. Proposed Data Reporting on Patients for the IRF Quality Reporting Program Beginning With the FY 2022 IRF QRP

We received public input suggesting that the quality measures used in the IRF QRP should be calculated using data collected from all IRF patients, regardless of the patients' payer. This input was provided to us via comments requested about quality measure development on the CMS Measures Management System Blueprint

[189] Northwestern University. (2017). PROMIS Item Bank v. 1.0—Emotional Distress—Anger—Short Form 1.

website,[190] as well as through comments we received from stakeholders via our IRF QRP mailbox, and feedback received from the NQF-convened MAP as part of their recommendations on Coordination Strategy for Post-Acute Care and Long-Term Care Performance Measurement.[191] Further, in the FY 2018 IRF PPS proposed rule (82 FR 20740), we sought input on expanding the reporting of quality measures to include all patients, regardless of payer, so as to ensure that the IRF QRP makes publicly available information regarding the quality of the services furnished to the IRF population as a whole, rather than just those patients who have Medicare.

In response to that request for public input, several commenters, including MedPAC, submitted comments stating that they would be supportive of an effort to collect data specified under the IRF QRP from all IRF patients regardless of their payer. Many commenters noted that this would not be overly burdensome, as most of their organizations' members currently complete the IRF–PAI on all patients, regardless of their payer. A few commenters had concerns, including recommending that CMS continue to align the patient assessment instruments across PAC settings and whether the use of the data would outweigh any additional reporting burden. For a more detailed discussion, we refer readers to the FY 2018 IRF final rule (82 FR 36292). We have taken these concerns under consideration in proposing this policy.

Further, given that we do not have access to other payer claims, we believe that the most accurate representation of the quality provided in IRFs would be best conveyed using data collected via the IRF–PAI on all IRF patients, regardless of payer, for the purposes of the IRF QRP. Medicare is the primary payer for approximately 60 percent of IRF patients.[192]

We also believe that data reporting on standardized patient assessment data elements using IRF–PAI should include all IRF patients for the same reasons for collecting data on all residents for the IRF QRP's quality measures: To promote higher quality and more efficient health care for Medicare beneficiaries and all patients receiving IRF services, for example through the exchange of information and longitudinal analysis of the data. With that, we believe that collecting quality measure and standardized patient assessment data via the IRF–PAI on all IRF patients ensures that quality care is provided for Medicare beneficiaries, and patients receiving IRF services as a whole. While we appreciate that collecting quality data on all patients regardless of payer may create additional burden, we also note that the effort to separate out Medicare beneficiaries from other patients is also burdensome. We are aware that it is common practice for IRFs to collect IRF–PAI data on all patients, regardless of their payer.

Further, we believe that patients may utilize various payer sources for services received during their stay, for example being admitted under one payer source including Medicare, and the payer source may change during the patient stay which would require the restart of the data collection and reporting in the midst of services rather than at the actual admission. Collecting data on all IRF patients will provide us with the most robust, accurate reflection of the quality of care delivered to Medicare beneficiaries as compared with non-Medicare patients and residents, and we intend to display the calculation of this data on IRF Compare in the future. Accordingly, we are proposing that IRFs collect data on all IRF patients to ensure that all patients, regardless of their payer, are receiving the same care and that provider metrics measure performance across the spectrum of patients.

Therefore, to meet the quality reporting requirements for IRFs for the FY 2022 payment determination and each subsequent year, we propose to expand the reporting of IRF–PAI data used for the IRF QRP to include data on all patients, regardless of their payer, beginning with patients discharged on or after October 1, 2020 for the FY 2022 IRF QRP and the IRF–PAI V4.0, effective October 1, 2020.

We invite public comment on this proposal.

I. Proposed Policies Regarding Public Display of Measure Data for the IRF QRP

Section 1886(j)(7)(E) of the Act requires the Secretary to establish procedures for making the IRF QRP data available to the public after ensuring that IRFs have the opportunity to review their data prior to public display. Measure data are currently displayed on the Inpatient Rehabilitation Facility Compare website, an interactive web tool that assists individuals by providing information on IRF quality of care. For more information on IRF Compare, we refer readers to the website at *https://www.medicare.gov/inpatientrehabilitationfacilitycompare/*. For a more detailed discussion about our policies regarding public display of IRF QRP measure data and procedures for the opportunity to review and correct data and information, we refer readers to the FY 2017 IRF PPS final rule (81 FR 52125 through 52131).

In this proposed rule, we are proposing to begin publicly displaying data for the Drug Regimen Review Conducted With Follow-Up for Identified Issues—PAC IRF QRP measure beginning CY 2020 or as soon as technically feasible. We finalized the Drug Regimen Review Conducted With Follow-Up for Identified Issues—PAC IRF QRP measure in the FY 2017 IRF PPS final rule (81 FR 52111 through 52116).

Data collection for this assessment-based measure began with patients discharged on or after October 1, 2018. We are proposing to display data based on four rolling quarters, initially using discharges from January 1, 2019 through December 31, 2019 (Quarter 1 2019 through Quarter 4 2019). To ensure the statistical reliability of the data, we are proposing that we would not publicly report an IRF's performance on the measure if the IRF had fewer than 20 eligible cases in any four consecutive rolling quarters. IRFs that have fewer than 20 eligible cases would be distinguished with a footnote that states, ''The number of cases/patient stays is too small to publicly report.''

We invite public comment on these proposals.

J. Proposed Removal of the List of Compliant IRFs

In the FY 2016 IRF PPS final rule (80 FR 47125 through 47127), we finalized that we would publish a list of IRFs that successfully met the reporting requirements for the applicable payment determination on the IRF QRP website and update the list on an annual basis.

We have received feedback from stakeholders that this list offers minimal benefit. Although the posting of successful providers was the final step in the applicable payment determination process, it does not provide new information or clarification to the providers regarding their annual

[190] Public Comment Summary Report Posting for Transfer of Health Information and Care Preferences. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-Cross-Setting-Transfer-of-Health-Information-Quality-Meas.pdf*.

[191] MAP Coordination Strategy for Post-Acute Care and Long-Term Care Performance Measurement. Feb 2012. *http://www.qualityforum.org/Publications/2012/02/MAP_Coordination_Strategy_for_Post-Acute_Care_and_Long-Term_Care_Performance_Measurement.aspx*.

[192] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for social risk factors in Medicare payment: Identifying social risk factors. Washington, DC: The National Academies Press.

payment update status. Therefore, in this proposed rule, we are proposing that we will no longer publish a list of compliant IRFs on the IRF QRP website, effective beginning with the FY 2020 payment determination.

We invite public comment on this proposal.

K. Method for Applying the Reduction to the FY 2020 IRF Increase Factor for IRFs That Fail To Meet the Quality Reporting Requirements

As previously noted, section 1886(j)(7)(A)(i) of the Act requires the application of a 2-percentage point reduction of the applicable market basket increase factor for payments for discharges occurring during such fiscal year for IRFs that fail to comply with the quality data submission requirements. We propose to apply a 2-percentage point reduction to the applicable FY 2020 proposed market basket increase factor in calculating an adjusted FY 2020 proposed standard payment conversion factor to apply to payments for only those IRFs that failed to comply with the data submission requirements. As previously noted, application of the 2-percentage point reduction may result in an update that is less than 0.0 for a fiscal year and in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year. Also, reporting-based reductions to the market basket increase factor will not be cumulative; they will only apply for the FY involved.

We invite public comment on the proposed method for applying the reduction to the FY 2020 IRF increase factor for IRFs that fail to meet the quality reporting requirements.

Table 20 shows the calculation of the proposed adjusted FY 2020 standard payment conversion factor that will be used to compute IRF PPS payment rates for any IRF that failed to meet the quality reporting requirements for the applicable reporting period.

TABLE 20: Calculations to Determine the Proposed Adjusted FY 2020 Standard Payment Conversion Factor for IRFs That Failed to Meet the Quality Reporting Requirement

Explanation for Adjustment	Calculations	
Standard Payment Conversion Factor for FY 2019		$ 16,021
Market Basket Increase Factor for FY 2020 (3.0 percent), reduced by 0.5 percentage point for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act, and further reduced by 2 percentage points for IRFs that failed to meet the quality reporting requirement	X	1. 005
Budget Neutrality Factor for the Wage Index and Labor-Related Share	X	1.0076
Budget Neutrality Factor for the Revisions to the CMGs and CMG Relative Weights	X	1.0016
Adjusted FY 2020 Standard Payment Conversion Factor	=	$ 16,249

IX. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the OMB for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency;
- The accuracy of our estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

This proposed rule makes reference to associated information collections that are not discussed in the regulation text contained in this document.

B. Collection of Information Requirements for Updates Related to the IRF QRP

An IRF that does not meet the requirements of the IRF QRP for a fiscal year will receive a 2 percentage point reduction to its otherwise applicable annual increase factor for that fiscal year. Information is not currently available to determine the precise number of IRFs that will receive less than the full annual increase factor for FY 2020 due to non-compliance with the requirements of the IRF QRP.

We believe that the burden associated with the IRF QRP is the time and effort associated with complying with the requirements of the IRF QRP. As of February 1, 2019, there are approximately 1,119 IRFs reporting quality data to CMS. For the purposes of calculating the costs associated with the collection of information requirements, we obtained mean hourly wages for these staff from the U.S. Bureau of Labor Statistics' May 2017 National Occupational Employment and Wage Estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). To account for overhead and fringe benefits, we have doubled the hourly wage. These amounts are detailed in Table 21.

TABLE 21: U.S. Bureau of Labor Statistics' May 2018 National Occupational Employment and Wage Estimates

Occupation title	Occupation code	Mean Hourly Wage ($/hr)	Overhead and Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Registered Nurse (RN)	29-1141	$35.36	$35.36	$70.72
Licensed Vocational Nurse (LVN)	29-2061	$21.98	$21.98	$43.96

As discussed in section VIII.D. of this proposed rule, we are proposing to adopt two new measures, (1) Transfer of Health Information to the Provider–Post-Acute Care (PAC); and (2) Transfer of Health Information to the Patient–Post-Acute Care (PAC), beginning with the FY 2022 IRF QRP. As a result, the estimated burden and cost for IRFs for complying with requirements of the FY 2022 IRF QRP will increase. Specifically, we believe that there will be a 0.9 minute addition in clinical staff time to report data per patient stay. We estimate 409,982 discharges from 1,119 IRFs annually. This equates to an increase of 8,200 hours in burden for all IRFs (0.02 hours per assessment × 409,982 discharges). Given 0.5 minutes of RN time at $70.72 per hour and 0.4 minutes of LVN time at $43.96 per hour, we estimate that the total cost will be increased by $330 per IRF annually, or $369,082 for all IRFs annually. This increase in burden will be accounted for in the information collection under OMB control number (0938–0842), which expires December 31, 2021.

In addition, we are proposing to add the standardized patient assessment data elements described in section VIII.F beginning with the FY 2022 IRF QRP. As a result, the estimated burden and cost for IRFs for complying with requirements of the FY 2022 IRF QRP will be increased. Specifically, we believe that there will be an addition of 7.4 minutes on admission, and 11.1 minutes on discharge, for a total of 8.9 minutes of additional clinical staff time to report data per patient stay. We estimate 409,982 discharges from 1,119 IRFs annually. This equates to an increase of 131,194 hours in burden for all IRFs (0.32 hours per assessment × 409,982 discharges). Given 11.3 minutes of RN time at $70.72 per hour and 7.6 minutes of LVN time at $43.96 per hour, we estimate that the total cost will be increased by $6,926 per IRF annually, or $7,750,194 for all IRFs annually. This increase in burden will be accounted for in the information collection under OMB control number (0938–0842), which expires December 31, 2021.

In summary, the proposed IRF QRP quality measures and standardized patient assessment data elements will result in a burden addition of $7,256 per IRF annually, and $8,119,276 for all IRFs annually.

C. Submission of PRA-Related Comments

We have submitted a copy of this rule's information collection and recordkeeping requirements to OMB for review and approval. These requirements are not effective until they have been approved by the OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit CMS's website at *www.cms.hhs.gov/PaperworkReductionActof1995,* or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please refer to the **DATES** and **ADDRESSES** sections of this rulemaking for instructions. We will consider all ICR-related comments received by the date and time specified in the **DATES** section, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

X. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

XI. Regulatory Impact Analysis

A. Statement of Need

This proposed rule updates the IRF prospective payment rates for FY 2020 as required under section 1886(j)(3)(C) of the Act. It responds to section 1886(j)(5) of the Act, which requires the Secretary to publish in the **Federal Register** on or before the August 1 that precedes the start of each fiscal year, the classification and weighting factors for the IRF PPS's case-mix groups, and a description of the methodology and data used in computing the prospective payment rates for that fiscal year.

This proposed rule also implements sections 1886(j)(3)(C) of the Act. Section 1886(j)(3)(C)(ii)(I) of the Act requires the Secretary to apply a multifactor productivity adjustment to the market basket increase factor. The productivity adjustment applies to FYs from 2012 forward.

Furthermore, this proposed rule also adopts policy changes under the statutory discretion afforded to the Secretary under section 1886(j)(7) of the Act. Specifically, we are proposing to rebase and revise the IRF market basket to reflect a 2016 base year rather than the current 2012 base year, revise the CMGs, make a technical correction to the regulatory language to indicate that that the determination of whether a treating physician has specialized training and experience in inpatient rehabilitation is made by the IRF and update regulatory language related to IRF QRP data collection.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 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), the Congressional Review Act (5 U.S.C. 804(2) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

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). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate the total impact of the policy updates described in this proposed rule by comparing the estimated payments in FY 2020 with those in FY 2019. This analysis results in an estimated $195 million increase for FY 2020 IRF PPS payments. Additionally we estimate that

costs associated with the proposals to update the reporting requirements under the IRF quality reporting program result in an estimated $8.1 million addition in costs in FY 2020 for IRFs. We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Also, the rule has been reviewed by OMB. Accordingly, we have prepared a Regulatory Impact Analysis that, to the best of our ability, presents the costs and benefits of the rulemaking.

C. Anticipated Effects

1. Effects on IRFs

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most IRFs and most other providers and suppliers are small entities, either by having revenues of $7.5 million to $38.5 million or less in any 1 year depending on industry classification, or by being nonprofit organizations that are not dominant in their markets. (For details, see the Small Business Administration's final rule that set forth size standards for health care industries, at 65 FR 69432 at *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf,* effective March 26, 2012 and updated on February 26, 2016.) Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary IRFs or the proportion of IRFs' revenue that is derived from Medicare payments. Therefore, we assume that all IRFs (an approximate total of 1,120 IRFs, of which approximately 55 percent are nonprofit facilities) are considered small entities and that Medicare payment constitutes the majority of their revenues. The HHS generally uses a revenue impact of 3 to 5 percent as a significance threshold under the RFA. As shown in Table 22, we estimate that the net revenue impact of this proposed rule on all IRFs is to increase estimated payments by approximately 2.3 percent. The rates and policies set forth in this proposed rule will not have a significant impact (not greater than 3 percent) on a substantial number of small entities. Medicare Administrative Contractors are not considered to be small entities. Individuals and states are not included in the definition of a small entity.

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 603 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. As discussed in detail below in this section, the rates and policies set forth in this proposed rule will not have a significant impact (not greater than 3 percent) on a substantial number of rural hospitals based on the data of the 136 rural units and 11 rural hospitals in our database of 1,119 IRFs for which data were available.

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–04, enacted on March 22, 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 2019, that threshold is approximately $154 million. This proposed rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues 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. As stated, this proposed rule will not have a substantial effect on state and local governments, preempt state law, or otherwise have a federalism implication.

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This proposed rule is considered an E.O. 13771 deregulatory action. We estimate that this rule would generate $6.18 million in annualized cost, discounted at 7 percent relative to year 2016, over a perpetual time horizon. Details on the estimated costs of this rule can be found in the preceding analyses.

2. Detailed Economic Analysis

This proposed rule updates to the IRF PPS rates contained in the FY 2019 IRF PPS final rule (83 FR 38514). Specifically, this proposed rule updates the CMG relative weights and average length of stay values, the wage index, and the outlier threshold for high-cost cases. This proposed rule applies a MFP adjustment to the FY 2020 IRF market basket increase factor in accordance with section 1886(j)(3)(C)(ii)(I) of the Act. Further, this proposed rule proposes to rebase and revise the IRF market basket to reflect a 2016 base year rather than the current 2012 base year, revise the CMGs based on FY 2017 and 2018 data and to make a technical correction to the regulatory language to indicate that the determination of whether a treating physician has specialized training and experience in inpatient rehabilitation is made by the IRF.

We estimate that the impact of the changes and updates described in this proposed rule would be a net estimated increase of $195 million in payments to IRF providers. This estimate does not include the implementation of the required 2 percentage point reduction of the market basket increase factor for any IRF that fails to meet the IRF quality reporting requirements (as discussed in section VIII.J. of this proposed rule). The impact analysis in Table 22 of this proposed rule represents the projected effects of the updates to IRF PPS payments for FY 2020 compared with the estimated IRF PPS payments in FY 2019. We determine the effects by estimating payments while holding all other payment variables constant. We use the best data available, but we do not attempt to predict behavioral responses to these changes, and we do not make adjustments for future changes in such variables as number of discharges or case-mix.

We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to forecasting errors because of other changes in the forecasted impact time period. Some examples could be legislative changes made by the Congress to the Medicare program that would impact program funding, or changes specifically related to IRFs. Although some of these changes may not necessarily be specific to the IRF PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon IRFs.

In updating the rates for FY 2020, we are proposing standard annual revisions described in this proposed rule (for example, the update to the wage and market basket indexes used to adjust the

federal rates). We are also implementing a productivity adjustment to the FY 2020 IRF market basket increase factor in accordance with section 1886(j)(3)(C)(ii)(I) of the Act. We estimate the total increase in payments to IRFs in FY 2020, relative to FY 2019, will be approximately $195 million.

This estimate is derived from the application of the FY 2020 IRF market basket increase factor, as reduced by a productivity adjustment in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, which yields an estimated increase in aggregate payments to IRFs of $210 million. Furthermore, there is an additional estimated $15 million decrease in aggregate payments to IRFs due to the proposed update to the outlier threshold amount. Outlier payments are estimated to decrease from approximately 3.2 percent in FY 2019 to 3.0 percent in FY 2020. Therefore, summed together, we estimate that these updates will result in a net increase in estimated payments of $195 million from FY 2019 to FY 2020.

The effects of the proposed updates that impact IRF PPS payment rates are shown in Table 22. The following proposed updates that affect the IRF PPS payment rates are discussed separately below:

- The effects of the proposed update to the outlier threshold amount, from approximately 3.2 percent to 3.0 percent of total estimated payments for FY 2020, consistent with section 1886(j)(4) of the Act.
- The effects of the proposed annual market basket update (using the IRF market basket) to IRF PPS payment rates, as required by section 1886(j)(3)(A)(i) and section 1886(j)(3)(C) of the Act, including a productivity adjustment in accordance with section 1886(j)(3)(C)(i)(I) of the Act.
- The effects of applying the proposed budget-neutral labor-related share and wage index adjustment, as required under section 1886(j)(6) of the Act.
- The effects of the proposed budget-neutral changes to the CMGs, relative weights and average length of stay values, under the authority of section 1886(j)(2)(C)(i) of the Act.
- The total change in estimated payments based on the proposed FY 2020 payment changes relative to the estimated FY 2019 payments.

3. Description of Table 22

Table 22 categorizes IRFs by geographic location, including urban or rural location, and location for CMS's 9 Census divisions (as defined on the cost report) of the country. In addition, the table divides IRFs into those that are separate rehabilitation hospitals (otherwise called freestanding hospitals in this section), those that are rehabilitation units of a hospital (otherwise called hospital units in this section), rural or urban facilities, ownership (otherwise called for-profit, non-profit, and government), by teaching status, and by DSH PP. The top row of Table 22 shows the overall impact on the 1,119 IRFs included in the analysis.

The next 12 rows of Table 22 contain IRFs categorized according to their geographic location, designation as either a freestanding hospital or a unit of a hospital, and by type of ownership; all urban, which is further divided into urban units of a hospital, urban freestanding hospitals, and by type of ownership; and all rural, which is further divided into rural units of a hospital, rural freestanding hospitals, and by type of ownership. There are 972 IRFs located in urban areas included in our analysis. Among these, there are 696 IRF units of hospitals located in urban areas and 276 freestanding IRF hospitals located in urban areas. There are 147 IRFs located in rural areas included in our analysis. Among these, there are 136 IRF units of hospitals located in rural areas and 11 freestanding IRF hospitals located in rural areas. There are 393 for-profit IRFs. Among these, there are 357 IRFs in urban areas and 36 IRFs in rural areas. There are 612 non-profit IRFs. Among these, there are 522 urban IRFs and 90 rural IRFs. There are 114 government-owned IRFs. Among these, there are 93 urban IRFs and 21 rural IRFs.

The remaining four parts of Table 22 show IRFs grouped by their geographic location within a region, by teaching status, and by DSH PP. First, IRFs located in urban areas are categorized for their location within a particular one of the nine Census geographic regions. Second, IRFs located in rural areas are categorized for their location within a particular one of the nine Census geographic regions. In some cases, especially for rural IRFs located in the New England, Mountain, and Pacific regions, the number of IRFs represented is small. IRFs are then grouped by teaching status, including non-teaching IRFs, IRFs with an intern and resident to average daily census (ADC) ratio less than 10 percent, IRFs with an intern and resident to ADC ratio greater than or equal to 10 percent and less than or equal to 19 percent, and IRFs with an intern and resident to ADC ratio greater than 19 percent. Finally, IRFs are grouped by DSH PP, including IRFs with zero DSH PP, IRFs with a DSH PP less than 5 percent, IRFs with a DSH PP between 5 and less than 10 percent, IRFs with a DSH PP between 10 and 20 percent, and IRFs with a DSH PP greater than 20 percent.

The estimated impacts of each policy described in this rule to the facility categories listed are shown in the columns of Table 22. The description of each column is as follows:

- Column (1) shows the facility classification categories.
- Column (2) shows the number of IRFs in each category in our FY 2020 analysis file.
- Column (3) shows the number of cases in each category in our FY 2020 analysis file.
- Column (4) shows the estimated effect of the proposed adjustment to the outlier threshold amount.
- Column (5) shows the estimated effect of the proposed update to the IRF labor-related share and wage index, in a budget-neutral manner.
- Column (6) shows the estimated effect of the proposed update to the CMGs, relative weights, and average length of stay values, in a budget-neutral manner.
- Column (7) compares our estimates of the payments per discharge, incorporating all of the policies reflected in this proposed rule for FY 2020 to our estimates of payments per discharge in FY 2019.

The average estimated increase for all IRFs is approximately 2.3 percent. This estimated net increase includes the effects of the proposed IRF market basket increase factor for FY 2020 of 3.0 percent, reduced by a productivity adjustment of 0.5 percentage point in accordance with section 1886(j)(3)(C)(ii)(I) of the Act. It also includes the approximate 0.2 percent overall decrease in estimated IRF outlier payments from the proposed update to the outlier threshold amount. Since we are making the updates to the IRF wage index and the CMG relative weights in a budget-neutral manner, they will not be expected to affect total estimated IRF payments in the aggregate. However, as described in more detail in each section, they will be expected to affect the estimated distribution of payments among providers.

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TABLE 22: IRF Impact Table for FY 2020 (Columns 4 through 7 in percentage)

Facility Classification	Number of IRFs	Number of Cases	Outlier	FY 2020 CBSA wage index and labor-share	CMG Weights	Total Percent Change [1]
(1)	(2)	(3)	(4)	(5)	(6)	(7)
Total	1,119	409,982	-0.2	0.0	0.0	2.3
Urban unit	696	166,872	-0.3	0.1	2.5	4.8
Rural unit	136	21,700	-0.3	0.4	2.9	5.6
Urban hospital	276	216,894	-0.1	-0.1	-2.2	0.0
Rural hospital	11	4,516	0.0	-0.8	-3.6	-2.0
Urban For-Profit	357	211,280	-0.1	-0.1	-1.8	0.5
Rural For-Profit	36	7,920	-0.2	-0.3	0.1	2.2
Urban Non-Profit	522	150,310	-0.3	0.1	1.6	4.0
Rural Non-Profit	90	15,166	-0.3	0.4	2.2	4.9
Urban Government	93	22,176	-0.3	0.0	3.1	5.2
Rural Government	21	3,130	-0.1	0.2	4.1	6.9
Urban	972	383,766	-0.2	0.0	-0.1	2.2
Rural	147	26,216	-0.2	0.2	1.8	4.3
Urban by region						
Urban New England	29	16,260	-0.1	-0.1	-2.3	-0.2
Urban Middle Atlantic	135	51,539	-0.2	-0.1	-1.6	0.6
Urban South Atlantic	147	77,315	-0.1	-0.6	-0.5	1.3
Urban East North Central	165	50,466	-0.2	-0.2	2.3	4.3
Urban East South Central	56	27,966	-0.1	-0.6	-0.6	1.1
Urban West North Central	74	20,822	-0.2	0.2	1.0	3.4
Urban West South Central	184	84,068	-0.1	0.4	-0.5	2.3
Urban Mountain	83	30,294	-0.2	-0.7	-0.6	1.0
Urban Pacific	99	25,036	-0.4	1.6	2.1	5.9
Rural by region						
Rural New England	5	1,317	-0.2	-2.4	-2.4	-2.6
Rural Middle Atlantic	12	1,248	-0.5	0.0	1.2	3.2
Rural South Atlantic	16	3,639	-0.2	0.6	-2.4	0.4
Rural East North Central	23	4,061	-0.2	0.3	1.5	4.2
Rural East South Central	21	4,523	-0.1	-0.1	3.9	6.3
Rural West North Central	22	3,178	-0.3	0.4	2.4	5.1
Rural West South Central	40	7,332	-0.3	0.6	3.6	6.5
Rural Mountain	5	626	-0.1	1.0	1.8	5.3
Rural Pacific	3	292	-0.6	0.2	3.0	5.2
Teaching status						
Non-teaching	1,014	362,675	-0.2	0.0	-0.2	2.1
Resident to ADC less than 10%	60	34,000	-0.2	0.1	0.7	3.1
Resident to ADC 10%-19%	31	11,784	-0.4	-0.1	2.6	4.7
Resident to ADC greater than 19%	14	1,523	-0.2	0.0	4.3	6.7
Disproportionate share patient percentage (DSH PP)						
DSH PP = 0%	29	5,300	-0.2	-0.7	-1.3	0.2
DSH PP <5%	139	60,003	-0.1	-0.1	-1.6	0.7

Facility Classification	Number of IRFs	Number of Cases	Outlier	FY 2020 CBSA wage index and labor-share	CMG Weights	Total Percent Change [1]
DSH PP 5%-10%	299	127,442	-0.1	-0.1	-0.7	1.6
DSH PP 10%-20%	371	139,001	-0.2	-0.1	0.0	2.2
DSH PP greater than 20%	281	78,236	-0.3	0.3	2.1	4.7

[1] This column includes the impact of the updates in columns (4), (5), and (6) above, and of the proposed IRF market basket increase factor for FY 2020 (3.0 percent), reduced by 0.5 percentage point for the proposed productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act.

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4. Impact of the Proposed Update to the Outlier Threshold Amount

The estimated effects of the proposed update to the outlier threshold adjustment are presented in column 4 of Table 22. In the FY 2019 IRF PPS final rule (83 FR 38531 through 38532), we used FY 2017 IRF claims data (the best, most complete data available at that time) to set the outlier threshold amount for FY 2019 so that estimated outlier payments would equal 3 percent of total estimated payments for FY 2019.

For this proposed rule, we are using preliminary FY 2018 IRF claims data, and, based on that preliminary analysis, we estimated that IRF outlier payments as a percentage of total estimated IRF payments would be 3.2 percent in FY 2019. Thus, we propose to adjust the outlier threshold amount in this proposed rule to set total estimated outlier payments equal to 3 percent of total estimated payments in FY 2020.The estimated change in total IRF payments for FY 2020, therefore, includes an approximate 0.2 percent decrease in payments because the estimated outlier portion of total payments is estimated to decrease from approximately 3.2 percent to 3 percent.

The impact of this proposed outlier adjustment update (as shown in column 4 of Table 22) is to decrease estimated overall payments to IRFs by about 0.2 percent. We estimate the largest decrease in payments from the update to the outlier threshold amount to be 0.6 percent for rural IRFs in the Pacific region.

5. Impact of the Proposed CBSA Wage Index and Labor-Related Share

In column 5 of Table 22, we present the effects of the proposed budget-neutral update of the wage index and labor-related share. The proposed changes to the wage index and the labor-related share are discussed together because the wage index is applied to the labor-related share portion of payments, so the proposed changes in the two have a combined effect on payments to providers. As discussed in section V.E. of this proposed rule, we are proposing to update the labor-related share from 70.5 percent in FY 2019 to 72.6 percent in FY 2020.

6. Impact of the Proposed Update to the CMG Relative Weights and Average Length of Stay Values.

In column 6 of Table 22, we present the effects of the proposed budget-neutral update of the CMGs, relative weights and average length of stay values. In the aggregate, we do not estimate that these proposed updates will affect overall estimated payments of IRFs. However, we do expect these updates to have small distributional effects.

7. Effects of the Requirements for the IRF QRP for FY 2020

In accordance with section 1886(j)(7)(A) of the Act, the Secretary must reduce by 2 percentage points the market basket increase factor otherwise applicable to an IRF for a fiscal year if the IRF does not comply with the requirements of the IRF QRP for that fiscal year. In section VIII.J of this proposed rule, we discuss the proposed method for applying the 2 percentage point reduction to IRFs that fail to meet the IRF QRP requirements.

As discussed in section VIII.D. of this proposed rule, we are proposing to add two measures to the IRF QRP (1) Transfer of Health Information to the Provider—Post-Acute Care (PAC); and (2) Transfer of Health Information to the Patient—Post-Acute Care (PAC), beginning with the FY 2022 IRF QRP. We are also proposing to add standardized patient assessment data elements, as discussed in section IV.G of this proposed rule. We describe the estimated burden and cost reductions for both of these measures in section VIII.C of this proposed rule. In summary, the proposed changes to the IRF QRP will result in a burden addition of $7,806 per IRF annually, and $8,119,276 for all IRFs annually.

We intend to continue to closely monitor the effects of the IRF QRP on IRFs and to help perpetuate successful reporting outcomes through ongoing stakeholder education, national trainings, IRF announcements, website postings, CMS Open Door Forums, and general and technical help desks.

D. Alternatives Considered

The following is a discussion of the alternatives considered for the IRF PPS updates contained in this proposed rule.

Section 1886(j)(3)(C) of the Act requires the Secretary to update the IRF PPS payment rates by an increase factor that reflects changes over time in the prices of an appropriate mix of goods and services included in the covered IRF services.

We are proposing a market basket increase factor for FY 2020 that is based on a proposed rebased market basket reflecting a 2016 base year. We considered the alternative of continuing to use the IRF market basket without rebasing to determine the market basket increase factor for FY 2020. However, we typically rebase and revise the market baskets for the various PPS every 4 to 5 years so that the cost weights and price proxies reflect more recent data. Therefore, we believe it is more technically appropriate to use a 2016-based IRF market basket since it allows for the FY 2020 market basket increase factor to reflect a more up-to-date cost structure experienced by IRFs.

As noted previously in this proposed rule, section 1886(j)(3)(C)(ii)(I) of the Act requires the Secretary to apply a productivity adjustment to the market basket increase factor for FY 2020. Thus, in accordance with section 1886(j)(3)(C) of the Act, we propose to update the IRF prospective payments in this proposed rule by 2.5 percent (which equals the

proposed 3.0 percent estimated IRF market basket increase factor for FY 2020 reduced by a 0.5 percentage point proposed productivity adjustment as determined under section 1886(b)(3)(B)(xi)(II) of the Act (as required by section 1886(j)(3)(C)(ii)(I) of the Act)).

As we finalized in the FY 2019 IRF PPS final rule (83 FR 38514) use of the Quality Indicators items in determining payment and the associated CMG and CMG relative weight revisions using two years of data (FY 2017 and FY 2018) beginning with FY 2020, we did not consider any alternative to proposing these changes.

However, we did consider whether or not to apply a weighting methodology to the IRF motor score that was finalized in the FY 2019 IRF PPS final rule (83 FR 38514) to assign patients to CMGs beginning in FY 2020. In light of recent analysis that indicates that weighting the motor score would improve the accuracy of payments under the IRF PPS, we believe that it is appropriate to propose to weight the motor score that would be effective on October 1, 2019.

We considered not removing the item GG0170A1 Roll left and right from the composition of the motor score. However, this item did not behave as expected in the models considered to develop the weights. Therefore, we believe it is appropriate to propose to remove this item from the construction of the weighted motor score.

We considered updating facility-level adjustment factors for FY 2020. However, as discussed in more detail in the FY 2015 final rule (79 FR 45872), we believe that freezing the facility-level adjustments at FY 2014 levels for FY 2015 and all subsequent years (unless and until the data indicate that they need to be further updated) will allow us an opportunity to monitor the effects of the substantial changes to the adjustment factors for FY 2014, and will allow IRFs time to adjust to the previous changes.

We considered not updating the IRF wage index to use the concurrent fiscal year's IPPS wage index and instead continuing to use a one-year lag of the IPPS wage index. However, we believe that updating the IRF wage index based on the concurrent year's IPPS wage index will better align the data across acute and post-acute care settings in support of our efforts to move toward more unified Medicare payments across post-acute care settings.

We considered maintaining the existing outlier threshold amount for FY 2020. However, analysis of updated FY 2020 data indicates that estimated outlier payments would be higher than 3 percent of total estimated payments for FY 2020, by approximately 0.2 percent, unless we updated the outlier threshold amount. Consequently, we propose adjusting the outlier threshold amount in this proposed rule to reflect a 0.2 percent decrease thereby setting the total outlier payments equal to 3 percent, instead of 3.2 percent, of aggregate estimated payments in FY 2020.

We considered not amending § 412.622(a)(3)(iv) to clarify that the determination as to whether a physician qualifies as a rehabilitation physician (that is, a licensed physician with specialized training and experience in inpatient rehabilitation is made by the IRF. However, we believe that it is important to clarify this definition to ensure that IRF providers and Medicare contractors have a shared understanding of these regulatory requirements.

E. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on the FY 2019 IRF PPS proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this proposed rule. It is possible that not all commenters reviewed the FY 2019 IRF PPS proposed rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We sought comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $107.38 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 would take approximately 2 hours for the staff to review half of this proposed rule. For each IRF that reviews the rule, the estimated cost is $214.76 (2 hours × $107.38). Therefore, we estimate that the total cost of reviewing this regulation is $23,194.08 ($214.76 × 108 reviewers).

F. Accounting Statement and Table

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf*), in Table 23, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule. Table 23 provides our best estimate of the increase in Medicare payments under the IRF PPS as a result of the proposed updates presented in this proposed rule based on the data for 1,119 IRFs in our database. In addition, Table 23 presents the costs associated with the new IRF quality reporting program requirements for FY 2020.

TABLE 23: Accounting Statement: Classification of Estimated Expenditure

Change in Estimated Transfers from FY 2019 IRF PPS to FY 2020 IRF PPS	**Category**	**Transfers**
	Annualized Monetized Transfers	$195 million
	From Whom to Whom?	Federal Government to IRF Medicare Providers
Change in Estimated Costs	**Category**	**Costs**
	Annualized monetized cost in FY 2020 for IRFs due to new quality reporting program requirements	$8.1 million

G. Conclusion

Overall, the estimated payments per discharge for IRFs in FY 2020 are projected to increase by 2.3 percent, compared with the estimated payments in FY 2019, as reflected in column 7 of Table 22.

IRF payments per discharge are estimated to increase by 2.2 percent in urban areas and 4.3 percent in rural areas, compared with estimated FY 2019 payments. Payments per discharge to rehabilitation units are estimated to increase 4.8 percent in urban areas and 5.6 percent in rural areas. Payments per discharge to freestanding rehabilitation hospitals are estimated to increase 0.0 percent in urban areas and decrease 2.0 percent in rural areas.

Overall, IRFs are estimated to experience a net increase in payments as a result of the proposed policies in this proposed rule. The largest payment increase is estimated to be a 6.9 percent increase for rural government IRFs. The analysis above, together with the remainder of this preamble, provides a Regulatory Impact Analysis.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as follows:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 1. The authority citation for part 412 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 412.622 is amended by—

■ a. Revising paragraphs (a)(3)(iv), (a)(4)(i)(A), (a)(4)(iii)(A), and (a)(5)(i); and

■ b. Adding paragraph (c).

The revisions and addition read as follows:

§ 412.622 Basis of payment.

(a) * * *

(3) * * *

(iv) Requires physician supervision by a rehabilitation physician. The requirement for medical supervision means that the rehabilitation physician must conduct face-to-face visits with the patient at least 3 days per week throughout the patient's stay in the IRF to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process. The post-admission physician evaluation described in paragraph (a)(4)(ii) of this section may count as one of the face-to-face visits.

(4) * * *

(i) * * *

(A) It is conducted by a licensed or certified clinician(s) designated by a rehabilitation physician within the 48 hours immediately preceding the IRF admission. A preadmission screening that includes all of the required elements, but that is conducted more than 48 hours immediately preceding the IRF admission, will be accepted as long as an update is conducted in person or by telephone to update the patient's medical and functional status within the 48 hours immediately preceding the IRF admission and is documented in the patient's medical record.

* * * * *

(iii) * * *

(A) It is developed by a rehabilitation physician with input from the interdisciplinary team within 4 days of the patient's admission to the IRF.

* * * * *

(5) * * *

(i) The team meetings are led by a rehabilitation physician and further consist of a registered nurse with specialized training or experience in rehabilitation; a social worker or case manager (or both); and a licensed or certified therapist from each therapy discipline involved in treating the patient. All team members must have current knowledge of the patient's medical and functional status. The rehabilitation physician may lead the interdisciplinary team meeting remotely via a mode of communication such as video or telephone conferencing.

* * * * *

(c) *Definitions.* As used in this section—

Rehabilitation physician means a licensed physician who is determined by the IRF to have specialized training and experience in inpatient rehabilitation.

■ 3. Section 412.634 is amended by revising paragraphs (a)(1), (d)(1) and (5), and (f)(1) to read as follows:

§ 412.634 Requirements under the Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP).

(a) * * *

(1) For the FY 2018 payment determination and subsequent years, an IRF must begin reporting data under the IRF QRP requirements no later than the first day of the calendar quarter subsequent to 30 days after the date on its CMS Certification Number (CCN) notification letter, which designates the IRF as operating in the CMS designated data submission system.

* * * * *

(d) * * *

(1) IRFs that do not meet the requirement in paragraph (b) of this section for a program year will receive a written notification of non-compliance through at least one of the following methods: The CMS designated data submission system, the United States Postal Service, or via an email from the Medicare Administrative Contractor (MAC).

* * * * *

(5) CMS will notify IRFs, in writing, of its final decision regarding any reconsideration request through at least one of the following methods: The CMS designated data submission system, the United States Postal Service, or via an email from the Medicare Administrative Contractor (MAC).

* * * * *

(f) * * *

(1) IRFs must meet or exceed two separate data completeness thresholds: One threshold set at 95 percent for completion of required quality measures data and standardized patient assessment data collected using the IRF–PAI submitted through the CMS designated data submission system; and a second threshold set at 100 percent for measures data collected and submitted using the CDC NHSN.

* * * * *

Dated: March 26, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: March 28, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–07885 Filed 4–17–19; 4:15 pm]

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FEDERAL REGISTER

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No. 79 April 24, 2019

Part III

The President

Proclamation 9864—National Park Week, 2019

Federal Register
Vol. 84, No. 79
Wednesday, April 24, 2019

Presidential Documents

Title 3—

The President

Proclamation 9864 of April 19, 2019

National Park Week, 2019

By the President of the United States of America

A Proclamation

Our National Parks System is a stunning tribute to our country's history, traditions, and heritage. Since the creation of Yellowstone National Park in 1872 by an Act of Congress, countless Americans have experienced the majesty, the wonder, the adventure, and the history of our national parks. Many leave with a deepened appreciation for the beauty of nature, the history of our country, and their place in the universe. During National Park Week, we celebrate our national parks and marvel with appreciation at the splendor of our Nation's landscapes and landmarks.

From sea to shining sea, America offers a vast array of national parks and monuments for the public to enjoy. The National Parks System includes 419 areas that cover more than 85 million acres. Each location is unique, offering a window into a particular chapter of the Nation's history, a lofty view from a mountaintop, or a fleeting glimpse of rarely seen wildlife. From the gorges of Yosemite to the fountains of the World War II Memorial, these sites provide millions of visitors each year with places of remembrance, reflection, and recreation. There is a park for each of our Nation's adventurers, no matter their age or interests.

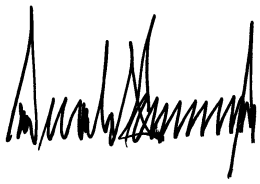
We must give our parks special care and attention to preserve them and the special natural and cultural sites they contain. In recent years, however, many roads, buildings, utility systems, and other infrastructure systems in our national parks have not received important repairs or maintenance, creating a backlog of postponed work projects that totals nearly $12 billion. My Administration is committed to working with the Congress to significantly reduce this backlog, including through the establishment of a Public Lands Infrastructure Fund. In addition, through public-private partnerships, we are bringing together leaders from across the country to improve the management of our public lands. By working across government and with the private sector, we can preserve our parks for generations to come, and provide Americans with more opportunities to experience our country's exhilarating mountain peaks, calming valleys, scenic vistas, sprawling forests, and compelling historic cultural sites.

Laying the cornerstone for the gateway to Yellowstone National Park in 1903, President Theodore Roosevelt observed: ''The essential feature in the present management of Yellowstone Park, as in all similar places, is its essential democracy—it is the preservation of the scenery, of the forests, of the wilderness life and the wilderness game for the people as a whole.'' A century later, Teddy's vision for our national parks endures. As we observe National Park Week, I encourage Americans to take advantage of the accessibility of our national parks and to get outside and experience these magnificent natural and historic treasures.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim April 20 through April 28, 2019, as National Park Week. I encourage all Americans to celebrate by visiting our national parks and learning more about the natural, cultural,

and historical heritage that belongs to each and every citizen of the United States of America.

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



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