



# FEDERAL REGISTER

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**Title 3—****Proclamation 9914 of August 4, 2019****The President****Honoring the Victims of the Tragedies in El Paso, Texas, and Dayton, Ohio****By the President of the United States of America****A Proclamation**

Our Nation mourns with those whose loved ones were murdered in the tragic shootings in El Paso, Texas, and Dayton, Ohio, and we share in the pain and suffering of all those who were injured in these two senseless attacks. We condemn these hateful and cowardly acts. Through our grief, America stands united with the people of El Paso and Dayton. May God be with the victims of these two horrific crimes and bring aid and comfort to their families and friends. As a mark of solemn respect for the victims of the terrible acts of violence perpetrated on August 3, 2019, in El Paso, Texas, and on August 4, 2019, in Dayton, Ohio, by the authority vested in me as President of the United States by the Constitution and the laws of the United States of America, I hereby order that the flag of the United States shall be flown at half-staff at the White House and upon all public buildings and grounds, at all military posts and naval stations, and on all naval vessels of the Federal Government in the District of Columbia and throughout the United States and its Territories and possessions until sunset, August 8, 2019. I also direct that the flag shall be flown at half-staff for the same length of time at all United States embassies, legations, consular offices, and other facilities abroad, including all military facilities and naval vessels and stations.

IN WITNESS WHEREOF, I have hereunto set my hand this fourth day of August, in the year of our Lord two thousand nineteen, and of the Independence of the United States of America two hundred forty-fourth.



# Rules and Regulations

Federal Register

Vol. 84, No. 153

Thursday, August 8, 2019

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

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

## NATIONAL CREDIT UNION ADMINISTRATION

### 12 CFR Part 790

RIN 3133-AF04

#### Office Name Change

**AGENCY:** National Credit Union Administration (NCUA).

**ACTION:** Final rule.

**SUMMARY:** The NCUA Board (Board) is issuing a final rule to update its regulations to reflect the renaming of its “Office of Public and Congressional Affairs.” The office was recently renamed the “Office of External Affairs and Communications.”

**DATES:** The final rule is effective August 8, 2019.

**FOR FURTHER INFORMATION CONTACT:** Thomas I. Zells, Staff Attorney, Office of General Counsel, at 1775 Duke Street, Alexandria, VA 22314 or telephone: (703) 548-2478.

#### SUPPLEMENTARY INFORMATION:

- I. Background
- II. Regulatory Procedures

#### I. Background

The Board renamed the “Office of Public and Congressional Affairs” to the “Office of External Affairs and Communications” on July 18, 2019. The new name for the office better encapsulates its scope and duties. This rulemaking amends part 790 of the NCUA’s regulations to reflect the office’s new name.

#### II. Regulatory Procedures

##### A. Final Rule Under the Administrative Procedure Act (APA)

Generally, the APA requires a federal agency to provide the public with notice and an opportunity to comment on agency rulemakings.<sup>1</sup> This rule is exempt from the APA’s notice and comment requirement because it only

addresses the NCUA’s organization and structure.<sup>2</sup>

##### B. Effective Date

The APA also generally requires publication of a rule in the **Federal Register** at least 30 days before the effective date of the rule. Agencies can dispense with the 30-day requirement for good cause.<sup>3</sup> The NCUA finds good cause to dispense with the 30-day effective date requirement, as this rule is technical rather than substantive. The rule will be effective immediately upon publication.

##### C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires that, in connection with a final rule, an agency prepare and make available for public comment a final regulatory flexibility analysis that describes the impact of the final rule on small entities. A regulatory flexibility analysis is not required, however, if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities (defined for purposes of the RFA to include credit unions with assets less than \$100 million)<sup>4</sup> and publishes its certification and a short, explanatory statement in the **Federal Register** together with the rule. The final rule makes only technical changes and will not have an impact on small credit unions. Accordingly, the NCUA certifies that this final rule will not have a significant economic impact on a substantial number of small credit unions.

##### D. Paperwork Reduction Act

This final rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995.<sup>5</sup>

##### E. Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on state and local interests. In adherence to fundamental federalism principles, the NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the executive order. This rulemaking will not have a

substantial direct effect on the states, on the connection between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. The NCUA has determined that this final rule does not constitute a policy that has federalism implications for purposes of the executive order.

##### F. Assessment of Federal Regulations and Policies on Families

The NCUA has determined that this final rule will not affect family well-being within the meaning of Section 654 of the Treasury and General Government Appropriations Act, 1999.<sup>6</sup>

#### List of Subjects in 12 CFR Part 790

Organization and functions (Government agencies).

By the National Credit Union Administration Board on July 30, 2019.

**Gerard Poliquin,**

*Secretary of the Board.*

For the reasons discussed above, the Board amends 12 CFR part 790 as follows:

#### PART 790—DESCRIPTION OF NCUA; REQUESTS FOR AGENCY ACTION

■ 1. The authority citation for part 790 continues to read as follows:

**Authority:** 12 U.S.C. 1766, 1789, 1795f.

■ 2. Amend § 790.2 by revising paragraphs (b)(6) and (11) to read as follows:

##### § 790.2 Central and field office organization.

\* \* \* \* \*

(b) \* \* \*

(6) *Office of the Executive Director.* The Executive Director reports to the entire NCUA Board. The Executive Director translates the NCUA Board policy decisions into workable programs, delegates responsibility for these programs to appropriate staff members, and coordinates the activities of the senior executive staff, which includes: The General Counsel; the Regional Directors; and the Office Directors for the Asset Management and Assistance Center, Chief Economist, Chief Financial Officer, Chief Information Officer, Consumer Financial Protection, Continuity and

<sup>2</sup> *Id.* (b)(A).

<sup>3</sup> *Id.* 553(d)(3).

<sup>4</sup> See 80 FR 57512 (Sept. 24, 2015).

<sup>5</sup> 44 U.S.C. *et seq.*

<sup>6</sup> Public Law 105-277, 112 Stat. 2681 (1998).

<sup>1</sup> 5 U.S.C. 553(b).

Security Management, Credit Union Resources and Expansion, Examination and Insurance, Human Resources, Minority and Women Inclusion, National Examinations and Supervision, and External Affairs and Communications. Because of the nature of the attorney/client relationship between the Board and General Counsel, the General Counsel may be directed by the Board not to disclose discussions and/or assignments with anyone, including the Executive Director. The Executive Director is otherwise to be privy to all matters within senior executive staff's responsibility. The Office of the Executive Director also supervises the agency's ombudsman. The ombudsman investigates complaints and recommends solutions on regulatory issues that cannot be resolved at the regional level.

\* \* \* \* \*

(11) *Office of External Affairs and Communications*. The Director of the Office of External Affairs and Communications is responsible for maintaining NCUA's relationship with the public and the media; for liaison with the U.S. Congress, and with other Executive Branch agencies concerning legislative matters; and for the analysis and development of legislative proposals and public affairs programs.

\* \* \* \* \*

### § 790.3 [Amended]

■ 3. Amend § 790.3 by removing the words "Office of Public and Congressional Affairs" and adding in their place "Office of External Affairs and Communications".

[FR Doc. 2019-17009 Filed 8-7-19; 8:45 am]

BILLING CODE 7535-01-P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2019-0527; Product Identifier 2019-NM-112-AD; Amendment 39-19684; AD 2019-14-06]

RIN 2120-AA64

#### Airworthiness Directives; Airbus SAS Airplanes

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule; request for comments.

**SUMMARY:** The FAA is adopting a new airworthiness directive (AD) for certain Airbus SAS Model A319-111, -112, -115, and -131 airplanes, and Model

A320-214 and -232 airplanes. This AD was prompted by a report of the fracture of a main landing gear (MLG) sliding tube axle, and an investigation that determined the cause to be an incorrect repair. This AD requires a repetitive magnetic particle inspection (MPI) of affected MLG sliding tubes for discrepancies; a one-time Barkhausen noise inspection (BNI) or alternative non-destructive test (NDT) inspection, and a detailed visual inspection of affected MLG sliding tube axles for discrepancies; and corrective actions if necessary, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. Accomplishing the BNI and applicable corrective actions, or replacing the affected parts, constitutes terminating action for the repetitive MPI. The FAA is issuing this AD to address the unsafe condition on these products.

**DATES:** This AD becomes effective August 23, 2019.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 23, 2019.

We must receive comments on this AD by September 23, 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 material incorporated by reference (IBR) in this AD, contact the EASA, at Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 1000; email [ADs@easa.europa.eu](mailto:ADs@easa.europa.eu); internet [www.easa.europa.eu](http://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> by searching for

and locating Docket No. FAA-2019-0527.

#### 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-2019-0527; 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 regulatory evaluation, any comments received, and other information. The street address for Docket Operations is listed above. 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:

##### Discussion

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA Emergency AD 2019-0151-E, dated June 28, 2019 ("EASA Emergency AD 2019-0151-E") (also referred to as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition for certain Airbus SAS Model A319-111, -112, -115, and -131 airplanes, and Model A320-214 and -232 airplanes. The MCAI states:

An occurrence was reported where, during pushback of an aeroplane, a MLG sliding tube axle fractured. Investigation results revealed an incorrect accomplishment of a repair at the previous overhaul of the chromium plated axle diameters, which resulted in the overheat damage to the sliding tube axle journal(s). This initiated a crack which, under fatigue effects, led to fracture of the MLG sliding tube axle. A limited number of MLG sliding tubes has been identified that may have been subject to the same incorrect repair.

This condition, if not detected, could lead to MLG sliding tube axle fracture, possibly resulting in MLG collapse, damage to the aeroplane, and injury to occupants.

To address this potential unsafe condition, SAFRAN Landing Systems issued the SB [service bulletin] (later revised), providing the list of affected parts and inspection instructions. Consequently, EASA issued AD 2019-0147 to require a one-time inspection of affected parts and, depending on findings, accomplishment of applicable corrective action(s).

Since that [EASA] AD was issued, after chrome removal on one affected part, a crack was found on the inner chromed land area. Airbus issued the AOT [Alert Operators Transmission] to provide instructions for repetitive magnetic particle inspections

(MPI), pending accomplishment of the SB. In addition, further investigation identified that a limited number of MLG sliding tubes were incorrectly repaired, thereby reducing the number of affected aeroplanes.

For the reasons described above, this [EASA Emergency] AD retains part of the requirements of EASA AD 2019-0147, which is superseded, amends the Applicability, and requires additional repetitive inspections, and, depending on findings, accomplishment of applicable corrective action(s).

**Related IBR Material Under 1 CFR Part 51**

EASA Emergency AD 2019-0151-E describes procedures for a repetitive MPI of affected MLG sliding tubes for discrepancies (e.g., cracks or damage), a one-time BNI of affected MLG sliding tube axles for discrepancies (e.g., cracks or damage), and corrective actions, i.e., repair, if necessary. Corrective actions include repair or replacement of affected parts. EASA Emergency AD 2019-0151-E also describes an optional method of compliance for accomplishing corrective actions by replacing affected parts with serviceable parts, and terminating actions for the repetitive MPI, which consist of accomplishing the BNI and applicable corrective actions, or replacing the affected parts.

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

**FAA’s Determination**

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to a bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI referenced above. The FAA is issuing this AD because the agency evaluated all pertinent information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

**Requirements of This AD**

This AD requires accomplishing the actions specified in EASA Emergency AD 2019-0151-E described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this AD. This AD also requires sending the inspection results to Safran Landing Systems.

**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 Emergency AD 2019-0151-E is incorporated by reference in the FAA final rule. This AD, therefore, requires compliance with the provisions specified in EASA Emergency AD 2019-0151-E, except for any differences identified as exceptions in the regulatory text of this AD. Using common terms that are the same as the heading of a particular section in the EASA Emergency AD does not mean that operators need comply only with that section. For example, where the AD requirement refers to “all required actions and compliance times,” compliance with this AD requirement is not limited to the section titled “Required Action(s) and Compliance Time(s)” in the EASA Emergency AD. Service information specified in EASA Emergency AD 2019-0151-E that is required for compliance with EASA Emergency AD 2019-0151-E is available on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2019-0527.

**FAA’s Justification and Determination of the Effective Date**

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption.

The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because failure to detect and correct cracks or damage in the MLG sliding tube axle could lead to MLG sliding tube axle fracture, possibly resulting in MLG collapse. Therefore, the FAA finds good cause that notice and opportunity for prior public comment are impracticable. In addition, for the reasons stated above, the FAA finds that good cause exists for making this amendment effective in less than 30 days.

**Comments Invited**

This AD is a final rule that involves requirements affecting flight safety, and the FAA did not precede it by notice and opportunity for public comment. The FAA invites you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under the ADDRESSES section. Include “Docket No. FAA-2019-0527; Product Identifier 2019-NM-112-AD” at the beginning of your comments. The FAA specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. The FAA will consider all comments received by the closing date and may amend this AD based on those comments.

The FAA will post all comments received, without change, to <http://www.regulations.gov>, including any personal information you provide. The FAA will also post a report summarizing each substantive verbal contact received about this AD.

**Costs of Compliance**

The FAA estimates that this AD affects 1 airplane of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS \*

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Up to 14 work-hours × \$85 per hour = Up to \$1,190 .....	\$0	\$1,190	Up to \$1,190

\* Table does not include estimated costs for reporting.

The FAA estimates that it takes about 1 work-hour per product to comply with the reporting requirement in this AD. The average labor rate is \$85 per hour. Based on these figures, the FAA estimates the cost of reporting the

inspection results on U.S. operators to be \$85 per product.

The FAA has received no definitive data that would enable us to provide cost estimates for the optional actions

and on-condition actions specified in this AD.

**Paperwork Reduction Act**

A federal agency may not conduct or sponsor, and a person is not required to

respond to, nor shall a person be subject to penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB control number. The control number for the collection of information required by this AD is 2120–0056. The paperwork cost associated with this AD has been detailed in the Costs of Compliance section of this document and includes time for reviewing instructions, as well as completing and reviewing the collection of information. Therefore, all reporting associated with this AD is mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at 800 Independence Ave. SW, Washington, DC 20591, ATTN: Information Collection Clearance Officer, AES–200.

#### Authority for This Rulemaking

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

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

This 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

The FAA determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship

between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

- (1) Is not a "significant regulatory action" under Executive Order 12866,
- (2) Will not affect intrastate aviation in Alaska, and
- (3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

#### List of Subjects in 14 CFR Part 39

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

#### 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):

**2019–14–06 Airbus SAS:** Amendment 39–19684; Docket No. FAA–2019–0527; Product Identifier 2019–NM–112–AD.

#### (a) Effective Date

This AD becomes effective August 23, 2019.

#### (b) Affected ADs

None.

#### (c) Applicability

This AD applies to Airbus SAS Model A319–111, –112, –115, and –131 airplanes, and Airbus SAS Model A320–214 and –232 airplanes, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) Emergency AD 2019–0151–E, dated June 28, 2019 ("EASA Emergency AD 2019–0151–E").

#### (d) Subject

Air Transport Association (ATA) of America Code 32, Landing gear.

#### (e) Reason

This AD was prompted by a report of the fracture of a main landing gear (MLG) sliding tube axle, and an investigation that determined the cause to be an incorrect repair. The FAA is issuing this AD to address cracks and damage in the MLG sliding tube axle, which if not detected and corrected,

could lead to MLG sliding tube axle fracture, possibly resulting in MLG collapse.

#### (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 Emergency AD 2019–0151–E.

#### (h) Exceptions to EASA Emergency AD 2019–0151–E

(1) For purposes of determining compliance with the requirements of this AD: Where EASA Emergency AD 2019–0151–E refers to its effective date, this AD requires using the effective date of this AD.

(2) The "Remarks" section of EASA Emergency AD 2019–0151–E does not apply to this AD.

(3) For purposes of determining compliance with the requirements of this AD: Where paragraph (2) of EASA Emergency AD 2019–0151–E refers to "28 June, 2019," this AD requires using the effective date of this AD.

(4) Where paragraph (6) of EASA Emergency AD 2019–0151–E specifies to report the inspection results, this AD requires reporting the inspection results at the applicable time specified in paragraph (h)(4)(i) or (h)(4)(ii) of this AD. If operators have reported findings as part of obtaining any corrective actions approved by Airbus SAS's EASA Design Organization Approval (DOA), operators are not required to report those findings as specified in this paragraph.

(i) If the inspection was done on or after the effective date of this AD: Submit the report within 30 days after the inspection.

(ii) If the inspection was done before the effective date of this AD: Submit the report within 30 days after the effective date of this AD.

#### (i) Special Flight Permit

Special flight permits, as described in 14 CFR 21.197 and 21.199, are not allowed except as specified in Note 1 of EASA Emergency AD 2019–0151–E.

#### (j) 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 (k) of this AD. Information may be emailed to: [9-ANM-116-AMOC-REQUESTS@faa.gov](mailto:9-ANM-116-AMOC-REQUESTS@faa.gov). 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.

(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 Emergency AD 2019-0151-E that contains RC procedures and tests: Except as required by paragraph (j)(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.

(4) *Paperwork Reduction Act Burden Statement:* A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120-0056. Public reporting for this collection of information is estimated to be approximately 1 hour per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW, Washington, DC 20591, Attn: Information Collection Clearance Officer, AES-200.

#### (k) Related Information

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.

#### (l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) Emergency AD 2019-0151-E, dated June 28, 2019.

(ii) [Reserved]

(3) For EASA Emergency AD 2019-0151-E, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 6017; email [ADs@easa.europa.eu](mailto:ADs@easa.europa.eu);

internet [www.easa.europa.eu](http://www.easa.europa.eu). You may find this EASA Emergency AD on the EASA website at <https://ad.easa.europa.eu>.

(4) You may view this EASA Emergency 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 Emergency AD 2019-0151-E may be found in the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2019-0527.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Des Moines, Washington, on July 16, 2019.

**Suzanne Masterson,**

*Acting Director, System Oversight Division, Aircraft Certification Service.*

[FR Doc. 2019-16898 Filed 8-7-19; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

**[Docket No. FAA-2019-0251; Product Identifier 2019-NM-057-AD; Amendment 39-19685; AD 2019-14-07]**

**RIN 2120-AA64**

#### Airworthiness Directives; Airbus SAS Airplanes

**AGENCY:** Federal Aviation Administration (FAA), Department of Transportation (DOT).

**ACTION:** Final rule.

**SUMMARY:** The FAA is adopting a new airworthiness directive (AD) for certain Airbus SAS Model A320-251N and -271N airplanes; and Model A321-251N, -253N, -271N, and -272N airplanes. This AD was prompted by a report that during a calibration check, some torqueing tools used on the final assembly line have been found out of tolerance. This AD requires retorquing each affected connection of sense and fire extinguishing lines within the pylon area to a correct torque value, as specified in an European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

**DATES:** This AD is effective September 12, 2019.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of September 12, 2019.

**ADDRESSES:** For the material incorporated by reference (IBR) in this AD, contact the EASA, at Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 1000; email [ADs@easa.europa.eu](mailto:ADs@easa.europa.eu); internet [www.easa.europa.eu](http://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> by searching for and locating Docket No. FAA-2019-0251.

#### 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-2019-0251; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

**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:

##### Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Airbus SAS Model A320-251N and -271N airplanes; and Model A321-251N, -253N, -271N, and -272N airplanes. The NPRM published in the **Federal Register** on May 7, 2019 (84 FR 19879). The NPRM was prompted by a report that during a calibration check, some torqueing tools used on the final assembly line have been found out of tolerance. The NPRM proposed to require retorquing each affected connection of sense and fire extinguishing lines within the pylon area to a correct torque value.

The FAA is issuing this AD to address connections of sense and fire extinguishing lines within the pylon area that have been under-torqued, which could lead to leaks or

disconnections of those lines and possibly result in reduced engine control and reduced safety margin in case of engine fire.

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2019-0081, dated April 3, 2019 (“EASA AD 2019-0081”) (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for certain Airbus SAS Model A320-251N and -271N airplanes; and Model A321-251N, -253N, -271N, and -272N airplanes. The MCAI states:

During periodic calibration check, some torquing tools used on the final assembly line have been found out-of-tolerance. The subsequent investigation determined that connections of sense and fire extinguishing lines within the pylon area have been under-torqued on a group of aeroplanes.

This condition, if not corrected, could lead to leaks or disconnections of those lines, possibly resulting in reduced engine control and/or reduced safety margin in case of engine fire.

To address this potential unsafe condition, Airbus issued the applicable SB [service bulletin], providing instructions to restore the correct torque value of those affected connections.

For the reason described above, this [EASA] AD requires re-torquing to the correct value the affected connections.

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-2019-0251.

**Comments**

The FAA gave the public the opportunity to participate in developing this final rule. The FAA has considered the comment received. The Air Line Pilots Association, International (ALPA) stated that it supports the NPRM.

**Conclusion**

The FAA reviewed the relevant data, considered the comment received, and determined that air safety and the public interest require adopting this final rule as proposed, except for minor editorial changes. The FAA has determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

**Explanation of Revised Exception Language**

In paragraph (i)(3) of the NPRM, which describes exceptions to Required for Compliance (RC) procedures and tests, an exception for paragraph (i)(2) of the NPRM was inadvertently left out. Also inadvertently included were exceptions for paragraphs (h)(1) and (h)(2) of the NPRM, which are standard exceptions that do not affect how to accomplish the RC actions. Paragraph (i)(3) of this final rule has been revised accordingly.

**Related IBR Material Under 1 CFR Part 51**

EASA AD 2019-0081 describes procedures for retorquing each affected connection of sense and fire extinguishing lines within the pylon area to a correct torque value.

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

**Costs of Compliance**

The FAA estimates that this AD affects 15 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

**ESTIMATED COSTS FOR REQUIRED ACTIONS**

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
10 work-hours × \$85 per hour = \$850 .....	\$0	\$850	\$12,750

**Authority for This Rulemaking**

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

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

This 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**

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

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

- (1) Is not a “significant regulatory action” under Executive Order 12866,

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

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

**List of Subjects in 14 CFR Part 39**

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

**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):

**2019–14–07 Airbus SAS:** Amendment 39–19685; Docket No. FAA–2019–0251; Product Identifier 2019–NM–057–AD.

**(a) Effective Date**

This AD is effective September 12, 2019.

**(b) Affected ADs**

None.

**(c) Applicability**

This AD applies to Airbus SAS Model A320–251N and –271N airplanes; and Model A321–251N, –253N, –271N, and –272N airplanes; certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2019–0081, dated April 3, 2019 (“EASA AD 2019–0081”).

**(d) Subject**

Air Transport Association (ATA) of America Code 26, Fire protection.

**(e) Reason**

This AD was prompted by a report that during a calibration check, some torquing tools used on the final assembly line have been found out of tolerance. The FAA is issuing this AD to address connections of sense and fire extinguishing lines within the pylon area that have been under-torqued, which could lead to leaks or disconnections of those lines and possibly result in reduced engine control and reduced safety margin in case of engine fire.

**(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 2019–0081.

**(h) Exceptions to EASA AD 2019–0081**

(1) For purposes of determining compliance with the requirements of this AD: Where EASA AD 2019–0081 refers to its effective date, this AD requires using the effective date of this AD.

(2) The “Remarks” section of EASA AD 2019–0081 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) of this AD. Information may be emailed to: [9-ANM-116-AMOC-REQUESTS@](mailto:9-ANM-116-AMOC-REQUESTS@faa.gov)

[faa.gov](mailto:faa.gov). 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.

(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 Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* For any service information referenced in EASA AD 2019–0081 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**

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.

**(k) Material Incorporated by Reference**

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2019–0081, dated April 3, 2019.

(ii) [Reserved]

(3) For EASA AD 2019–0081, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 6017; email [ADs@easa.europa.eu](mailto:ADs@easa.europa.eu); Internet [www.easa.europa.eu](http://www.easa.europa.eu). You may find this EASA AD on the EASA website at <https://ad.easa.europa.eu>.

(4) 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 2019–0081 may be found in the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2019–0251.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Des Moines, Washington, on July 22, 2019.

**Dionne Palermo,**

*Acting Director, System Oversight Division, Aircraft Certification Service.*

[FR Doc. 2019–16814 Filed 8–7–19; 8:45 am]

**BILLING CODE 4910–13–P**

**DEPARTMENT OF TRANSPORTATION****Federal Aviation Administration****14 CFR Part 39**

**[Docket No. FAA–2018–1011; Product Identifier 2018–NM–131–AD; Amendment 39–19691; AD 2019–14–13]**

**RIN 2120–AA64**

**Airworthiness Directives; The Boeing Company Airplanes**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** The FAA is adopting a new airworthiness directive (AD) for all The Boeing Company Model 767–200, –300, –300F, and –400ER series airplanes. This AD was prompted by reports of uncommanded fore/aft movements of the Captain’s and First Officer’s seats. This AD requires an identification of the part number, and if applicable the serial number, of the Captain’s and First Officer’s seats, and applicable on-condition actions. This AD also requires a one-time detailed inspection and repetitive checks of the horizontal movement system of the Captain’s and First Officer’s seats, and applicable on-condition actions. This AD also provides an optional terminating action for the repetitive checks of the horizontal movement system for certain airplanes. The FAA is issuing this AD to address the unsafe condition on these products.

**DATES:** This AD is effective September 12, 2019.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of September 12, 2019.

**ADDRESSES:** For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminister Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet <https://www.myboeingfleet.com>. You may view this service information 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 on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2018–1011.

### 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–2018–1011; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

### FOR FURTHER INFORMATION CONTACT:

Brandon Lucero, Aerospace Engineer, Cabin Safety and Environmental Systems Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3569; email: [Brandon.Lucero@faa.gov](mailto:Brandon.Lucero@faa.gov).

### SUPPLEMENTARY INFORMATION:

#### Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all The Boeing Company Model 767–200, –300, –300F, and –400ER series airplanes. The NPRM published in the **Federal Register** on December 26, 2018 (83 FR 66172). The NPRM was prompted by reports of uncommanded fore/aft movements of the Captain's and First Officer's seats. The NPRM proposed to require an identification of the part number, and if applicable the serial number, of the Captain's and First Officer's seats, and applicable on-condition actions. The NPRM also proposed to require a one-time detailed inspection and repetitive checks of the horizontal movement system of the Captain's and First Officer's seats, and applicable on-condition actions. The NPRM also proposed to provide an optional terminating action for the repetitive checks of the horizontal movement system for certain airplanes.

#### Comments

The FAA gave the public the opportunity to participate in developing this final rule. The following presents the comments received on the NPRM and the FAA's response to each comment.

### Support for the NPRM

Air Line Pilots Association, International (ALPA), supported the intent of the NPRM. FedEx had no objection to the NPRM.

### Effect of Winglets on Accomplishment of the Proposed Actions

Aviation Partners Boeing stated that accomplishing Supplemental Type Certificate (STC) ST01920SE does not affect the actions specified in the proposed AD.

The FAA concurs with the commenter. Paragraph (c) of the proposed AD has been redesignated as paragraph (c)(1) of this AD, and paragraph (c)(2) has been added to this AD to state that installation of STC ST01920SE does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST01920SE is installed, a "change in product" alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

### Requests To Include Records Review

ABX AIR, American Airlines, and Delta Air Lines (Delta) requested that the proposed AD include a provision to allow operators to do a records review to determine which airplanes have the affected seat part numbers installed. The commenters stated that not all of their Model 767 airplane fleets have the affected Captain's and First Officer's seats installed. Delta asserted that the affected seats are rotatable parts that could later be installed on airplanes that were initially delivered with acceptable seats, thereby subjecting those airplanes to the identified unsafe condition. Delta pointed out that the affected seats are trackable and maintenance records and configuration control mechanisms can be used to ensure the affected seats are addressed. The commenters also noted that adding a records review would remove the undue burden on operators (*i.e.*, need to create work instructions/task cards and added maintenance down time for inspecting airplanes and components that are not affected by the identified unsafe condition).

The FAA agrees with the commenters' requests. A records review will provide an acceptable means for operators to identify the part numbers of the Captain's and First Officer's seats installed on an airplane. Paragraph (g) of this AD has been revised to include the following statement: "A review of airplane maintenance records is acceptable in lieu of this inspection if the part number and serial number of the Captain's and First Officer's seats

can be conclusively determined from that review."

### Request To Change to Component AD

United Parcel Service (UPS) requested that the applicability of the proposed AD be changed from Model 767 airplanes to the Captain's and First Officer's seats. The commenter also requested that operators use the Ipeco service information instead of the Boeing service information. The commenter noted that it is aware there will be other proposed ADs on other airplane models that would address the same unsafe condition identified in the proposed AD. The commenter noted that the affected Captain's and First Officer's seats are interchangeable across several airplane models and mandating ADs against those airplane models could result in a specific seat being installed on a Model 747 airplane with records identifying compliance with an AD that includes Model 767 airplanes in the applicability. The commenter stated that this could lead to confusion and questions regarding compliance when there is no effective difference between the two ADs.

The FAA infers that the commenter is requesting that this AD be changed to a component AD. The FAA does not agree with the commenter's request. A component AD would require any operator with an Ipeco seat installed on an airplane in its fleet to inspect all of the airplanes in its fleet to determine if an affected seat part number is installed. By limiting the applicability of this AD to the airplane model on which the affected Ipeco part numbers are known to be installed, the burden is reduced on operators. We acknowledge that the affected seats may be installed on other airplane models, such as the Model 747, 757, and 777. The FAA is considering other rulemaking to address the unsafe condition on those models. This AD has not been changed in regard to this issue.

### Conclusion

The FAA reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this final rule with the changes described previously and minor editorial changes. The FAA has determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

The FAA has also determined that these changes will not increase the

economic burden on any operator or increase the scope of this final rule.

**Additional Change to This Final Rule**

The proposed AD referred to “uncommanded movement” in the description of the unsafe condition. This final rule clarifies the type of movement by specifying “uncommanded fore/aft movement” in the SUMMARY and Discussion sections, and paragraph (e), of this AD.

**Related Service Information Under 1 CFR Part 51**

The FAA reviewed Boeing Special Attention Service Bulletin 767–25–0539, Revision 1, dated July 17, 2018 (“BSASB 767–25–0539, Revision 1”). The service information describes procedures for identification of the part number, and, if applicable, the serial

number of the Captain’s and First Officer’s seats, and applicable on-condition actions. The on-condition actions include an inspection of each seat’s fore/aft and vertical manual control levers for looseness, installation of serviceable seats, and a seat functional test after any cable adjustment.

The FAA also reviewed Boeing Special Attention Service Bulletin 767–25–0549, Revision 1, dated August 10, 2018 (“BSASB 767–25–0549, Revision 1”). The service information describes procedures for a one-time detailed inspection and repetitive checks of the horizontal movement system of the Captain’s and First Officer’s seats for findings (e.g., evidence of cracks, scores, corrosion, dents, deformation or visible wear); and incorrectly assembled

components (e.g., microswitch assemblies, actuators, and limit switches), and applicable on-condition actions. The on-condition actions include overhaul of the horizontal movement system, clearing the seat tracks of foreign object debris (FOD), replacement of the horizontal actuator, and replacement of the horizontal movement system. The service information also describes procedures for an optional terminating action for the repetitive checks by installing a serviceable Captain’s or First Officer’s seat.

**Costs of Compliance**

The FAA estimates that this AD affects 90 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

**ESTIMATED COSTS FOR REQUIRED ACTIONS**

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Identification, seat .....	1 work-hour × \$85 per hour = \$85 per seat .....	\$0	\$85 per seat .....	\$7,650 per seat.
Detailed inspection, horizontal movement system.	1 work-hour × \$85 per hour = \$85, per seat .....	0	\$85 per seat .....	\$7,650 per seat.
Checks, horizontal movement system.	2 work-hour × \$85 per hour = \$170 per seat, per check cycle.	0	\$170 per seat, per check cycle.	\$15,130 per seat, per check cycle.

The FAA estimates the following costs to do any necessary on-condition

actions that would be required. The FAA has no way of determining the

number of aircraft that might need these on-condition actions:

**ESTIMATED COSTS OF ON-CONDITION ACTIONS \***

Action	Labor cost	Parts cost	Cost per product
Adjustment, control lever cable .....	1 work-hour × \$85 per hour = \$85, per seat .....	\$0 .....	\$85 per seat.
Overhaul or replacement, horizontal movement system	Up to 15 work-hours × \$85 per hour = \$1,275, per seat.	Up to \$6,400 per seat.	Up to \$7,675 per seat.
Inspection of each seat’s fore/aft and vertical manual control levers.	1 work-hour × \$85 per hour = \$85, per seat .....	\$0 .....	\$85 per seat.
Installation of serviceable seats .....	1 work-hour × \$85 per hour = \$85, per seat .....	\$0 .....	\$85 per seat.
Clearing FOD .....	1 work-hour × \$85 per hour = \$85, per seat .....	\$0 .....	\$85 per seat.
Replacement of the horizontal actuator .....	1 work-hour × \$85 per hour = \$85, per actuator .....	\$205 .....	\$290, per actuator.
Functional test, adjusted control lever cable .....	1 work-hour × \$85 per hour = \$85, per seat .....	\$0 .....	\$85, per seat.

\* The estimated cost for tooling to align an affected seat for adjustment of the control lever cable is up to \$46,064.

The FAA has received no definitive data that would enable the agency to provide cost estimates for the optional terminating action for the on-condition repetitive checks specified in this AD.

**Authority for This Rulemaking**

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

detail the scope of the Agency’s authority.

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

unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

This 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

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

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

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

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

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

### List of Subjects in 14 CFR Part 39

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

### 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):

**2019–14–13 The Boeing Company:**  
Amendment 39–19691; Docket No. FAA–2018–1011; Product Identifier 2018–NM–131–AD.

#### (a) Effective Date

This AD is effective September 12, 2019.

#### (b) Affected ADs

None.

#### (c) Applicability

(1) This AD applies to all The Boeing Company Model 767–200, –300, –300F, and –400ER series airplanes, certificated in any category.

(2) Installation of Supplemental Type Certificate (STC) ST01920SE does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST01920SE is installed, a “change in product” alternative method of compliance

(AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

#### (d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/Furnishings.

#### (e) Unsafe Condition

This AD was prompted by reports of uncommanded fore/aft movements of the Captain’s and First Officer’s seats. The FAA is issuing this AD to address uncommanded fore/aft movement of the Captain’s and First Officer’s seats. An uncommanded fore/aft seat movement during a critical part of a flight, such as take-off or landing, could cause a flight control obstruction or unintended flight control input, which could result in the loss of the ability to control the airplane.

#### (f) Compliance

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

#### (g) Seat Identification and On-Condition Actions

Within 36 months after the effective date of this AD, do an inspection to determine the part number, and serial number as applicable, of the Captain’s and First Officer’s seats, and do all applicable on-condition actions, in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 767–25–0539, Revision 1, dated July 17, 2018. A review of airplane maintenance records is acceptable in lieu of this inspection if the part number and serial number of the Captain’s and First Officer’s seats can be conclusively determined from that review.

#### (h) Detailed Inspection and Repetitive Checks of Horizontal Movement System and On-Condition Actions

Except as specified in paragraph (i) of this AD: At the applicable times specified in paragraph 1.E., “Compliance,” of Boeing Special Attention Service Bulletin 767–25–0549, Revision 1, dated August 10, 2018 (“BSASB 767–25–0549, Revision 1”), do all applicable actions identified as “RC” (required for compliance) in, and in accordance with, the Accomplishment Instructions of BSASB 767–25–0549, Revision 1.

#### (i) Exceptions to Service Information Specifications

For purposes of determining compliance with the requirements of this AD: Where BSASB 767–25–0549, Revision 1, uses the phrase “the original issue date of this service bulletin,” this AD requires using “the effective date of this AD.”

#### (j) Optional Terminating Action for Repetitive Checks

(1) For Group 1, Configuration 2 and 4 airplanes identified in BSASB 767–25–0549, Revision 1: Installation of a serviceable Captain’s seat, as specified in, and in accordance with, the Accomplishment Instructions of BSASB 767–25–0549, Revision 1, terminates the repetitive checks

of the Captain’s seat as required by paragraph (h) of this AD for that airplane only.

(2) For Group 1, Configuration 3 and 4 airplanes identified in BSASB 767–25–0549, Revision 1: Installation of a serviceable First Officer’s seat, as specified in, and in accordance with, the Accomplishment Instructions of BSASB 767–25–0549, Revision 1, terminates the repetitive checks of the First Officer’s seat as required by paragraph (h) of this AD for that airplane only.

#### (k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (l) of this AD. Information may be emailed to: [9-ANM-Seattle-ACO-AMOC-Requests@faa.gov](mailto:9-ANM-Seattle-ACO-AMOC-Requests@faa.gov).

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (k)(4)(i) and (k)(4)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or substep is labeled “RC Exempt,” then the RC requirement is removed from that step or substep. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled 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 RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

#### (l) Related Information

For more information about this AD, contact Brandon Lucero, Aerospace Engineer, Cabin Safety and Environmental Systems Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3569; email: [Brandon.Lucero@faa.gov](mailto:Brandon.Lucero@faa.gov).

**(m) Material Incorporated by Reference**

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

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

(i) Boeing Special Attention Service Bulletin 767-25-0539, Revision 1, dated July 17, 2018.

(ii) Boeing Special Attention Service Bulletin 767-25-0549, Revision 1, dated August 10, 2018.

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminister Blvd., MC 110-SK57, Seal Beach, CA 90740-5600; telephone 562-797-1717; internet <https://www.myboeingfleet.com>.

(4) You may view this service information 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.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Des Moines, Washington, on July 23, 2019.

**Dionne Palermo,**

*Acting Director, System Oversight Division, Aircraft Certification Service.*

[FR Doc. 2019-16813 Filed 8-7-19; 8:45 am]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF TRANSPORTATION****Federal Aviation Administration****14 CFR Part 39**

**[Docket No. FAA-2019-0574; Product Identifier 2018-NM-150-AD; Amendment 39-19688; AD 2019-14-10]**

**RIN 2120-AA64**

**Airworthiness Directives; Airbus SAS Airplanes**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule; request for comments.

**SUMMARY:** The FAA is superseding Airworthiness Directive (AD) 2018-02-11, which applies to certain Airbus SAS Model A330-301, -321, -322, and -342 airplanes. AD 2018-02-11 requires contacting the FAA to obtain instructions for addressing the unsafe condition on these products, and doing the actions specified in those

instructions. Since the FAA issued AD 2018-02-11, the agency received a report of additional cracking found on different airplane models, and of an update to the fatigue and damage tolerance analysis. This AD requires repetitive detailed inspections of the horizontal stabilizer (HS) center box (CB) top skin integral flange area, and repair if necessary. This AD also expands the applicability to include additional airplane models. The FAA is issuing this AD to address the unsafe condition on these products.

**DATES:** This AD becomes effective August 23, 2019.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 23, 2019.

The FAA must receive comments on this AD by September 23, 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 material incorporated by reference (IBR) in this AD, contact the EASA, at Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89900 1000; email [ADs@easa.europa.eu](mailto:ADs@easa.europa.eu); internet [www.easa.europa.eu](http://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-2019-0574; 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 regulatory evaluation, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

**FOR FURTHER INFORMATION CONTACT:** Vladimir Ulyanov, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206-231-3229.

**SUPPLEMENTARY INFORMATION:****Discussion**

The FAA issued AD 2018-02-11, Amendment 39-19164 (83 FR 2894, January 22, 2018) (“AD 2018-02-11”), for certain Airbus SAS Model A330-301, -321, -322, and -342 airplanes. AD 2018-02-11 requires contacting the FAA to obtain instructions for addressing the unsafe condition on these products, and doing the actions specified in those instructions. AD 2018-02-11 resulted from a report of cracking in the top skin of the HS CB of an airplane in pre-modification 41330 configuration. The FAA issued AD 2018-02-11 to address cracking in the HS CB, which could lead to reduced structural integrity of the airplane.

**Actions Since AD 2018-02-11 Was Issued**

Since the FAA issued AD 2018-02-11, the FAA received a report of additional cracking found on different airplane models, and of an update to the fatigue and damage tolerance analysis. The FAA has determined that additional airplanes are subject to the unsafe condition.

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018-0226, dated October 22, 2018 (“EASA AD 2018-0226”) (also referred to as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for certain Airbus SAS Model A330-223, -243, -301, -302, -321, -322, -323, -341, -342, and -343 airplanes; and Model A340-200 and -300 series airplanes. The MCAI states:

Cracks were found in the horizontal stabilizer (HS) centre box (CB) top skin of an A330 aeroplane in pre-mod 41330 configuration. The cracks were initiated at the upper flange corner at Rib 3 rear spar area on left hand side of the CB.

This condition, if not detected and corrected, could lead to reduced structural integrity of the HS CB of the aeroplane.

To address this unsafe condition, Airbus published SB [service bulletin] A330-55-3046 to provide inspection instructions for

the affected area (see Appendix 1 of this [EASA] AD), only applicable to some pre-mod 41330 A330 MSN [manufacturer serial number]. Consequently, EASA issued AD 2017-0078 (which corresponds to FAA AD 2018-02-11) to require a one-time special detailed inspection (SDI) of the HS CB top skin integral flange area and, depending on findings, accomplishment of applicable corrective action(s).

Since that [EASA] AD was issued, new crack finding occurrences were reported on different aeroplanes. Based on the reported findings, and the updated fatigue and damage tolerance analysis, it is necessary to extend the inspection to all pre-mod 41330 aeroplanes as well as to a limited number of post-mod aeroplanes, and to introduce repetitive inspections for all affected aeroplanes. Consequently, Airbus published the applicable SB to provide instructions for repetitive inspections for the affected area.

For the reasons described above, this [EASA] AD retains the requirements of EASA AD 2017-0078, which is superseded, expands the Applicability to include A340 and additional A330 aeroplanes, and introduces repetitive inspections.

**Explanation of Retained Requirements**

Although this AD does not explicitly restate the requirements of AD 2018-02-11, this AD would retain requirements equivalent to those of AD 2018-02-11. Those requirements are referenced in EASA AD 2018-0226, which, in turn, is referenced in paragraph (g) of this AD.

**Related IBR Material Under 1 CFR Part 51**

EASA AD 2018-0226 describes procedures for repetitive special detailed inspections (SDI) of the HS CB top skin integral flange area and, repair if necessary. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

**FAA’s Determination**

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to a bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI referenced above. The FAA is issuing this AD because the agency evaluated all pertinent information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

**Requirements of This AD**

This AD requires accomplishing the actions specified in EASA AD 2018-0226 described previously, except for any differences identified as exceptions in the regulatory text of this AD. This AD also requires sending the inspection results to Airbus.

**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 2018-0226 is incorporated by reference in the FAA final rule. This AD, therefore, requires compliance with the provisions specified in EASA AD 2018-0226, except for any differences identified as exceptions in the regulatory text of this AD. Service information specified in EASA AD 2018-0226 that is required for compliance with EASA AD 2018-0226 is available on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2019-0574.

**FAA’s Justification and Determination of the Effective Date**

Since there are currently no domestic operators of this product, notice and opportunity for public comment before issuing this AD are unnecessary. In addition, for the reasons stated above, the FAA finds that good cause exists for making this amendment effective in less than 30 days.

**Comments Invited**

This AD is a final rule that involves requirements affecting flight safety, and the FAA did not precede it by notice and opportunity for public comment. The FAA invites you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under the ADDRESSES section. Include “Docket No. FAA-2019-0574; Product Identifier 2018-NM-150-AD” at the beginning of your comments. The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this AD. The FAA will consider all comments received by the closing date and may amend this AD based on those comments.

The FAA will post all comments received, without change, to <http://www.regulations.gov>, including any personal information you provide. The FAA will also post a report summarizing each substantive verbal contact received about this AD.

**Costs of Compliance**

Currently, there are no affected U.S.-registered airplanes. If an affected airplane is imported and placed on the U.S. Register in the future, the following are cost estimates to comply with this AD:

**ESTIMATED COSTS FOR REQUIRED ACTIONS**

Labor cost	Parts cost	Cost per product
1 work-hour × \$85 per hour = \$85 .....	\$0	\$85 per inspection.

The FAA estimates that it would take about 1 work-hour per product to comply with the on-condition reporting requirement in this AD. The average labor rate is \$85 per hour. Based on these figures, the FAA estimates the cost of reporting the inspection results on U.S. operators to be \$85 per product.

The FAA has received no definitive data that would enable the agency to provide cost estimates for the on-condition actions specified in this AD.

**Paperwork Reduction Act**

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB control number. The control number for the collection of information required by this AD is 2120-0056. The

paperwork cost associated with this AD has been detailed in the Costs of Compliance section of this document and includes time for reviewing instructions, as well as completing and reviewing the collection of information. Therefore, all reporting associated with this AD is mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at 800 Independence Ave. SW, Washington,

DC 20591, ATTN: Information Collection Clearance Officer, AES-200.

### Authority for This Rulemaking

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

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

This 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

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

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

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Will not affect intrastate aviation in Alaska; and
3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

### List of Subjects in 14 CFR Part 39

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

### 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 removing Airworthiness Directive (AD) 2018-02-11, Amendment 39-19164 (83 FR 2894, January 22, 2018), and adding the following new AD:

**2019-14-10 Airbus SAS:** Amendment 39-19688; Docket No. FAA-2019-0574; Product Identifier 2018-NM-150-AD.

#### (a) Effective Date

This AD becomes effective August 23, 2019.

#### (b) Affected ADs

This AD replaces AD 2018-02-11, Amendment 39-19164 (83 FR 2894, January 22, 2018) ("AD 2018-02-11").

#### (c) Applicability

This AD applies to Airbus SAS Model A330-223, -243, -301, -302, -321, -322, -323, -341, -342, and -343 airplanes; and Model A340-211, -212, -213, -311, -312, and -313 airplanes; certificated in any category; as identified in European Aviation Safety Agency (EASA) AD 2018-0226, dated October 22, 2018 ("EASA AD 2018-0226").

#### (d) Subject

Air Transport Association (ATA) of America Code 55, Stabilizers.

#### (e) Reason

This AD was prompted by a report of cracking in the top skin of the horizontal stabilizer (HS) center box (CB) of an airplane in pre-modification 41330 configuration. This AD was also prompted by report of additional cracking found on different airplanes, and of an update to the fatigue and damage tolerance analysis. The FAA is issuing this AD to address cracking in the horizontal stabilizer center box, which could lead to reduced 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 2018-0226.

#### (h) Exceptions to EASA AD 2018-0226

- (1) For purposes of determining compliance with the requirements of this AD:

Where EASA AD 2018-0226 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where EASA AD 2018-0226 refers to a compliance time of after May 17, 2017, this AD requires using February 6, 2018 (the effective date of AD 2018-02-11).

(3) The "Remarks" section of EASA AD 2018-0226 does not apply to this AD.

(4) Paragraphs (5) and (6) of EASA AD 2018-0226 specify to report "no discrepancy" inspection results to Airbus at certain times. For this AD, report inspection results at the applicable time specified in paragraph (h)(4)(i) or (h)(4)(ii) of this AD.

(i) If the inspection was done on or after the effective date of this AD: Submit the report within 30 days after the inspection.

(ii) If the inspection was done before the effective date of this AD: Submit the report within 30 days after the effective date of 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) of this AD. Information may be emailed to: [9-ANM-116-AMOC-REQUESTS@faa.gov](mailto:9-ANM-116-AMOC-REQUESTS@faa.gov). 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.

(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 Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* For any service information referenced in EASA AD 2018-0226 that contains RC procedures and tests: Except as required by paragraph (h)(4) and (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.

(4) *Paperwork Reduction Act Burden Statement:* A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to

a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120-0056. Public reporting for this collection of information is estimated to be approximately 1 hour per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW, Washington, DC 20591, Attn: Information Collection Clearance Officer, AES-200.

#### (j) Related Information

For more information about this AD, contact Vladimir Ulyanov, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206-231-3229.

#### (k) Material Incorporated by Reference

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

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

(i) European Aviation Safety Agency (EASA) AD 2018-0226, dated October 22, 2018.

(ii) [Reserved]

(3) For EASA AD 2018-0226, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 6017; email [ADs@easa.europa.eu](mailto:ADs@easa.europa.eu); internet [www.easa.europa.eu](http://www.easa.europa.eu). You may find this EASA AD on the EASA website at <https://ad.easa.europa.eu>.

(4) 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 2018-0226 may be found in the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2019-0574.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Des Moines, Washington, on July 23, 2019.

#### Dionne Palermo,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019-16812 Filed 8-7-19; 8:45 am]

BILLING CODE 4910-13-P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2019-0578; Product Identifier 2019-NM-111-AD; Amendment 39-19697; AD 2019-15-04]

RIN 2120-AA64

#### Airworthiness Directives; Bombardier, Inc. Airplanes

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule; request for comments.

**SUMMARY:** The FAA is adopting a new airworthiness directive (AD) for certain Bombardier, Inc., Model BD-100-1A10 airplanes. This AD was prompted by a report of a mis-installed no-back pawl discovered on a horizontal stabilizer trim actuator (HSTA). This AD requires an inspection to verify the horizontal stabilizer trim electronic control unit (HSTECU) part number, a software upgrade for certain HSTECUs, and installation of HSTECUs with upgraded software. The FAA is issuing this AD to address the unsafe condition on these products.

**DATES:** This AD becomes effective August 23, 2019.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 23, 2019.

The FAA must receive comments on this AD by September 23, 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, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this final rule, contact Bombardier, Inc., 200 Côte-Vertu Road West, Dorval, Québec H4S 2A3, Canada; North America toll-free telephone 1-866-538-1247 or direct-dial telephone 1-514-855-2999; email [ac.yul@](mailto:ac.yul@)

[aero.bombardier.com](http://aero.bombardier.com); internet <http://www.bombardier.com>. You may view this referenced service information 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 on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2019-0578.

#### 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-2019-0578; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office is listed above. Comments will be available in the AD docket shortly after receipt.

#### FOR FURTHER INFORMATION CONTACT:

Darren Gassetto, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516-228-7323; fax 516-794-5531; email [9-avs-nyaco-cos@faa.gov](mailto:9-avs-nyaco-cos@faa.gov).

#### SUPPLEMENTARY INFORMATION:

##### Discussion

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian AD CF-2019-23, dated June 18, 2019 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for certain Bombardier, Inc., Model BD-100-1A10 airplanes. The MCAI states:

During an unscheduled inspection, a mis-installed no-back pawl was discovered on a Horizontal Stabilizer Trim Actuator (HSTA). The no-back mechanism is a primary means to prevent back driving of the HSTA, and the Motor Brake Assemblies (MBA) are the secondary means. If not corrected, unavailability of the no-back mechanism in combination with loss of, or degraded HSTA MBA braking capability, could lead to a loss of the aeroplane.

This [TCCA] AD mandates a software upgrade for the HSTECU to verify the MBA for braking capability during the power up test.

You may examine the MCAI on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2019-0578.

**Related Service Information Under 1 CFR Part 51**

Bombardier has issued Service Bulletin 100-27-15, Revision 01, dated June 11, 2019. This service information describes procedures for an inspection to verify the HSTECU part number, a software upgrade for certain HSTECUs, and installation of HSTECUs with upgraded software. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

**FAA's Determination**

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, the agency has been notified of the unsafe condition described in the MCAI and service information referenced above. The FAA is issuing this AD because it has evaluated all pertinent information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

**Requirements of This AD**

This AD requires accomplishing the actions specified in the service information described previously.

**Justification for Immediate Adoption and Determination of the Effective Date**

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5

U.S.C.) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for "good cause," finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under this section, an agency, upon finding good cause, may issue a final rule without seeking comment prior to the rulemaking. Similarly, Section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

The FAA has received a report that a mis-installed no-back pawl was discovered on a HSTA. The no-back pawl is a primary means to prevent back driving of the HSTA, and the MBA are the secondary means. If not corrected, unavailability of the no-back pawl, in combination with loss of or degraded HSTA MBA braking capability, could lead to a loss of the airplane.

The FAA therefore considers the prompt identification and prevention of this unsafe condition to be an urgent safety issue. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b)(3)(B). In addition, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days.

**Regulatory Flexibility Act (RFA)**

The requirements of the RFA do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment.

Because the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

**Comments Invited**

This AD is a final rule that involves requirements affecting flight safety, and was not preceded by notice and opportunity for public comment. The FAA invites you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under the ADDRESSES section. Include "Docket No. FAA-2019-0578; Product Identifier 2019-NM-111-AD" at the beginning of your comments. The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this AD. The agency will consider all comments received by the closing date and may amend this AD based on those comments.

The FAA will post all comments received, without change, to <http://www.regulations.gov>, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this AD.

**Costs of Compliance**

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

**ESTIMATED COSTS FOR REQUIRED ACTIONS**

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Up to 4 work-hours × \$85 per hour = Up to \$340 .....	Up to \$27,138 .....	Up to \$27,478 .....	Up to \$247,302.

According to the manufacturer, some or all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage for affected individuals. As a result, the agency has included all known costs in its cost estimate.

**Authority for This Rulemaking**

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

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

This 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**

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

power and responsibilities among the various levels of government.

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

- (1) Is not a “significant regulatory action” under Executive Order 12866, and
- (2) Will not affect intrastate aviation in Alaska.

#### 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):

**2019–15–04 Bombardier, Inc.:** Amendment 39–19697; Docket No. FAA–2019–0578; Product Identifier 2019–NM–111–AD.

#### (a) Effective Date

This AD becomes effective August 23, 2019.

#### (b) Affected ADs

None.

#### (c) Applicability

This AD applies to Bombardier, Inc., Model BD–100–1A10 airplanes, certificated in any category, serial numbers 20001 through 20337 inclusive.

#### (d) Subject

Air Transport Association (ATA) of America Code 27, Flight controls.

#### (e) Reason

This AD was prompted by a report of a mis-installed no-back pawl discovered on a horizontal stabilizer trim actuator (HSTA). The FAA is issuing this AD to address the possible unavailability of the no-back pawl which, in combination with loss of or degraded HSTA motor brake assembly (MBA) braking capability, could lead to a loss of the airplane.

#### (f) Compliance

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

#### (g) Inspection

Within 100 flight hours or 60 days, whichever occurs first, after the effective date of this AD: Perform an inspection to verify

the part number (P/N) of the horizontal stabilizer trim electronic control unit (HSTECU) installed on the airplane, in accordance with paragraph 2.B.(1) of the Accomplishment Instructions of Bombardier Service Bulletin 100–27–15, Revision 01, dated June 11, 2019. If the installed HSTECU has P/N C47329–007 or subsequent configurations, no further action is required by this paragraph.

#### (h) Installation of HSTECUs With Upgraded Software

(1) If, during the inspection specified in paragraph (g) of this AD, the installed HSTECU has P/N C47329–003: Within 100 flight hours or 60 days, whichever occurs first, after the effective date of this AD, remove the HSTECU and install an upgraded HSTECU having P/N C47329–010, C47329–011 or C47329–012, in accordance with paragraphs 2.B.(2) through 2.B.(4) of the Accomplishment Instructions of Bombardier Service Bulletin 100–27–15, Revision 01, dated June 11, 2019.

(2) If, during the inspection specified in paragraph (g) of this AD, the installed HSTECU has P/N C47329–004, C47329–005 or C47329–006: Within 100 flight hours or 60 days, whichever occurs first, after the effective date of this AD, remove the HSTECU, upgrade the HSTECU software, and reinstall the upgraded HSTECU, in accordance with paragraphs 2.B.(2) through 2.B.(4) of the Accomplishment Instructions of Bombardier Service Bulletin 100–27–15, Revision 01, dated June 11, 2019.

#### (i) Parts Installation Limitation

As of the effective date of this AD, no person may install, on any airplane, an HSTECU having P/N C47329–003, C47329–004, C47329–005 or C47329–006.

#### (j) No Reporting Requirement

Although Bombardier Service Bulletin 100–27–15, Revision 01, dated June 11, 2019, specifies to submit certain information to the manufacturer, this AD does not include that requirement.

#### (k) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. 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.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must

be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.’s TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

#### (l) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian AD CF–2019–23, dated June 18, 2019, for related information. This MCAI may be found in the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2019–0578.

(2) For more information about this AD, contact Darren Gassetto, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7323; fax 516–794–5531; email [9-avs-nyacos@faa.gov](mailto:9-avs-nyacos@faa.gov).

#### (m) Material Incorporated by Reference

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

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

(i) Bombardier Service Bulletin 100–27–15, Revision 01, dated June 11, 2019.

(ii) [Reserved]

(3) For service information identified in this AD, contact Bombardier, Inc., 200 Côte-Vertu Road West, Dorval, Québec H4S 2A3, Canada; North America toll-free telephone 1–866–538–1247 or direct-dial telephone 1–514–855–2999; email [ac.yul@aero.bombardier.com](mailto:ac.yul@aero.bombardier.com); internet <http://www.bombardier.com>.

(4) You may view this service information 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.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Des Moines, Washington, on July 23, 2019.

#### Dionne Palermo,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–16811 Filed 8–7–19; 8:45 am]

**BILLING CODE 4910–13–P**

**DEPARTMENT OF TRANSPORTATION****Federal Aviation Administration****14 CFR Part 71**

[Docket No. FAA-2019-0277; **Airspace**  
Docket No. 19-ACE-4]

RIN 2120-AA66

**Revocation of Class E Airspace; Sioux Center, IA**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** This action removes Class E airspace extending upward from 700 feet above the surface at Sioux Center Municipal Airport, Sioux Center, IA. This action is due to the closure of the airport requiring cancellation of the standard instrument approach procedures as they are no longer necessary.

**DATES:** Effective 0901 UTC, October 10, 2019. The Director of the Federal Register approves this incorporation by reference action under Title 1 Code of Federal Regulations part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

**ADDRESSES:** FAA Order 7400.11C, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at [http://www.faa.gov/air\\_traffic/publications/](http://www.faa.gov/air_traffic/publications/). For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267-8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11C at NARA, call (202) 741-6030, or go to <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

**FOR FURTHER INFORMATION CONTACT:** Rebecca Shelby, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222-5857.

**SUPPLEMENTARY INFORMATION:****Authority for This Rulemaking**

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code.

Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it supports the removal of Class E airspace extending upward from 700 feet above the surface at Sioux Center Municipal Airport, Sioux Center, IA.

**History**

The FAA published a notice of proposed rulemaking in the **Federal Register** (84 FR 20306; May 9, 2019) for Docket No. FAA-2019-0277 to remove Class E airspace extending upward from 700 feet above the surface at Sioux Center Municipal Airport, Sioux Center, IA. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraphs 6005 of FAA Order 7400.11C, dated August 3, 2018, and effective September 15, 2018, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

**Availability and Summary of Documents for Incorporation by Reference**

This document amends FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 3, 2018, and effective September 15, 2018. FAA Order 7400.11C is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11C lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

**The Rule**

This amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 removes the Class E airspace extending upward from 700 feet above the surface at Sioux Center Municipal Airport, Sioux Center, IA.

This action due to the closure of the Sioux Center Municipal Airport and cancellation of the standard instrument approach procedures at the airport making the airspace no longer necessary.

**Regulatory Notices and Analyses**

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

**Environmental Review**

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures," paragraph 5-6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

**Lists of Subjects in 14 CFR Part 71**

Airspace, Incorporation by reference, Navigation (air).

**Adoption of the Amendment**

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

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

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

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

**§ 71.1 [Amended]**

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 3, 2018, and effective September 15, 2018, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

ACE IA E5 Sioux Center, IA [Removed]

Issued in Fort Worth, Texas, on July 31, 2019.

John Witucki,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2019-16800 Filed 8-7-19; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9865]

RIN 1545-BO64

Limitation on Deduction for Dividends Received From Certain Foreign Corporations and Amounts Eligible for Section 954 Look-Through Exception; Correcting Amendment

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to Treasury Decision 9865, which was published in the Federal Register for Tuesday, June 18, 2019. Treasury Decision 9865 contained temporary regulations under section 245A of the Internal Revenue Code (the "Code") that limit the dividends received deduction available for certain dividends received from current or former controlled foreign corporations.

DATES: Effective date. These corrections are effective on August 8, 2019 and applicable June 18, 2019.

FOR FURTHER INFORMATION CONTACT: Logan M. Kincheloe at (202) 317-6937 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The temporary regulations (TD 9865) that are the subject of this correction are under sections 245A, 954(c)(6), and 6038 of the Internal Revenue Code.

Need for Correction

As published June 18, 2019 (84 FR 28398), the temporary regulations (TD 9865; FR 2019-12442) contained errors that may prove misleading and therefore 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 corrected by making the following correcting amendments:

PART 1—INCOME TAXES

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

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

§§ 1.245A-1T through 1.245A-4T [Reserved]

Par. 2. Reserved §§ 1.245A-1 through 1.245A-4 are revised to read §§ 1.245A-1T through 1.245A-4T [Reserved].

Par. 3. Section 1.245A-5T is amended by:

1. In the first sentence of paragraph (c)(3)(i)(B), removing "a SFC" and adding in its place "an SFC".

2. Adding two sentences at the end of paragraph (c)(3)(iv).

3. In paragraphs (e)(3)(i)(C)(1) and (2), removing "required by paragraph (e)(3)(iv)" and adding in its place "described in paragraph (e)(3)(i)(D)".

4. In paragraph (e)(3)(i)(D), removing "(e)(3)(iii)" and adding in its place "(e)(3)(i)(C)".

5. In paragraph (e)(3)(ii), removing "amount with" and adding in its place "amount (or, with respect to a lower-tier CFC, a tiered extraordinary reduction amount under paragraph (f) of this section) with".

The additions read as follows:

§ 1.245A-5T Limitation of section 245A deduction and section 954(c)(6) exception (temporary).

\* \* \* \* \*

(c) \* \* \*

(3) \* \* \*

(iv) \* \* \* Specified property is also property with respect to which a loss was recognized during the disqualified period if the loss is properly allocable to income not described in section 951A(c)(2)(A)(i)(I) through (V) under the principles of section 954(b)(5) (specified loss). If only a portion of the loss recognized with respect to property during the disqualified period is specified loss, then a portion of the property is treated as specified property in an amount that bears the same ratio to the value of the property as the amount of specified loss bears to the total amount of loss recognized with

respect to such property during the disqualified period.

\* \* \* \* \*

Martin V. Franks,

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

[FR Doc. 2019-16630 Filed 8-7-19; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9865]

RIN 1545-BO64

Limitation on Deduction for Dividends Received From Certain Foreign Corporations and Amounts Eligible for Section 954 Look-Through Exception; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final temporary regulations; correction.

SUMMARY: This document contains a correction to a Treasury Decision 9865, which was published in the Federal Register on Tuesday, June 18, 2019. Treasury Decision 9865 contains temporary regulations under section 245A of the Internal Revenue Code (the "Code") that limit the dividends received from current or former controlled foreign corporations.

DATES: Effective date: These regulations are effective August 8, 2019 and applicable June 18, 2019.

FOR FURTHER INFORMATION CONTACT: Logan M. Kincheloe at (202) 317-6937 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9865) that are the subject of this correction are issued under sections 245A, 954, and 6038.

Need for Correction

As published, the final regulations (TD 9865), contains errors that may prove to be misleading and are in need of clarification.

Correction to Publication

Accordingly, the final regulations (TD 9865), that are the subject of FR 2019-12442, in the issue of June 18, 2019, are corrected as follows:

1. On page 28398, in the third column, in the tenth line of the second full

paragraph, “intangible lowed-taxed” is corrected to read “intangible low-taxed”.

■ 2. On page 28403, in the third column, in the fifth line of the first partial paragraph, “§ 1.245A-5T(g)(3)(iv)” is corrected to read “§ 1.245A-5T(g)(4)(i)”.

■ 3. On the same page, in the same column, in the twelfth line of the first full paragraph, “§ 1.245A-5T(g)(5)” is corrected to read “§ 1.245A-5T(g)(4)(i)”.

■ 4. On page 28404, in the first column, under the heading “A. In General”, in the second paragraph, “Explanations of Provisions” is corrected to read “Explanation of Provisions”.

**Martin V. Franks,**

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

[FR Doc. 2019-16631 Filed 8-7-19; 8:45 am]

**BILLING CODE 4830-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 100

[Docket Number USCG-2019-0300]

RIN 1625-AA08

#### Special Local Regulations; Festival of Sail Duluth 2019, Lake Superior, Duluth, MN

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary special local regulation for a designated area of the Duluth Harbor entrance to Superior Bay on Lake Superior during the Festival of Sail 2019 event in Duluth, MN. This action is necessary to provide for the safety of life on these navigable waters around the port of Duluth, MN. This rulemaking prohibits persons and vessels from being in the designated region unless authorized by the Captain of the Port Duluth or a designated representative.

**DATES:** This rule is effective from 7 a.m. on August 11, 2019, through 5 p.m. on August 13, 2019.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2019-0300 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 about this

rulemaking, call or email Lieutenant Abbie Lyons, Waterways Management, MSU Duluth, U.S. Coast Guard; telephone 218-725-3818, email [Abbie.E.Lyons@uscg.mil](mailto:Abbie.E.Lyons@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

On December 11, 2018 Draw Events LLC notified the Coast Guard that it will be conducting a Festival of Sail event in Duluth, MN from August 11 through August 13, 2019. The Coast Guard published a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** on May 8, 2019. A public comment period was held from May 8, 2019 to July 7, 2019 with no comments received. A Supplemental Notice of Proposed Rulemaking (SNPRM) was submitted to the **Federal Register** with a comment period held from July 3, 2019 to July 17, 2019, extending the Special Local Regulation through the duration of the event. During the comment period we received no comments.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because action is needed during the Festival of Sail to respond to the potential safety hazards associated with increased vessel traffic within Superior Harbor.

##### III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Duluth (COTP) has determined that potential hazards associated with increased traffic during the Festival of Sail starting at 7 a.m. on August 11, 2019 will be a safety concern for anyone the designated area. The likely combination of recreational vessels, paddling craft, and Tall Ships present an unacceptable risk of collisions which could result in serious injuries or fatalities. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the special local regulation during the event.

##### IV. Discussion of Comments, Changes, and the Rule

No comments were received on the SNPRM published July 3, 2019. There are no changes in the regulatory text of this rule from the proposed rule in the SNPRM.

This rule establishes a Special Local Regulation from 7 a.m. on August 11, 2019 through 5 p.m. on August 13, 2019. The duration of the zone is intended to protect the safety of vessels and these navigable waters before, during, and immediately after the scheduled Festival of Sail. Only the designated Tall Ships associated with the event are permitted within the zone while it is being enforced. No other vessels or persons will be permitted to enter the zone without obtaining permission from the COTP or a designated representative during the enforcement period. The COTP or a designated representative may be contacted via VHF Channel 16 or by telephone at (218) 428-9357. The regulatory text appears at the end of this document.

##### 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 availability of the Superior Harbor entrance as an alternate entry into Superior Bay, the short time frame of the special local regulation, and the estimated number of spectator vessels around the Duluth Harbor entrance for the event. We anticipate that it will have minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant or loan recipients,

and will not raise any novel legal or policy issues. The Coast Guard will issue a Broadcast Notice to Mariners via VHF-FM marine Channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

#### B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard 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 restricted area may be small entities, for the reasons stated in section V.A above, this rule would not have a significant economic impact on any vessel owner or operator.

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

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this 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 Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human

environment. This rule involves a special local regulation lasting 3 days that would prohibit entry within a designated area around the Duluth Harbor entrance. Normally such actions are categorically excluded from further review under paragraph L[61] in Table 3–1 of U.S. Coast Guard Environmental Planning Implementing Procedures.

#### 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 100

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

#### PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

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

**Authority:** 46 U.S.C. 70041; 33 CFR 1.05–1.

- 2. Add § 100.T09–0300 to read as follows:

#### § 100.T09–0300 Special Local Regulations; Festival of Sail Duluth 2019, Lake Superior, Duluth, MN.

(a) *Regulated area.* This area includes all waters of Lake Superior and Duluth Harbor bounded by Rice’s Point to the west and Duluth to the north, within the following boundaries: Beginning at position 46°46’48.36” N, 092°05’16.44” W, across Duluth Harbor to 46°47’02.76” N, 092°05’17.88” W, turning north toward the Duluth Lift Bridge to 46°47’19.32” N, 092°04’04.80” W, to 46°46’50.88” N, 092°05’17.88” W, out the Duluth Harbor Entrance at 46°46’45.12” N, 092°05’35.16” W, then northwest to 46°46’45.12” N, 092°05’39.84” W back to the north Duluth Entrance Light at 46°47’01.32” N, 092°05’51.00” W, through the canal at 46°47’00.60” N, 092°05’52.08” W, then along Minnesota Point at 46°46’51.60” N, 092°05’46.32” W, entering Minnesota Slip at 46°46’39.00” N, 092°06’03.96” W, encompassing the slip from 46°46’32.16” N, 092°05’38.76” W to 46°46’41.52” N, 092°05’36.24” W and back out the slip at 46°46’42.60” N, 092°05’34.44” W and back to the starting

position of 46°46'48.36" N, 092°05'16.44" W.

(b) *Special local regulations.* (1) In accordance with the general regulations in § 100.35 of this part, entry into, transiting, or anchoring within the regulated areas is prohibited unless authorized by the Captain of the Port (COTP) Duluth or on-scene representatives.

(2) Vessels and persons receiving COTP Duluth or on-scene representative authorization to enter the area of this special local regulation must do so in accordance with the following restrictions:

(i) Vessels and persons must transit at a speed not exceed six (6) knots or at no wake speed, whichever is less. Vessels proceeding under sail will not be allowed in this Area unless also propelled by machinery, due to limited maneuvering ability around numerous other spectator craft viewing the Festival of Sail.

(ii) Vessels and persons will not be permitted to impede the parade of sail from 7 a.m. to 1 p.m. on August 11, 2019 once it has commenced, as the tall ships are extremely limited in their ability to maneuver.

(3) The Coast Guard will provide notice of the regulated area prior to the event through Local Notice to Mariners and Broadcast Notice to Mariners. Notice of the requirements of this rule will also be provided as a courtesy by on-scene representatives, as available. Notice of actual enforcement will be provided by on-scene representatives.

(4) The "on-scene representative" of the COTP Duluth is any Coast Guard commissioned, warrant, or petty officer and any Federal, State, or local officer designated by the COTP to act on her behalf.

(5) Vessel operators desiring to enter or operate within the regulated area shall contact the COTP Duluth by telephone at (218) 428-9357, or on-scene representative via VHF radio on Channel 16, to obtain permission to do so. Vessel operators given permission to enter, operate, transit through, anchor in, or remain within the regulated areas must comply with all instructions given by COTP Duluth or on-scene representatives.

(c) *Effective date.* These regulations are effective from 7 a.m. on August 11, 2019, through 5 p.m. on August 13, 2019. These regulations will be enforced from 7 a.m. on August 11, 2019 through 5 p.m. on August 13, 2019, during the Parade of Sail, and during various periods of time by the on-scene representative throughout the event.

Dated: August 2, 2019.

**F.M. Smith,**

*Commander, U.S. Coast Guard, Captain of the Port Duluth.*

[FR Doc. 2019-16959 Filed 8-7-19; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG-2019-0670]

RIN 1625-AA00

#### Safety Zone; Balloon Glow Fireworks, Manitowoc River, Manitowoc, WI

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone for certain navigable waters of the Manitowoc River and Manitowoc Harbor in Manitowoc, WI during the Balloon Glow Fireworks event. This temporary safety zone is necessary to protect spectators, mariners, vessels, and property from potential hazards associated with a fireworks display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Lake Michigan.

**DATES:** This rule is effective from 8:30 p.m. through 10 p.m. on August 16, 2019.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2019-0670 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 Kyle Weitzell, Sector Lake Michigan Waterways Management Division, U.S. Coast Guard; telephone 414-747-7148, email [Kyle.W.Weitzell@uscg.mil](mailto:Kyle.W.Weitzell@uscg.mil).

#### SUPPLEMENTARY INFORMATION:

##### I. Table of Abbreviations

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

##### II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and

opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the Coast Guard did not receive the final details of this fireworks display in sufficient time to publish an NPRM. Delaying the effective date of this rule to wait for a comment period to run would be both impracticable and contrary to the public interest because it would inhibit the Coast Guard's ability to protect the public, mariners, vessels, and property from the hazards associated with this event which is scheduled on August 16, 2019.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to respond to the potential safety hazards associated with a fireworks display scheduled for August 16, 2019.

##### III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Lake Michigan has determined that potential hazards associated with a fireworks display on August 16, 2019, will be a safety concern for anyone within a 500-foot radius of a vessel used to launch fireworks near the mouth of the Manitowoc River in Manitowoc, WI at coordinates 44°05'31" N, 087°39'07" W. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone during the fireworks display.

##### IV. Discussion of the Rule

This rule establishes a safety zone from 8:30 p.m. through 10 p.m. on August 16, 2019 for navigable waters of the Manitowoc River and Manitowoc Harbor of Lake Michigan in Manitowoc, WI within 500 feet of a vessel used to launch fireworks at coordinates 44°05'31" N, 087°39'07" W. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters from falling embers and fireworks debris during the fireworks

display. Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the COTP or a designated on-scene representative. The COTP or a designated on-scene representative may be contacted via VHF Channel 16.

## 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 and duration of this action. The safety zone created by this rule will be relatively small and is designed to minimize its impact on navigable waters. This rule will prohibit entry into an area of the Manitowoc River and Manitowoc Harbor of Lake Michigan in Manitowoc, WI that is within 500 feet of a vessel used to launch fireworks at coordinates 44°05'31" N, 087°39'07" W during the fireworks display, not to exceed one and one half hour in duration. Thus, restrictions on vessel movement within that particular area are expected to be minimal. Under certain conditions, moreover, vessels may still transit through the safety zone when permitted by the Captain of the Port Lake Michigan.

### B. Impact on Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

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

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

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

### C. Collection of Information

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

### D. Federalism and Indian Tribal Governments

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

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian

tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

### 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 Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves establishment of a safety zone lasting not more than one and one half hour that will prohibit entry within 500 feet of a vessel used to launch fireworks. It is categorically excluded from further review under paragraph L60(a) in Table 3–1 of U.S. Coast Guard Environmental Planning Implementing Procedures. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES** once it is completed.

### G. Protest Activities

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

### List of Subjects in 33 CFR Part 165

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

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

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

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

**Authority:** 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T09–0670 to read as follows:

### § 165.T09–0670 Safety Zone; Balloon Glow Fireworks, Manitowoc River, Manitowoc, WI.

(a) *Location.* All navigable waters of the Manitowoc River and Manitowoc Harbor of Lake Michigan in Manitowoc, WI within 500 feet of a vessel used to launch fireworks at coordinates 44°05'31" N, 087°39'07" W.

(b) *Enforcement period.* This rule will be enforced from 8:30 p.m. through 10 p.m. on August 16, 2019.

(c) *Regulations.* (1) In accordance with the general regulations in section § 165.23 of this part, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Sector Lake Michigan (COTP) or a designated on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the COTP or a designated on-scene representative.

(3) The “on-scene representative” of the COTP is any Coast Guard commissioned, warrant or petty officer who has been designated by the COTP to act on his or her behalf.

(4) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or an on-scene representative to obtain permission to do so. The COTP or an on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP or an on-scene representative.

Dated: August 2, 2019.

**L.M. Lusk,**

*Commander, U.S. Coast Guard, Acting Captain of the Port Sector Lake Michigan.*

[FR Doc. 2019–16958 Filed 8–7–19; 8:45 am]

**BILLING CODE 9110–04–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG–2019–0672]

RIN 1625–AA00

### Safety Zone; St. Norbert College Fireworks, Fox River, De Pere, WI

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone for certain navigable waters of the Fox River in De Pere, WI for the St. Norbert College Fireworks event. This temporary safety zone is necessary to protect spectators, mariners, vessels, and property from potential hazards associated with a fireworks display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Lake Michigan.

**DATES:** This rule is effective from 7:30 p.m. through 9 p.m. on August 25, 2019.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2019–0672 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 Kyle Weitzell, Sector Lake Michigan Waterways Management Division, U.S. Coast Guard; telephone 414–747–7148, email [Kyle.W.Weitzell@uscg.mil](mailto:Kyle.W.Weitzell@uscg.mil).

#### SUPPLEMENTARY INFORMATION:

##### I. Table of Abbreviations

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

##### II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary

to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the Coast Guard did not receive the final details of this fireworks display in sufficient time to publish an NPRM. Delaying the effective date of this rule to wait for a comment period to run would be both impracticable and contrary to the public interest because it would inhibit the Coast Guard’s ability to protect the public, mariners, vessels, and property from the hazards associated with this event which is scheduled on August 25, 2019.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable and contrary to public interest because waiting for an NPRM and final publication would inhibit the Coast Guard’s ability to protect spectators and vessels from the potential safety hazards associated with a fireworks display.

##### III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Lake Michigan has determined that potential hazards associated with the St. Norbert College Fireworks display on August 25, 2019, will be a safety concern for anyone within a 500-foot radius of a vessel used to launch fireworks in the Fox River in De Pere, WI at coordinates 44°26'55" N, 088°03'50" W. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone during the fireworks display.

##### IV. Discussion of the Rule

This rule establishes a safety zone from 7:30 p.m. through 9 p.m. on August 25, 2019 for the waters of the Fox River in De Pere, WI at coordinates 44°26'55" N, 088°03'50" W. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters from falling embers and fireworks debris during the St. Norbert College Fireworks display. The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the fireworks display. Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the COTP or a designated on-scene representative. The COTP or a

designated on-scene representative may be contacted via VHF Channel 16.

## 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 characteristics of the safety zone. The safety zone created by this rule will be relatively small and is designed to minimize its impact on navigable waters. This rule will prohibit entry into certain navigable waters in the Fox River, Du Pere, WI not to exceed one and one half hour in duration. Thus, restrictions on vessel movement within that particular area are expected to be minimal. Under certain conditions, moreover, vessels may still transit through the safety zone when permitted by the Captain of the Port Lake Michigan.

### B. Impact on Small Entities

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

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

economic impact on any vessel owner or operator.

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

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

### C. Collection of Information

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

### D. Federalism and Indian Tribal Governments

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

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

**FURTHER INFORMATION CONTACT** section above.

### 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 Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves establishment of a safety zone. It is categorically excluded from further review under paragraph L60(a) in Table 3–1 of U.S. Coast Guard Environmental Planning Implementing Procedures. A Record of Environmental Consideration supporting this determination will be available in the docket where indicated under **ADDRESSES** once it is completed.

### G. Protest Activities

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

### List of Subjects in 33 CFR Part 165

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

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

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

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

**Authority:** 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5;

Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T09–0672 to read as follows:

**§ 165.T09–0672 Safety Zone; St. Norbert College Fireworks, Fox River, De Pere, WI.**

(a) *Location.* All navigable waters of the Fox River in De Pere, WI within 500 feet of a vessel used to launch fireworks at coordinates 44°26'55" N, 088°03'50" W.

(b) *Enforcement Period.* The regulated area described in paragraph (a) will be enforced from 7:30 p.m. through 9 p.m. on August 25, 2019.

(c) *Regulations.* (1) In accordance with the general regulations in section § 165.23, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Lake Michigan (COTP) or a designated on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the COTP or a designated on-scene representative.

(3) The “on-scene representative” of the COTP is any Coast Guard commissioned, warrant or petty officer who has been designated by the COTP to act on his or her behalf.

(4) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or an on-scene representative to obtain permission to do so. The COTP or an on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP or an on-scene representative.

Dated: August 2, 2019.

**L.M. Lusk,**

*Commander, U.S. Coast Guard, Acting Captain of the Port Sector Lake Michigan.*

[FR Doc. 2019–16960 Filed 8–7–19; 8:45 am]

**BILLING CODE 9110–04–P**

## DEPARTMENT OF DEFENSE

### Department of the Army, Corps of Engineers

#### 33 CFR Part 334

[COE–2017–0006]

#### Little Creek Harbor, Fisherman’s Cove, Joint Expeditionary Base Little Creek-Fort Story, Little Creek, Virginia, Restricted Areas

**AGENCY:** U.S. Army Corps of Engineers, DoD.

**ACTION:** Final rule.

**SUMMARY:** The Corps of Engineers is establishing restricted areas in the waters of Fisherman’s Cove and Little Creek Harbor at Joint Expeditionary Base Little Creek-Fort Story, Little Creek (JEBLCFS) in Virginia Beach, Virginia. JEBLCFS is the homeport of numerous ships, small boats, and special operational units. The restricted areas are necessary to better protect vessels and personnel assigned to JEBLCFS by implementing a waterside security program. The regulation establishes the restricted areas in waters within the boundary of the existing installation and in the entry channel into the harbor.

**DATES:** Effective September 9, 2019.

**ADDRESSES:** U.S. Army Corps of Engineers, Attn: CECW–CO (David Olson), 441 G Street NW, Washington, DC 20314–1000.

**FOR FURTHER INFORMATION CONTACT:** Mr. David Olson, Headquarters, Operations and Regulatory Community of Practice, Washington, DC at 202–761–4922, or Ms. Nicole Woodward, Corps of Engineers, Norfolk District, Regulatory Branch, at 757–201–7122.

**SUPPLEMENTARY INFORMATION:** The proposed rule was published in the May 23, 2018, edition of the **Federal Register** (83 FR 23867) and the *regulations.gov* docket number was COE–2017–0006. In response to the proposed rule, two comments were received.

One commenter stated that additional clarification was needed regarding the coordinates for the proposed restricted areas because as written it is unclear what the intended extent of the areas should be. The Navy provided corrected coordinates and modified the rule text to address the charting concerns.

Another commenter questioned the need for the additional restrictions to enhance security within the waterway, and the commenter expressed concerns regarding the enforceability of the proposed restrictions, as well as what impacts they would have on local businesses, property values, and navigational access. The proposed rule would have provided greater restrictions within Little Creek Harbor, including requiring all vessels transiting inbound/outbound of the Outer Harbor to notify the Little Creek Port Control of their destination and intentions using VHF–FM channel 12 at all times. In response to these comments, the restrictions were modified to allow for all privately owned vessels, properly registered and bearing identification in accordance with Federal and/or State laws and regulations, and all Government owned vessels (public vessels), to enter or exit the restricted area at any time at a speed commensurate with minimum wake,

except for when the Commanding Officer, JEBLCFS, is ordered to implement Force Protection Condition (FPCON) Charlie/Delta, or when specific authority is granted by the District Engineer, at which time vessel traffic movement within the Outer Harbor may be restricted temporarily. This rule will not prevent the public from entering the areas at all times; it will merely restrict the amount of time during which individuals may enter and stay within those areas, particularly during periods of increased threats. In order to improve the safety of military assets, as well as to the public, the rule also requires vessels entering those areas to provide additional notification and be given permission to enter the area. The regulation does not grant the Navy additional legal authority beyond their current authorities; however, it allows them to use additional resources to enforce the waterway, such as the U.S. Coast Guard and Virginia Marine Resource Commission acting within their own authorities to police the waterway. If conditions warrant elevating restrictions within the Outer Harbor Restricted Area due to implementation of FPCON Charlie/Delta or when specifically authorized by the District Engineer, then JEBLCFS will coordinate with the U.S. Coast Guard to allow vessel entry into the restricted area upon request. Vessels will still be able to transit the waterway to access the businesses and private properties located upstream of the restricted area; therefore, the impacts on businesses and property values are anticipated to be minimal.

Due to the location of JEBLCFS, which is located south of a narrow inlet off of the Chesapeake Bay, alternatives to the location of a restricted area within the waterway near the entrance to the water based side of the installation are limited. This regulation establishes a restricted area within the Outer Harbor which will be enacted on a temporary basis during periods of heightened threat conditions. Reducing the speeds of vessels within the waterway allows the Navy to better assess vessels as they approach through the narrow opening to the Inner Harbor. The Navy will be better able to determine whether the vessels are a threat intending to approach the installation or if they will make the 90-degree turn west toward the commercial and private facilities within Fisherman’s Cove. Full-time restrictions on the Inner Harbor Restricted Area will allow the Navy to assess the safety of all vessels that approach in close vicinity of Government owned vessels and

property in order to better protect those military assets and the personal stationed at Little Creek. There are current measures in place, such as existing barriers and regulations to protect the Navy vessels within the harbor. However, the restricted areas will provide a more permanent safety measure and allow for enhanced measures to be enacted to protect additional property and personnel within the installation as needed.

In response to the Norfolk District's public notice, 178 individuals submitted requests to the district for a public hearing. The purpose of a public hearing is to gain information regarding the proposal that is pertinent to the decision-making process that cannot be obtained through other means. In accordance with the Corps' regulations at 33 CFR 334.4(c), the district engineer decides whether to hold a public hearing for a proposed restricted area or danger zone. The Norfolk District denied the request for a public hearing because it determined that, through the proposed rule published in the **Federal Register** and the public notice for the proposed rule issued by the Norfolk District, it received sufficient information to evaluate the proposal, and that the comments received in response to the proposed rule have been fully addressed. Therefore, we have determined that public hearing is not necessary in order to make a decision because a public hearing is unlikely to provide additional substantive information for this rulemaking action.

In response to a request by the United States Navy, and pursuant to its authorities in Section 7 of the Rivers and Harbors Act of 1917 (40 Stat. 266; 33 U.S.C. 1) and Chapter XIX of the Army Appropriations Act of 1919 (40 Stat. 892; 33 U.S.C. 3), the Corps of Engineers is amending 33 CFR part 334 to establish a permanent restricted area, in the waters of Fisherman's Cove and Little Creek Harbor adjacent to Joint Expeditionary Base Little Creek-Fort Story, Little Creek (JEBLCFS) in Virginia Beach, Virginia.

### Procedural Requirements

#### 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. For the reasons stated below, this final rule is not a "significant regulatory action" under

Executive Order 12866. Accordingly, this final 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.

The Corps determined this final rule is not a significant regulatory action because this restricted area regulation allows all privately owned vessels that are properly registered and bearing identification in accordance with federal and/or state laws and regulations, as well as all government-owned vessels, to enter or exit the Outer Harbor restricted area at any time at a speed commensurate with minimum wake, except when the Commanding Officer, JEBLCFS, is ordered to implement Force Protection Condition (FPCON) Charlie/Delta, or when specific authority is granted by the District Engineer, at which time vessel traffic movement within the Outer Harbor may be restricted temporarily. The Inner Harbor Restricted Area is restricted to those privately owned vessels or persons calling upon the commercial/private piers located within the Inner Harbor and government-owned vessels transiting to and from U.S. Navy or U.S. Coast Guard facilities and authorized DOD patrons of the U.S. Navy recreational marina, plus any other vessels or persons granted specific authorization by Commanding Officer, Joint Expeditionary Base Little Creek-Fort Story, and/or other persons or agencies as he/she may designate. This rule is issued with respect to a military function of the Department of Defense and the provisions of Executive Order 12866 do not apply.

#### 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 Corps certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities. While some owners or operators of vessels that intend to transit the restricted area may be small entities, for the reasons stated in paragraph (a) above, this rule would not have a significant economic impact on any vessel owner or operator because it allows, with exceptions provide in the rule text, all privately owned vessels

that are properly registered and bearing identification in accordance with federal and/or state laws and regulations, as well as all government-owned vessels, to enter or exit the restricted areas at any time at a speed commensurate with minimum wake. In addition, the restricted areas are necessary to protect vessels and personnel assigned to JEBLCFS by implementing a waterside security program. Small entities can also utilize navigable waters outside of the restricted areas. Small entities that need to transit the restricted areas may do so as long as the operator of the vessel obtains permission from Little Creek Port Control or the Commanding Officer, JEBLCFS, and/or other persons or agencies as he/she may designate. The restricted areas are necessary for security of JEBLCFS. After considering the economic impacts of this final restricted area regulation on small entities, I certify that this action will not have a significant impact on a substantial number of small entities.

#### c. Review Under the National Environmental Policy Act

Due to the administrative nature of this action and because there is no intended change in the use of the area, the Corps expects that this regulation, if adopted, will not have a significant impact to the quality of the human environment and, therefore, preparation of an environmental impact statement is not required. An environmental assessment has been prepared. It may be reviewed at the District office listed at the end of the **FOR FURTHER INFORMATION CONTACT** section, above.

#### d. Unfunded Mandates Act

This proposed rule does not impose an enforceable duty among the private sector and, therefore, it is not a Federal private sector mandate and it is not subject to the requirements of either Section 202 or Section 205 of the Unfunded Mandates Act. We have also found under Section 203 of the Act, that small governments will not be significantly and uniquely affected by this rulemaking.

#### e. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, 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. We will submit a report containing the final rule and other required information to the U.S. Senate, the U.S. House of

Representatives, and the Comptroller General of the United States. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

#### List of Subjects in 33 CFR Part 334

Danger zones, Marine safety, Navigation (water), Restricted areas, Waterways.

For the reasons set out in the preamble, the Corps amends 33 CFR part 334 as follows:

#### PART 334—DANGER ZONE AND RESTRICTED AREA REGULATIONS

■ 1. The authority citation for 33 CFR Part 334 continues to read as follows:

**Authority:** 40 Stat. 266 (33 U.S.C. 1) and 40 Stat. 892 (33 U.S.C. 3).

■ 2. Add 334.305 to read as follows:

##### § 334.305 Little Creek Harbor, Fisherman's Cove, Joint Expeditionary Base Little Creek-Fort Story, Little Creek, Virginia, Restricted Areas.

(a) *The Little Creek Restricted Areas.* The Little Creek Restricted Areas consist of two distinct areas: The Outer Harbor Restricted Area and the Inner Harbor Restricted Area. The datum for the coordinates in this section is NAD-83.

(1) *The Outer Harbor Restricted Area.* The waters within an area beginning at latitude 36°55'57.7" N, longitude 76°10'35" W; thence southwesterly to a point at latitude 36°55'53" N, longitude 76°10'44" W, thence southerly to latitude 36°55'21.2" N, longitude 76°10'42" W; thence southwesterly to latitude 36°55'18.3" N, longitude 76°10'49" W; thence northwesterly to a point in Fisherman's Cove at latitude 36°55'22" N, longitude 76°11'15.5" W; thence southerly to latitude 36°55'19.2" N, longitude 76°11'16" W, thence easterly near the southern shoreline of Fisherman's Cove, to latitude 36°55'15.8" N, longitude 76°10'58.8" W; and ending at latitude 36°55'18" N, longitude 76°10'30" W; thence to the point of origin.

(2) *The Inner Harbor Restricted Area.* The waters within Little Creek Harbor south of a line beginning at latitude 36°55'15.8" N, longitude 76°10'58.8" W; and ending at latitude 36°55'18" N, longitude 76°10'30" W.

(b) *The regulations—*(1) *The Outer Harbor Restricted Area.* (i) All privately owned vessels, properly registered and bearing identification in accordance with Federal and/or State laws and regulations, and all Government owned vessels (public vessels) may enter or exit the waters described in paragraph (a)(1) of this section at any time and transit

inbound/outbound of the marked dredged channel leading to Little Creek Harbor between jetties 8 miles westward of Cape Henry Light. All vessels transiting inbound/outbound of the channel except for those vessels listed in paragraph (c)(2) of this section shall proceed at speeds commensurate with minimum wake. Any vessel equipped with a marine radio can monitor VHF-FM channel 12 for message traffic from Little Creek Port Control.

(ii) When Commanding Officer, Joint Expeditionary Base Little Creek-Fort Story is ordered to implement Force Protection Conditions (FPCONs) Charlie/Delta, or when specific authority is granted by the District Engineer, all vessel traffic movement can be restricted except for those vessels that meet the criteria in paragraph (c)(2) of this section. FPCONs are a system of protective measures used by the Department of Defense (DOD) installations to guard against and deter terrorist attack. Senior commanders assign the FPCONs for their region, and installation commanders may raise FPCONs and tighten security measures based on local conditions. In the event FPCONs Charlie/Delta is implemented by the Commanding Officer, Joint Expeditionary Base Little Creek, which requires the restriction of vessel traffic movement in the Outer Harbor Restricted Area, the installation will coordinate with the U.S. Coast Guard, Fifth District; Army Corps of Engineers, Norfolk District; and state and local law enforcement and governmental authorities. The installation will also disseminate information to the public and local news media outlets. Information on whether vessel traffic movement has been restricted in the Outer Harbor Restricted Area due to the implementation of FPCONs Charlie/Delta will also be published and disseminated by the U.S. Coast Guard.

(2) *The Inner Harbor Restricted Area.* All vessels or persons intending to transit inbound/outbound of the Inner Harbor Restricted Area shall request permission from Little Creek Harbor Port Control using VHF-FM channel 12 prior to transiting and will provide their destination/intentions with the exception of those vessels that meet the criteria in paragraph (c)(2) of this section. The Inner Harbor Restricted Area is limited to those privately owned vessels or persons calling upon the commercial/private piers located within the Inner Harbor and government owned vessels (public vessels) transiting to and from U.S. Navy or U.S. Coast Guard facilities and authorized DOD patrons of the U.S. Navy recreational marina. No other vessels or persons may

enter or exit this area unless specific authorization is granted by Commanding Officer, Joint Expeditionary Base Little Creek-Fort Story, and/or other persons or agencies as he/she may designate.

(3) All vessels or persons transiting inbound/outbound of the Inner Harbor Restricted Area are subject to all applicable federal and state laws including laws or regulations designed to protect the naval facility and persons or vessels assigned therein. Federal and state law enforcement officials may at any time take action to ensure compliance with their respective laws. In addition, this regulation authorizes Navy security personnel, designated by Commander, Joint Expeditionary Base Little Creek-Fort Story or persons authorized to act in his/her behalf, the authority to ascertain the identity and intent of any vessels and/or persons transiting the restricted area that indicate by way of appearance or action they are a possible threat to government assets. If a determination is made that the vessel and/or persons are a threat to government assets located within the restricted area, Navy security units may take actions as provided by law or regulation that are deemed necessary to protect government personnel and assets located within the restricted area.

(c) *Enforcement.* (1) The regulation in this section shall be enforced by the Commanding Officer, Joint Expeditionary Base Little Creek-Fort Story, U.S. Coast Guard, local/state law enforcement, and/or persons or agencies as he/she may designate during emergency situations.

(2) Federal and state law enforcement vessels and personnel may enter anywhere in the restricted area at any time in the operation of their statutory missions or to enforce their respective laws.

(3) Nothing in this regulation is deemed to preempt 33 CFR 165.501.

(4) Vessels or persons calling upon the commercial/private piers located within the Inner Harbor with proper identification and clearance will be allowed entry subject to the same provisions described in paragraph (b) of this section. Commanding Officer, Joint Expeditionary Base Little Creek-Fort Story reserves the right to temporarily deny entry in emergency situations, elevated DOD Force Protection conditions in the Harbor, or other safety of navigation constraints.

Dated: August 1, 2019.

**Thomas P. Smith, P.E.,**

Chief, Operations and Regulatory Division,  
Directorate of Civil Works.

[FR Doc. 2019-16972 Filed 8-7-19; 8:45 am]

BILLING CODE 3720-58-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA-R04-OAR-2018-0257; FRL-9997-84-Region 4]

### Air Plan Approval; North Carolina: PSD Requirements for GHGs

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is finalizing approval of two State Implementation Plan (SIP) revisions dated July 30, 2012, and January 12, 2018, submitted by the State of North Carolina through the North Carolina Department of Environmental Quality (NCDEQ). These SIP revisions are related to the State's Prevention of Significant Deterioration (PSD) permitting program requirements for greenhouse gases (GHGs). EPA has determined that the July 30, 2012, and January 12, 2018, SIP revisions are consistent with the Clean Air Act (CAA or Act).

**DATES:** This rule will be effective September 9, 2019.

**ADDRESSES:** EPA has established a docket for this action under Docket Identification No. EPA-R04-OAR-2018-0257. All documents in the docket are listed on the [www.regulations.gov](http://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](http://www.regulations.gov) or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303-8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday

through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

#### FOR FURTHER INFORMATION CONTACT:

Andres Febres, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, Region 4, U.S. Environmental Protection Agency, 61 Forsyth Street SW, Atlanta, Georgia 30303-8960. Mr. Febres can be reached by telephone at (404) 562-8966 or via electronic mail at [febres-martinez.andres@epa.gov](mailto:febres-martinez.andres@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. What is the EPA finalizing today?

EPA received two SIP revisions from NCDEQ, dated July 30, 2012, and January 12, 2018, that include changes to North Carolina's SIP-approved air quality rule at 15 North Carolina Administrative Code (NCAC) 02D .0544—*Prevention of Significant Deterioration Requirements for Greenhouse Gases*.<sup>1 2 3</sup> The 2012 and 2018 revisions include several administrative and typographical changes to the rule, as well as a modification to the date associated with the incorporation by reference (IBR) of 40 CFR 51.166 that was initially meant to capture EPA's final action entitled "Deferral for CO<sub>2</sub> Emissions From Bioenergy and Other Biogenic Sources Under the Prevention of Significant Deterioration (PSD) and Title V Programs" (hereinafter referred to as the "Biomass Deferral Rule").<sup>4</sup> In a March 4, 2019, letter, North Carolina asked EPA to approve changes to the IBR-related paragraph in Section .0544, including the date modification, but to exclude the

<sup>1</sup> EPA notes that the Agency received the SIP revisions on August 3, 2012, and February 2, 2018, respectively.

<sup>2</sup> In the table of North Carolina regulations approved into the SIP at 40 CFR 52.1770(c), 15A NCAC 02D is referred to as "Subchapter 2D Air Pollution Control Requirements."

<sup>3</sup> The PSD permitting program is established in part C of title I of the CAA and applies in areas that meet the National Ambient Air Quality Standards (NAAQS)—"attainment areas"—as well as areas where there is insufficient information to determine if the area meets the NAAQS—"unclassifiable areas." EPA's regulations governing PSD implementation are located at 40 CFR 51.166 and 52.21.

<sup>4</sup> On July 20, 2011, EPA finalized the Biomass Deferral Rule, which deferred for a period of three years, the application of PSD and Title V permitting requirements to carbon dioxide (CO<sub>2</sub>) emissions from bioenergy and other biogenic stationary sources. See 76 FR 43490. Although the United States Court of Appeals for the District of Columbia Circuit vacated the Biomass Deferral Rule in 2013, EPA has not taken formal action to remove the Rule from the CFR at 40 CFR 51.166(b)(48)(ii)(a), 52.21(b)(49)(ii)(a), 70.2(2), and 71.2(2). For more information see the notice of proposed rulemaking associated with this final rulemaking on North Carolina's July 30, 2012, and January 12, 2018 SIP revisions at 84 FR 23750 (May 23, 2019).

adoption of the Biomass Deferral Rule from the IBR.<sup>5</sup>

The 2018 submittal also seeks to remove the PSD requirements for major stationary sources based solely on their GHG emissions; add a new paragraph—paragraph (d)—regarding the global warming potential for GHGs; and re-letter several paragraphs in the rule due to the addition of the new paragraph (*e.g.*, changing paragraph (d) in the existing SIP-approved rule to paragraph (e)).<sup>6</sup> The revisions removing PSD requirements based solely on GHG emissions are in response to court decisions invalidating and vacating the Federal regulations that applied PSD permitting requirements to major sources based solely on their GHG emissions.<sup>7</sup>

The changes to the North Carolina SIP that are the subject of this final rulemaking, as well as EPA's analysis of the changes and rationale for approving them, are described in further detail in a notice of proposed rulemaking (NPRM) published on May 23, 2019 (84 FR 23750). Comments on the NPRM were due on or before June 24, 2019. EPA received no comments on the proposed action and is now taking final action to approve these revisions.

##### II. Incorporation by Reference

In this document, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference, under Subchapter 2D, *Air Pollution Control Requirements*, of the North Carolina SIP, Section .0544—*Prevention of Significant Deterioration Requirements for Greenhouse Gases*, state-effective September 1, 2015.<sup>8</sup> EPA

<sup>5</sup> The March 4, 2019, supplemental letter is located in the docket for this rulemaking.

<sup>6</sup> In North Carolina's January 12, 2018, SIP revision cover letter, the State also mentions changes to rule 15 NCAC 02D Section .0502—*Applicability*, which relates to title V permitting requirements for GHGs. This rule is mentioned because it was approved, together with Section .0544, by the North Carolina Rules Review Commission, but the redline strikeout changes were not included as part of the January 12, 2018 SIP package. Additionally, North Carolina explains in its letter that they do not wish for EPA to review these changes because they are not part of the SIP but rather part of the State's title V operating permit program.

<sup>7</sup> See *Utility Air Regulatory Group (UARG) v. EPA*, 134 S. Ct. 2427 (2014); *Coalition for Responsible Regulation, Inc. v. EPA*, 606 Fed. Appx. 6, 7 (D.C. Cir. 2015).

<sup>8</sup> As discussed above and in the NPRM, EPA is excluding the Biomass Deferral Rule from the July 20, 2011 IBR of 40 CFR 51.166, found in Section .0544(o). The rule text is found at 40 CFR 51.166(b)(48)(ii)(a) and reads as follows: "For purposes of this paragraph (b)(48)(ii)(a), prior to July 21, 2014, the mass of the greenhouse gas carbon dioxide shall not include carbon dioxide

has made, and will continue to make, these materials generally available through [www.regulations.gov](http://www.regulations.gov) and at the EPA Region 4 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the State Implementation Plan, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.<sup>9</sup>

### III. Final Action

EPA is finalizing approval of North Carolina's July 30, 2012, and January 12, 2018, SIP revisions that revise the PSD requirements for GHGs under 15 NCAC 02D .0544—*Prevention of Significant Deterioration Requirements for Greenhouse Gases* as described above and in the NPRM. Specifically, EPA is approving language under paragraph (a) that will prevent the regulation of GHG-only sources; the adoption of new paragraph (d), regarding the definition of global warming potential for GHGs, and the re-lettering of Section .0544 following the new paragraph (d); the deletion of the term "immediately" from paragraph (b)(1); the adoption of paragraph (o), excluding incorporation of the Biomass Deferral Rule into the July 20, 2011 IFR of 40 CFR 51.166; and adoption of various administrative edits such as the addition of acronyms and typographical corrections throughout the rule. EPA believes that these changes are consistent with the requirements of the CAA and therefore is approving the aforementioned changes into the SIP.

### IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the 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 approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 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.

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 October 7, 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 in 40 CFR Part 52

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

Dated: July 29, 2019.

Mary S. Walker,  
Regional Administrator, Region 4.

40 CFR part 52 is 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 (II)—North Carolina

■ 2. Section 52.1770(c), Table (1) is amended under "Subchapter 2D Air Pollution Control Requirements" by revising the entry for "Section .0544" to read as follows:

#### § 52.1770 Identification of plan.

\* \* \* \* \*  
(c) \* \* \*

recovered from the decomposition of non-fossilized and biodegradable organic material)."'

<sup>9</sup> 62 FR 27968 (May 22, 1997).

emissions resulting from the combustion or decomposition of non-fossilized and biodegradable organic material originating from plants, animals, or micro-organisms (including products, by-products,

residues and waste from agriculture, forestry and related industries as well as the non-fossilized and biodegradable organic fractions of industrial and municipal wastes, including gases and liquids

(1) EPA APPROVED NORTH CAROLINA REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Explanation
<b>Subchapter 2D Air Pollution Control Requirements</b>				
<b>Section .0500 Emission Control Standards</b>				
* Section .0544 .....	* Prevention of Significant Deterioration Requirements for Greenhouse Gases.	* 9/1/2015	* 8/8/2019, [Insert citation of publication].	* The July 20, 2011 incorporation by reference date of 40 CFR 51.166 found in paragraph (o) does not incorporate the text of the federal Biomass Deferral Rule at 51.166(b)(48)(ii)(a).

\* \* \* \* \*  
[FR Doc. 2019-16781 Filed 8-7-19; 8:45 am]  
BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

[EPA-R02-OAR-2019-0157; FRL-9997-59-Region 2]

**Approval of Air Quality Implementation Plans; New York; Cross-State Air Pollution Rule; NO<sub>x</sub> Ozone Season Group 2, NO<sub>x</sub> Annual, and SO<sub>2</sub> Group 1 Trading Programs**

**AGENCY:** Environmental Protection Agency (EPA).  
**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is taking final action to approve revisions to the New York State Implementation Plan (SIP) addressing requirements of the Cross-State Air Pollution Rule (CSAPR). Under the CSAPR, large electricity generating units in New York are subject to Federal Implementation Plans (FIPs) requiring the units to participate in CSAPR federal trading programs for ozone season emissions of nitrogen oxides (NO<sub>x</sub>), annual emissions of NO<sub>x</sub>, and annual emissions of sulfur dioxide (SO<sub>2</sub>). This action approves into New York's SIP the State's regulations that replace the default allowance allocation provisions of the CSAPR federal trading programs for ozone season NO<sub>x</sub>, annual NO<sub>x</sub>, and annual SO<sub>2</sub> emissions.

**DATES:** This final rule is effective on August 8, 2019.

**ADDRESSES:** EPA has established a docket for this action under Docket ID number EPA-R02-OAR-2019-0157. All documents in the docket are listed on

the [www.regulations.gov](http://www.regulations.gov) website. Although listed in the index, some information is not publicly available, e.g., confidential business information or other information whose disclosure is restricted by 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 through [www.regulations.gov](http://www.regulations.gov), or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.  
**FOR FURTHER INFORMATION CONTACT:** Kenneth Fradkin, Air Programs Branch, Environmental Protection Agency, 290 Broadway, 25th Floor, New York, New York 10007-1866, (212) 637-3702, or by email at [fradkin.kenneth@epa.gov](mailto:fradkin.kenneth@epa.gov).

**SUPPLEMENTARY INFORMATION**

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- I. Background
- II. Public Comment and EPA Response
- III. What action is EPA taking?
- IV. Incorporation by Reference
- V. Statutory and Executive Order Reviews

**I. Background**

On May 21, 2019 (84 FR 22995 and 84 FR 22972), EPA simultaneously published a proposed rule and a direct final rule to approve New York's November 30, 2018 SIP submittal concerning CSAPR<sup>1</sup> trading programs for ozone-season emissions of NO<sub>x</sub>, annual emissions of NO<sub>x</sub>, and annual emissions of SO<sub>2</sub>. The proposed rule and direct final rule also acted to approve New York's revised list of

<sup>1</sup> Federal Implementation Plans; Interstate Transport of Fine Particulate Matter and Ozone and Correction of SIP Approvals, 76 FR 48208 (August 8, 2011) (codified as amended at 40 CFR 52.38 and 52.39 and 40 CFR part 97).

definitions that was submitted to the EPA on July 23, 2015.

The EPA received a public comment on the proposed rule and intended to withdraw the direct final rule prior to the effective date of June 20, 2019. However, the EPA inadvertently did not withdraw the direct final rule prior to that date and the rule prematurely became effective on June 20, 2019, revising the New York SIP to include revised versions of Title 6 of the New York Codes, Rules and Regulations (6 NYCRR), Part 200, Subpart 200.1; 6 NYCRR Part 200, Subpart 200.9; 6 NYCRR Part 243; 6 NYCRR Part 244; and 6 NYCRR 245 on that date. In this action, as described in more detail below, the EPA is responding to the public comment submitted on the proposed revisions to New York's SIP, approves the revised versions of these regulations in New York's SIP, and is amending the effective date of the regulations' inclusion into the SIP to correct our failure to withdraw the direct final rule prior to June 20, 2019.

Large Electric Generating Units (EGUs) in New York are subject to CSAPR FIPs that require the units to participate in the federal CSAPR NO<sub>x</sub> Ozone Season Group 2 Trading Program, the federal CSAPR NO<sub>x</sub> Annual Trading Program, and the federal CSAPR SO<sub>2</sub> Group 1 Trading Program. CSAPR provides a process for the submission and approval of SIP revisions to replace certain provisions of the CSAPR FIPs while the remaining FIP provisions continue to apply. This type of CSAPR SIP is termed an abbreviated SIP.

The New York State Department of Environmental Conservation (DEC) amended portions of Title 6 of the New York Codes, Rules and Regulations to incorporate CSAPR requirements into

the State's rules and allow the DEC to allocate CSAPR allowances to regulated entities in New York. 6 NYCRR Part 243, "Transport Rule NO<sub>x</sub> Ozone Season Trading Program," has been repealed and replaced in its entirety with a new rule, 6 NYCRR Part 243, "CSAPR NO<sub>x</sub> Ozone Season Group 2 Trading Program." 6 NYCRR Part 244, "Transport Rule NO<sub>x</sub> Annual Trading Program," has been repealed and replaced in its entirety with a new rule, 6 NYCRR Part 244, "CSAPR NO<sub>x</sub> Annual Trading Program." 6 NYCRR Part 245, "Transport Rule SO<sub>2</sub> Group 1 Trading Program," has also been repealed and replaced in its entirety with a new rule, 6 NYCRR Part 245, "CSAPR SO<sub>2</sub> Group 1 Trading Program." Attendant revisions were made to 6 NYCRR Part 200, "General Provisions," to update the list of referenced materials at Subpart 200.9 that are cited in the amended New York regulations.

In the notice of proposed rulemaking, the EPA had proposed to approve into the New York SIP the revised versions of 6 NYCRR Parts 200 (Subpart 200.9), 243, 244, and 245 included in the November 30, 2018 submission. The EPA also proposed to repeal from the SIP previous versions of 6 NYCRR Part 243, 6 NYCRR Part 244, and 6 NYCRR Part 245 which implemented New York's discontinued Clean Air Interstate Rule (CAIR) trading program. New York adopted amendments to 6 NYCRR Part 243, 6 NYCRR Part 244, and 6 NYCRR Part 245 that repealed and replaced CAIR trading program rules with CSAPR trading rules on November 12, 2015. Subsequently, on November 11, 2018, New York adopted amendments to 6 NYCRR Part 243, 6 NYCRR Part 244, and 6 NYCRR Part 245 that repealed and replaced the November 12, 2015 adopted rules that implemented New York's CSAPR program with new versions of New York's CSAPR trading program rules. The rules proposed to be repealed from the SIP were 6 NYCRR Part 243, "CAIR NO<sub>x</sub> Ozone Season Trading Program," 6 NYCRR Part 244, "CAIR NO<sub>x</sub> Annual Trading Program," and 6 NYCRR Part 245, "CAIR SO<sub>2</sub> Trading Program."

The EPA also proposed to approve into the New York SIP a revised version of 6 NYCRR Part 200 (Subpart 200.1) to address updated definitions at Part 200.1(f) that were submitted to the EPA on July 23, 2015, and that were associated with a repeal of 6 NYCRR Part 203, "Indirect Sources of Air Contamination."

The revised versions of 6 NYCRR Parts 200 (Subpart 200.9), 243, 244, and 245 included in the November 30, 2018

SIP submission replace the previous versions of those rules that were included in a December 1, 2015 SIP submission. The EPA identified deficiencies in the December 1, 2015 submission but on November 20, 2017 conditionally approved those previous versions of Parts 200, 244, and 245 (but not Part 243) into the SIP (82 FR 57362, December 5, 2017). In a July 6, 2017 letter to the EPA, New York committed to submitting a SIP revision that addressed the identified deficiencies by December 29, 2017. However, New York's response to the conditional approval was not submitted to the EPA by December 29, 2017. The November 30, 2018 SIP submittal addresses the identified deficiencies, but was submitted approximately 11 months late, so the conditional approval is treated as a disapproval.

The EPA did not take action on the previous version of 6 NYCRR Part 243 included in New York's December 1, 2015 submission. Following that submission, the EPA finalized the CSAPR Update rule<sup>2</sup> to address Eastern states' interstate air pollution mitigation obligations with regard to the 2008 Ozone National Ambient Air Quality Standard (NAAQS). Among other things, starting in 2017 the CSAPR Update required New York EGUs to participate in the new CSAPR NO<sub>x</sub> Ozone Season Group 2 Trading Program instead of the earlier CSAPR NO<sub>x</sub> Ozone Season Trading Program (now renamed the "Group 1" program) and replaced the ozone season budget for New York with a lower budget developed to address the revised and more stringent 2008 Ozone NAAQS. In a July 14, 2016 letter to the EPA, New York indicated that the State would revise 6 NYCRR Part 243 to conform with the final CSAPR Update. As indicated earlier in this section New York repealed 6 NYCRR Part 243 and replaced the rule in its entirety with a new rule, 6 NYCRR Part 243, "CSAPR NO<sub>x</sub> Ozone Season Group 2 Trading Program".

In this action, the EPA is responding to the public comment submitted on the proposed revisions to New York's SIP, approves the revised versions of 6 NYCRR Part 200, Subpart 200.1; 6 NYCRR Part 200, Subpart 200.9; 6 NYCRR Part 243; 6 NYCRR Part 244; and 6 NYCRR Part 245 regulations in New York's SIP, and is amending the effective date of the regulations' inclusion into the SIP to correct our failure to withdraw the direct final rule (after the EPA received adverse public comments) prior to the June 20, 2019 effective date of the direct final rule.

<sup>2</sup> 81 FR 74504 (October 26, 2016).

This action approves into New York's SIP state-determined allowance allocation procedures for ozone-season NO<sub>x</sub> allowances that would replace EPA's default allocation procedures for the control periods in 2021 and beyond. Additionally, this action EPA approves into the New York's SIP state-determined allowance allocation procedures for annual NO<sub>x</sub> and SO<sub>2</sub> allowances that would replace EPA's default allocation procedures for the control periods in 2023 and beyond. The approval of this SIP revision does not alter any provision, other than the allowance allocation provisions, of either the CSAPR NO<sub>x</sub> Ozone Season Group 2 Trading Program, the CSAPR NO<sub>x</sub> Annual Trading Program or the CSAPR SO<sub>2</sub> Group 1 Trading Program as applied to New York units. The FIP provisions requiring those units to participate in the programs (as modified by this SIP revision) remain in place.

## II. Public Comment and EPA Response

During the public comment period, the EPA received one relevant comment, which was submitted anonymously. The comment and the EPA's response are discussed in this section of this rulemaking action.

*Comment:* The commenter argues that EPA should disapprove New York's SIP revision because EPA's regulations do not allow for allocation to a separate account like the Energy Efficiency and Renewable Energy Technology (or EERET) account. The commenter states that New York has no authority to unilaterally designate emission credits to an account that is supposed to be for emission units to be able to operate and provide electricity generation to the citizens of New York and the surrounding states.

The commenter also states that the EPA must remove the FIP in place because the EPA has no authority to regulate electricity generation; the CSAPR Update FIPs are illegal and unauthorized as EPA has no authority to regulate beyond the fence line; and that multi-state and multi-facility emission control schemes are illegal. The commenter further states that the EPA must disapprove the SIP since it follows illegal rules and cites the EPA's June 19, 2019 Affordable Clean Energy (or ACE) rule as support for this position.

*Response:* The EPA disagrees with the commenter that EPA's regulations do not allow for allocation to a separate account like the EERET account, and that New York does not have the authority to designate emission credits to the EERET account. The commenter has not identified any provision of the

CSAPR regulations which they assert precludes New York's approach.

CSAPR includes provisions which allow states to submit, for approval into the SIP, revisions to modify or replace the CSAPR FIP requirements while allowing states to continue to meet their transport-related obligations.<sup>3</sup> Through such a SIP revision, a state may replace EPA's default provisions for allocating emission allowances among the state's units by employing any state-selected methodology to allocate or auction the allowances, subject to timing and other criteria. Additionally, EPA's CSAPR rule does not preclude the use of an energy efficiency set-aside by the state.

New York adopted amendments to 6 NYCRR Part 243, 6 NYCRR Part 244, and 6 NYCRR Part 245 on November 11, 2018. New York submitted amended 6 NYCRR Parts 243, 244, and 245 to the EPA as a SIP revision on November 30, 2018. The EPA reviewed and evaluated New York's submittal and proposed to find it approvable because it met CSAPR rule requirements. These requirements included: Meeting timeliness and completeness criteria for submission of the CSAPR SIP; New York's allocation methodology covered all allowances potentially requiring allocation by the state, including allocations to existing and new units, as well as provisions for the disposition of unallocated Indian country new-unit set-asides; New York's methodology provided assurance that state allocations do not exceed the state budget; New York's methodology provided for the submission of state determined allocations by CSAPR rule deadlines; New York's rules included no provisions allowing for alteration of allocations submitted to EPA or recorded; and New York's rules make no other substantive changes to the federal trading program regulations beyond the provisions addressing allowance allocations. The EPA's final approval of a State's rules would allow the state-selected methodology to replace EPA's default allocations, including allocating emissions allowances to an EERET account.

Because EPA's review of the SIP was only to evaluate compliance with the CSAPR regulations, the portions of the comment addressing the legality of the CSAPR Update FIPs are beyond the scope of this rulemaking. The rulemaking promulgating the CSAPR Update FIPs was separately finalized in 2016, and the EPA did not reopen the determinations made in the 2016 final action in its review of New York's SIP. Any comments on the legality of the CSAPR Update should have been raised

during the public comment period in that rulemaking pursuant to CAA section 307(d)(7)(B), and any challenges to the determinations made in that action are properly raised pursuant to CAA section 307(b)(1) in legal challenges to that final action. Such challenges are currently pending in the D.C. Circuit, *see Wisconsin v. EPA*, No. 16-1406 (D.C. Cir.). Such issues are not appropriately raised in comment on EPA's review of a SIP submission merely to determine the state's compliance with EPA's CSAPR regulations.

### III. What action is EPA taking?

The EPA is approving the New York SIP revision submitted on November 30, 2018 concerning allocations to New York units of CSAPR NO<sub>x</sub> Ozone Season Group 2 allowances for the control periods in 2021 and beyond and of CSAPR NO<sub>x</sub> Annual allowances and CSAPR SO<sub>2</sub> Group 1 allowances for the control periods in 2023 and beyond. This rule approves into the New York SIP amendments to 6 NYCRR Parts 243, 244 and 245 that incorporate CSAPR requirements into the State rules and allows the DEC to allocate CSAPR allowances to regulated entities in New York. The EPA is also approving the attendant revisions to 6 NYCRR Part 200 (Subpart 200.9) to update the list of referenced materials cited in the amended New York regulations. The EPA is also approving the New York SIP revision submitted on July 23, 2015, which included a revised version of 6 NYCRR Part 200 (Subpart 200.1) to address updated definitions associated with a repeal of 6 NYCRR Part 203, "Indirect Sources of Air Contamination".

The EPA is also approving the repeal from the SIP previous versions of 6 NYCRR Part 243, 6 NYCRR Part 244, and 6 NYCRR Part 245 which implemented New York's discontinued CAIR trading program. The rules being repealed from the SIP are 6 NYCRR Part 243, "CAIR NO<sub>x</sub> Ozone Season Trading Program,"; 6 NYCRR Part 244, "CAIR NO<sub>x</sub> Annual Trading Program,"; and 6 NYCRR Part 245, "CAIR SO<sub>2</sub> Trading Program."

The EPA is also amending the effective date of the inclusion of these revisions to New York's SIP because the revisions were added to the SIP prematurely on June 20, 2019 when EPA failed to withdraw its direct final rule after receiving a comment on our proposed approval of New York's regulations that replace the default allocation provisions of the CSAPR federal trading programs. This rule which responds to the comment

received finalizes our approval and corrects the premature effective date for inclusion in New York's SIP of revised versions of 6 NYCRR Part 200, Subpart 200.1; 6 NYCRR Part 200, Subpart 200.9; 6 NYCRR Part 243; 6 NYCRR Part 244; and 6 NYCRR Part 245.

Following the approval into the SIP of the revisions to 6 NYCRR Parts 200, 243, 244, and 245, allocations of CSAPR NO<sub>x</sub> Ozone Season Group 2 allowances, CSAPR NO<sub>x</sub> Annual allowances, and CSAPR SO<sub>2</sub> Group 1 allowances will be made according to the provisions of New York's SIP instead of 40 CFR 97.411(a), 97.411(b)(1), 97.412(a), 97.611(a), 97.611(b)(1), 97.612(a), CFR 97.811(a), 97.811(b)(1), and 97.812(a). The EPA's action on this SIP revision does not alter any provisions of the federal CSAPR NO<sub>x</sub> Ozone Season Group 2 Trading Program, the federal CSAPR NO<sub>x</sub> Annual Trading Program, and the federal CSAPR SO<sub>2</sub> Group 1 Trading Program as applied to New York units other than the allowance allocation provisions, and the FIPs requiring the units to participate in the programs (as modified by this SIP revision) remain in place. The EPA is approving Parts 200, 243, 244 and 245 because New York's rules meet the requirements of the CAA and the EPA's regulations for an abbreviated SIP revision and will replace EPA's default allocations of CSAPR emission allowances with state-determined allocations, as discussed in sections I and II above.

This final rule is effective immediately upon publication in the **Federal Register**. Section 553(d) of the Administrative Procedure Act (5 U.S.C. 553(d)), which generally provides that final rules may not take effect earlier than 30 days after publication in the **Federal Register** but allows exceptions where an agency finds good cause and publishes its finding with the rule, applies to this action. In this rule, in accordance with options CSAPR makes available to states, EPA is approving into New York's SIP the State's rules which include allocation provisions to replace the default federally-established allocations for control periods in 2021 and later years.<sup>4</sup> The sooner this rule is effective, the sooner allowances eligible for use for the 2021 control period can

<sup>4</sup> Under the CSAPR trading programs, allowance allocations are recorded up to four years in advance of the control periods for which the allowances are issued. New York's allowance allocation procedures for ozone season NO<sub>x</sub> allowances would replace EPA's default allocation procedures for the control periods in 2021 and beyond. New York's allowance allocation procedures for annual NO<sub>x</sub> and SO<sub>2</sub> allowances would replace EPA's default allocation procedures for the control periods in 2023 and beyond.

<sup>3</sup> See 40 CFR 52.38, 52.39.

be issued to affected sources in New York in the amounts determined under New York rules. EPA therefore finds good cause to make this final rule effective immediately upon publication in the **Federal Register**.

#### IV. Incorporation By Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of revisions to 6 NYCRR Parts 200, Subpart 200.1, entitled “General Provisions, Definitions,” adopted April 18, 2013; 6 NYCRR Part 200, Subpart 200.9, entitled “General Provisions, Referenced Material,” adopted on November 11, 2018; 6 NYCRR Part 243, entitled “CSAPR NO<sub>x</sub> Ozone Season Group 2 Trading Program,” adopted November 11, 2018; 6 NYCRR Part 244, entitled “CSAPR NO<sub>x</sub> Annual Trading Program,” adopted November 11, 2018; and NYCRR Part 245, entitled “CSAPR SO<sub>2</sub> Group 1 Trading Program,” adopted November 11, 2018. The EPA has made, and will continue to make, these materials generally available through [www.regulations.gov](http://www.regulations.gov), and at the EPA Region 2 Office. Copies of materials incorporated may be inspected at the Environmental Protection Agency, Region 2, Air Programs Branch, 290 Broadway, New York, New York 10007. Please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information. Therefore, these materials have been approved by the EPA for inclusion in the SIP, have been incorporated by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA’s approval, and will be incorporated by reference in the next update of the SIP compilation.<sup>5</sup>

#### V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the 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 Clean Air Act. Accordingly, this action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those

imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 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 Clean Air Act; 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 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).
- 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 Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 7, 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 in 40 CFR Part 52

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

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

Dated: July 22, 2019.

**Peter D. Lopez,**  
Regional Administrator, Region 2.

Part 52 chapter I, title 40 of the Code of Federal Regulations is 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 A—General Provisions

##### § 52.38 [Amended]

- 2. In § 52.38, paragraph (b)(13)(iii) is amended by removing “[none].” and adding in its place “New York.”.

#### Subpart HH—New York

- 3. In § 52.1670, paragraph (c) is amended by revising the table entries “Title 6, Part 200, Subpart 200.1”, “Title 6, Part 200, Subpart 200.9”, “Title 6,

<sup>5</sup> 62 FR 27968 (May 22, 1997).

Part 243”, “Title 6, Part 244”, and “Title 6, Part 245” to read as follows: **§ 52.1670 Identification of plan.** (c) \* \* \*

EPA-APPROVED NEW YORK STATE REGULATIONS AND LAWS

State citation	Title/subject	State effective date	EPA approval date	Comments
* Title 6, Part 200, Subpart 200.1.	* General Provisions, Definitions.	* 05/19/2013	* 08/08/2019	* The word odor is removed from the Subpart 200.1(d) definition of “air contaminant or air pollutant.”  Redesignation of non-attainment areas to attainment areas (200.1(av)) does not relieve a source from compliance with previously applicable requirements as per letter of Nov. 13, 1981 from H. Hovey, NYSDEC. Changes in definitions are acceptable to EPA unless a previously approved definition is necessary for implementation of an existing SIP regulation. EPA is including the definition of “federally enforceable” with the understanding that (1) the definition applies to provisions of a Title V permit that are correctly identified as federally enforceable, and (2) a source accepts operating limits and conditions to lower its potential to emit to become a minor source, not to “avoid” applicable requirements. • EPA is approving incorporation by reference of those documents that are not already federally enforceable. • EPA approval finalized at [insert <b>Federal Register</b> citation].
* Title 6, Part 200, Subpart 200.9.	* General Provisions, Referenced Material.	* 01/02/2019	* 08/08/2019	* • EPA is approving reference documents that are not Federally enforceable. • EPA approval finalized at [insert <b>Federal Register</b> citation].
* Title 6, Part 243 ..	* CSAPR NO <sub>x</sub> Ozone Season Group 2 Trading Program.	* 01/02/2019	* 08/08/2019	* • EPA approval finalized at [insert <b>Federal Register</b> citation].
* Title 6, Part 244 ..	* CSAPR NO <sub>x</sub> Annual Trading Program.	* 01/02/2019	* 08/08/2019	* • EPA approval finalized at [insert <b>Federal Register</b> citation].
* Title 6, Part 245 ..	* CSAPR SO <sub>2</sub> Group 1 Trading Program.	* 01/02/2019	* 08/08/2019	* • EPA approval finalized at [insert <b>Federal Register</b> citation].

\* \* \* \* \*  
[FR Doc. 2019-16789 Filed 8-7-19; 8:45 am]  
BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 300**

[EPA-HQ-SFUND-1987-0002; FRL-9997-43-Region 7]

**National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Partial Deletion of the Shaw Avenue Dump Superfund Site**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) Region 7 announces the deletion of Operable Unit 1—Chemical Fill and Contaminated Soil (OU1) of the Shaw Avenue Dump Superfund Site (Site) located in Charles City, Floyd County, Iowa, from the National Priorities List (NPL). The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). This partial deletion pertains to Operable Unit (OU) 1—Chemical Fill and Contaminated Soil. OU 2—Groundwater will remain on the NPL and is not being considered for deletion as part of this action. The EPA and the State of Iowa, through the Iowa Department of Natural Resources,

determined that all appropriate response actions under CERCLA other than operations and maintenance and five-year reviews have been completed at OU1. However, this deletion does not preclude future actions under CERCLA.

**DATES:** This action is effective August 8, 2019.

**ADDRESSES:** EPA has established a docket for this action under Docket ID no. EPA-HQ-SFUND-1987-0002. All documents in the docket are listed on the <http://www.regulations.gov> website. Although listed in the index, some information is not 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 <http://www.regulations.gov> or in hard copy at the Site information repository. Locations, contacts, and viewing hours of the Site information repository are listed below:

- EPA Region 7, 11201 Renner Boulevard, Lenexa, Kansas 66219, open from 8:00 a.m. to 4:00 p.m. Monday–Friday, excluding Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Hagenmaier, Remedial Project Manager, U.S. Environmental Protection Agency, Region 7, SEMD/LMSE, 11201 Renner Boulevard, Lenexa, KS 66219, telephone (913) 551-7939, email: [hagenmaier.elizabeth@epa.gov](mailto:hagenmaier.elizabeth@epa.gov).

**SUPPLEMENTARY INFORMATION:** The portion of the Site to be deleted from the NPL is Operable Unit 1—Chemical Fill and Contaminated Soil of the Shaw Avenue Dump Superfund site, Charles City, Iowa. A Notice of Intent for Partial Deletion for this Site was published in the **Federal Register** on June 4, 2019 (84 FR 25725).

The closing date for comments on the Notice of Intent for Partial Deletion was July 5, 2019. No public comments were received, and EPA has determined it will proceed with the partial deletion.

EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Deletion of a site from the NPL does not preclude further remedial action. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system. Deletion of portions of a site from the NPL does not affect responsible party liability, in the unlikely event that future conditions warrant further actions.

**List of Subjects in 40 CFR Part 300**

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Penalties, Reporting and recordkeeping

requirements, Superfund, Water pollution control, Water supply.

Dated: August 2, 2019.

**James Gulliford,**  
Regional Administrator, Region 7.

For reasons set out in the preamble, 40 CFR part 300 is amended as follows:

**PART 300—NATIONAL OIL AND HAZARDOUS SUBSTANCES POLLUTION CONTINGENCY PLAN**

- 1. The authority citation for part 300 continues to read as follows:

**Authority:** 33 U.S.C. 1321(d); 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3 CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

- 2. Table 1 of appendix B to part 300 is amended by revising the listing under Iowa for “Shaw Avenue Dump” to read as follows:

**Appendix B to Part 300—National Priorities List**

TABLE 1—GENERAL SUPERFUND SECTION

State	Site name	City/county	Notes (a)
IA	Shaw Avenue Dump	Charles City	P

(a) = Based on issuance of health advisory by Agency for Toxic Substances and Disease Registry (if scored, HRS score need not be greater than or equal to 28.50).

\* P = Sites with partial deletion(s).

[FR Doc. 2019-16904 Filed 8-7-19; 8:45 am]

BILLING CODE 6560-50-P

**DEPARTMENT OF THE INTERIOR**

**Fish and Wildlife Service**

**50 CFR Part 20**

[Docket No. FWS-HQ-MB-2019-0008; FF09M21200-189-FXMB1231099BPP0]

RIN 1018-BD90

**Migratory Bird Hunting; Normal Agricultural Operations**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Final rule.

**SUMMARY:** The Agriculture Improvement Act of 2018 includes a provision that directs the Secretary of the Interior to revise the Federal migratory bird hunting regulations in part 20 of title 50

of the Code of Federal Regulations. The provision directs the Secretary to clarify that rice ratooning and post-disaster flooding, when carried out as part of a normal agricultural operation, do not constitute baiting. Current Federal regulations in 50 CFR part 20 prohibit the use of baiting to attract birds when hunting. This rule implements the Congressional directives in the Agriculture Improvement Act of 2018 by making the necessary revisions to the migratory bird hunting regulations regarding rice ratooning and post-disaster flooding.

**DATES:** This action is effective August 8, 2019.

**ADDRESSES:** This final rule is available on the internet at <http://www.regulations.gov> in Docket No. FWS-HQ-MB-2019-0008.

**FOR FURTHER INFORMATION CONTACT:** Ron W. Kokel, U.S. Fish and Wildlife Service, Department of the Interior, MS: MB, 5275 Leesburg Pike, Falls Church,

VA 22041-3803; (703) 358-1967. If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service at 800-877-8339.

**SUPPLEMENTARY INFORMATION:**

**Background**

In 1916, the United States and Great Britain (on behalf of Canada), signed a treaty to protect migratory birds. In 1918, Congress passed the Migratory Bird Treaty Act (MBTA) (16 U.S.C. 703-711) to implement the treaty with Canada. Among other things, the MBTA, as enacted, prohibited unauthorized hunting and selling of birds covered by the treaty. The United States later signed bilateral treaties with Mexico, Japan, and the Union of Soviet Socialist Republics to protect migratory birds. After each treaty was signed, Congress amended the MBTA to cover the species addressed in that treaty. Unless permitted by regulation, the MBTA

prohibits the “taking” and “killing” of migratory birds (16 U.S.C. 703, 704).

“Take” is defined in part 10 of title 50 of the Code of Federal Regulations (CFR) as “to pursue, hunt, shoot, wound, kill, trap, capture, or collect, or attempt to pursue, hunt, shoot, wound, kill, trap, capture, or collect” (50 CFR 10.12). “Migratory bird” means any bird protected by any of the treaties and currently includes those bird species in the United States listed in 50 CFR 10.13, regardless of whether the particular species actually migrates.

Under the MBTA, the Secretary of the Interior is authorized to determine when “hunting, taking, capture, killing, possession, sale, purchase, shipment, transportation, carriage, or export” of migratory game birds can take place, and to adopt regulations for this purpose. The regulations governing the hunting of migratory game birds are located at 50 CFR part 20. The responsibility for issuing and enforcing the migratory game bird hunting regulations has been delegated to the U.S. Fish and Wildlife Service as the lead Federal agency for managing and conserving migratory birds in the United States.

#### Congressional Action

The Agriculture Improvement Act of 2018 (Pub. L. 115–334, Act) was enacted on December 20, 2018. A provision of that act directs the Secretary of the Interior, within 30 days of enactment of the law and in consultation with the Secretary of Agriculture, to revise part 20 of title 50, Code of Federal Regulations, to clarify that rice ratooning and post-disaster flooding, when carried out as part of a normal agricultural operation, do not constitute baiting. Specifically, section 12601 of the Agriculture Improvement Act of 2018 defined “*normal agricultural operation*” as having the meaning given the term in § 20.11 of title 50, Code of Federal Regulations (as in effect on the date of enactment of this Act). Post-disaster flooding is defined as the destruction of a crop through flooding in accordance with practices required by the Federal Crop Insurance Corporation for agricultural producers to obtain crop insurance under the Federal Crop Insurance Act (7 U.S.C. 1501 *et seq.*) on land on which a crop was not harvestable due to a natural disaster (including any hurricane, storm, tornado, flood, high water, wind-driven water, tidal wave, tsunami, earthquake, volcanic eruption, landslide, mudslide, drought, fire, snowstorm, or other catastrophe that is declared a major disaster by the President in accordance with section

401 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5170)) in the crop year—

- in which the natural disaster occurred; or
- immediately preceding the crop year in which the natural disaster occurred.

Section 12601 of the Act defines “*rice ratooning*” to mean the agricultural practice of harvesting rice by cutting the majority of the aboveground portion of the rice plant but leaving the roots and growing shoot apices intact to allow the plant to recover and produce a second crop yield.

In addition, the Act requires the Secretary of the Interior, in consultation with the Secretary of Agriculture, not later than 30 days after its enactment to revise part 20 of title 50, Code of Federal Regulations, to clarify that rice ratooning and post-disaster flooding, when carried out as part of a normal agricultural operation, do not constitute baiting.

#### Current Regulations

Terms that are used in the migratory bird hunting regulations in title 50 of the CFR are defined at 50 CFR 20.11 (2018 Edition). <https://www.govinfo.gov/content/pkg/CFR-2018-title50-vol9/pdf/CFR-2018-title50-vol9-sec20-11.pdf>. This section defines “*normal agricultural planting, harvesting, or post-harvest manipulation*” as meaning a planting or harvesting undertaken for the purpose of producing and gathering a crop, or manipulation after such harvest and removal of grain, that is conducted in accordance with official recommendations of State Extension Specialists of the Cooperative Extension Service of the U.S. Department of Agriculture. “*Normal agricultural operation*” is defined as meaning a normal agricultural planting, harvesting, post-harvest manipulation, or agricultural practice that is conducted in accordance with official recommendations of State Extension Specialists of the Cooperative Extension Service of the U.S. Department of Agriculture. “*Baited area*” means any area on which salt, grain, or other feed has been placed, exposed, deposited, distributed, or scattered, if that salt, grain, or other feed could serve as a lure or attraction for migratory game birds to, on, or over areas where hunters are attempting to take them. Any such area will remain a baited area for 10 days following the complete removal of all such salt, grain, or other feed. Finally, § 20.11 defines “*baiting*” to mean the direct or indirect placing, exposing, depositing, distributing, or scattering of

salt, grain, or other feed that could serve as a lure or attraction for migratory game birds to, on, or over any areas where hunters are attempting to take them.

The regulations in 50 CFR 20.21 (2018 Edition) address illegal methods of hunting migratory birds; one of the prohibited practices includes the use of baiting to attract birds. The regulations pertinent to this rule are found in paragraph (i) of that section, see <https://www.govinfo.gov/content/pkg/CFR-2018-title50-vol9/pdf/CFR-2018-title50-vol9-sec20-21.pdf>.

#### Effects of the Rule

This rule implements the directives set forth in section 12601 of Public Law 115–334. In compliance with that section, we have consulted with the office of the Secretary of Agriculture on this rule. That office concurs with this rulemaking action. To carry out the intent of Congress in the Agriculture Improvement Act of 2018 (Pub. L. 115–334), we hereby amend 50 CFR 20.11, by adding definitions of “post-disaster flooding” and “rice ratooning,” and 50 CFR 20.21(i)(1)(i), by adding these new terms to the regulations concerning baited areas. The new definitions and revised regulations are set forth at the end of this document in the rule portion.

Current regulations allow rice producers to grow rice to completion, harvest it, post-harvest manipulate it, flood it, and hunt over it. Rice growers may also grow rice to completion, not harvest or manipulate it, flood the rice, and hunt over it. If a rice grower chooses to manipulate un-harvested rice, then the growing area constitutes a baited area until all grain is removed at least 10 days prior to hunting. Under this rule, growers can grow rice to completion, harvest it, let the second growth establish, and hunt over it. Growers cannot manipulate the second growth in any way that may expose seed. If the second growth is manipulated, the growing area constitutes a baited area until all grain is removed at least 10 days prior to hunting.

Regulations currently allow the grower of any crop to grow, harvest, post-harvest manipulate, flood, and hunt over the crop. A grower can raise a crop to completion, not harvest or manipulate it, then intentionally flood the crop for the purposes of hunting. If a grower does not harvest a completed crop and decides to manipulate it, the grower must adhere to the 10-day baiting rule prior to hunting. The revised regulations will allow hunting over a crop that is rendered “not harvestable” because of a disaster

declaration under the Stafford Act and for which the Federal Crop Insurance Corporation has declared that the crop may be destroyed by flooding (and only flooding). No other manipulation is allowed. If the crop is manipulated by any means other than flooding, the growing area would be considered a baited area until all the grain is removed at least 10 days prior to hunting.

**Effective Date**

This rule is effective upon publication in the **Federal Register**. Section 12601 of subtitle F of Public Law 115–334 directs the Secretary of the Interior to issue, within 30 days of enactment of the law, this final rule. Therefore, under these circumstances, we have determined, pursuant to 5 U.S.C. 553(b)(B), that prior notice and opportunity for public comment are impracticable and unnecessary. We have further determined, pursuant to 5 U.S.C. 553(d)(3), that the Congressional mandates imposed on the Department of the Interior by the Agriculture Improvement Act of 2018 constitute good cause to make this rule effective upon publication.

**Required Determinations**

This rulemaking implements section 12601 of subtitle F of Public Law 115–334. Issuance of this rule is a nondiscretionary act for the U.S. Fish and Wildlife Service. Therefore, the promulgation of this rule is not subject to any other provision of statute or regulation that applies to the issuance of Federal rules. Accordingly, in issuing this rule, the Service has not made and is not required to make determinations otherwise required by statute, regulation, or Executive Order for the promulgation of Federal rules.

**List of Subjects in 50 CFR Part 20**

Exports, Hunting, Imports, Reporting and recordkeeping requirements, Transportation, Wildlife.

**Regulation Promulgation**

Accordingly, part 20, subchapter B, chapter I of title 50 of the Code of Federal Regulations is amended as follows:

**PART 20—MIGRATORY BIRD HUNTING**

■ 1. The authority citation for part 20 continues to read as follows:

**Authority:** 16 U.S.C. 703 *et seq.*, and 16 U.S.C. 742a–j.

■ 2. Amend § 20.11 by redesignating paragraphs (m) and (n) as paragraphs (o) and (p), respectively, and adding new

paragraphs (m) and (n) to read as follows:

**§ 20.11 What terms do I need to understand?**

\* \* \* \* \*

(m) *Rice ratooning* means the agricultural practice of harvesting rice by cutting the majority of the aboveground portion of the rice plant but leaving the roots and growing shoot apices intact to allow the plant to recover and produce a second crop yield.

(n) *Post-disaster flooding* means the destruction of a crop through flooding in accordance with practices required by the Federal Crop Insurance Corporation for agricultural producers to obtain crop insurance under the Federal Crop Insurance Act (7 U.S.C. 1501 *et seq.*) on land on which a crop was not harvestable due to a natural disaster (including any hurricane, storm, tornado, flood, high water, wind-driven water, tidal wave, tsunami, earthquake, volcanic eruption, landslide, mudslide, drought, fire, snowstorm, or other catastrophe that is declared a major disaster by the President in accordance with section 401 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5170)) in the crop year—

- (1) In which the natural disaster occurred; or
- (2) Immediately preceding the crop year in which the natural disaster occurred.

\* \* \* \* \*

■ 3. Amend § 20.21 by revising paragraph (i)(1)(i) to read as follows:

**§ 20.21 What hunting methods are illegal?**

\* \* \* \* \*

- (i) \* \* \*
- (1) \* \* \*

(i) Standing crops or flooded standing crops (including aquatics); standing, flooded, or manipulated natural vegetation; flooded harvested croplands; or lands or areas where seeds or grains have been scattered solely as the result of a normal agricultural planting, harvesting, post-harvest manipulation, rice ratooning, post-disaster flooding, or normal soil stabilization practice;

\* \* \* \* \*

Dated: July 23, 2019.

**Karen Budd-Falen,**  
*Deputy Solicitor for Parks and Wildlife,*  
*Exercising the Authority of the Assistant Secretary for Fish and Wildlife and Parks.*

[FR Doc. 2019–16629 Filed 8–7–19; 8:45 am]

**BILLING CODE 4333–15–P**

**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

**50 CFR Part 679**

[Docket No. 180831813–9170–02]

RIN 0648–XH071

**Fisheries of the Exclusive Economic Zone Off Alaska; Dusky Rockfish in the West Yakutat District of the Gulf of Alaska**

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

**ACTION:** Temporary rule; closure.

**SUMMARY:** NMFS is prohibiting directed fishing for dusky rockfish in the West Yakutat District of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the 2019 total allowable catch of dusky rockfish in the West Yakutat District of the GOA.

**DATES:** Effective 1200 hours, Alaska local time (A.l.t.), August 5, 2019, through 2400 hours, A.l.t., December 31, 2019.

**FOR FURTHER INFORMATION CONTACT:** Steve Whitney, 907–586–7228.

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

The 2019 total allowable catch (TAC) of dusky rockfish in the West Yakutat District of the GOA is 95 metric tons (mt) as established by the final 2019 and 2020 harvest specifications for groundfish of the (84 FR 9416, March 14, 2019).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2019 TAC of dusky rockfish in the West Yakutat District of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 90 mt, and is setting aside the remaining 5 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached.

Consequently, NMFS is prohibiting directed fishing for dusky rockfish in the West Yakutat District of the GOA. While this closure is effective the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

#### Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the prohibition of directed fishing for dusky rockfish in the West Yakutat District of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of August 2, 2019.

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

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

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

Dated: August 5, 2019.

**Jennifer M. Wallace,**

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

[FR Doc. 2019-16982 Filed 8-5-19; 4:15 pm]

**BILLING CODE 3510-22-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 679

[Docket No. 180831813-9170-02]

RIN 0648-XH070

#### Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Ocean Perch in the West Yakutat District of the Gulf of Alaska

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

**ACTION:** Temporary rule; closure.

**SUMMARY:** NMFS is prohibiting directed fishing for Pacific ocean perch in the West Yakutat District of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the 2019 total allowable catch of Pacific ocean perch in the West Yakutat District of the GOA.

**DATES:** Effective 1200 hours, Alaska local time (A.l.t.), August 5, 2019, through 2400 hours, A.l.t., December 31, 2019.

**FOR FURTHER INFORMATION CONTACT:**

Steve Whitney, 907-586-7228.

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

The 2019 total allowable catch (TAC) of Pacific ocean perch in the West Yakutat District of the GOA is 3,296 metric tons (mt) as established by the final 2019 and 2020 harvest specifications for groundfish of the (84 FR 9416, March 14, 2019).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2019 TAC of Pacific ocean perch in the West Yakutat District

of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 3,196 mt, and is setting aside the remaining 100 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific ocean perch in the West Yakutat District of the GOA. While this closure is effective the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

#### Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of directed fishing for Pacific ocean perch in the West Yakutat District of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of August 2, 2019.

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

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

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

Dated: August 5, 2019.

**Jennifer M. Wallace,**

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

[FR Doc. 2019-16985 Filed 8-5-19; 4:15 pm]

**BILLING CODE 3510-22-P**

# Proposed Rules

Federal Register

Vol. 84, No. 153

Thursday, August 8, 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 TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2019-0576; Product Identifier 2019-NM-049-AD]

RIN 2120-AA64

#### Airworthiness Directives; The Boeing Company Airplanes

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** The FAA proposes to adopt a new airworthiness directive (AD) for all The Boeing Company Model 747-400, 747-400F, 747-8F, and 747-8 series airplanes. This proposed AD was prompted by reports of dual flight management computer (FMC) cold starts during a critical flight phase such as takeoff and approach. This proposed AD would require an inspection to determine if certain software is installed, installation of FMC operational program software (OPS) and a software configuration check, and applicable concurrent requirements. The FAA is proposing this AD to address the unsafe condition on these products.

**DATES:** The FAA must receive comments on this proposed AD by September 23, 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:* Deliver to Mail address above between 9 a.m. and 5

p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminister Blvd., MC 110-SK57, Seal Beach, CA 90740-5600; telephone 562-797-1717; internet <https://www.myboeingfleet.com>. You may view this referenced service information 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 on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2019-0576.

#### 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-2019-0576; 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 is listed above. Comments will be available in the AD docket shortly after receipt.

**FOR FURTHER INFORMATION CONTACT:** Nelson Sanchez, Aerospace Engineer, Systems and Equipment Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; telephone and fax: 206-231-3543; email: [nelson.sanchez@faa.gov](mailto:nelson.sanchez@faa.gov).

#### SUPPLEMENTARY INFORMATION:

##### Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA-2019-0576; Product Identifier 2019-NM-049-AD" at the beginning of your comments. The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. The agency will consider all comments received by the closing date and may amend this NPRM because of those comments.

The FAA will post all comments, without change, to <http://www.regulations.gov>, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this proposed AD.

*www.regulations.gov*, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this proposed AD.

#### Discussion

The FAA has received reports indicating that some operators experienced dual FMC cold starts during a critical flight phase such as takeoff and approach. A cold start is a computer reset that is equivalent to starting from an unpowered (cold) state. During a cold start, the computer is not available to perform its intended function. Dual FMC cold starts can result in a loss of flight critical data from flight deck displays during a high workload phase of flight. This condition, if not addressed, could reduce the flightcrew's situational awareness, resulting in a loss of continued safe flight and landing.

#### Related Service Information Under 14 CFR Part 51

The FAA reviewed Boeing Alert Requirements Bulletin 747-34A3119 RB, dated February 15, 2019; and Boeing Alert Requirements Bulletin 747-34A3125 RB, dated February 15, 2019. The service information describes procedures for installation of the FMC OPS, part number (P/N) HNP5A-AL11-9008, or later-approved software version, and a software configuration check, and applicable concurrent requirements (installing certain software and hardware). These documents are distinct since they apply to airplanes in different configurations.

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

#### FAA's Determination

The FAA is proposing this AD because the agency evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

#### Proposed AD Requirements

This proposed AD would require an inspection to determine if certain software is installed, and if necessary, accomplishment of the actions

identified in Boeing Alert Requirements Bulletin 747-34A3119 RB, dated February 15, 2019; and Boeing Alert Requirements Bulletin 747-34A3125 RB, dated February 15, 2019; described previously, except as discussed under “Differences Between this Proposed AD and the Service Information” and except for any differences identified as exceptions in the regulatory text of this proposed AD.

For information on the procedures and compliance times, see this service information at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2019-0576.

**Explanation of Requirements Bulletin**

The FAA worked in conjunction with industry, under the Airworthiness Directive Implementation Aviation Rulemaking Committee (AD ARC), to enhance the AD system. One enhancement is a process for annotating which steps in the service information are “required for compliance” (RC) with

an AD. Boeing has implemented this RC concept into Boeing service bulletins.

In an effort to further improve the quality of ADs and AD-related Boeing service information, a joint process improvement initiative was worked between the FAA and Boeing. The initiative resulted in the development of a new process in which the service information more clearly identifies the actions needed to address the unsafe condition in the “Accomplishment Instructions.” The new process results in a Boeing Requirements Bulletin, which contains only the actions needed to address the unsafe condition (*i.e.*, only the RC actions).

**Differences Between This Proposed AD and the Service Information**

The effectivity of Boeing Alert Requirements Bulletin 747-34A3119 RB, dated February 15, 2019; and Boeing Alert Requirements Bulletin 747-34A3125 RB, dated February 15, 2019; is limited to certain airplanes as identified in the service information.

However, the applicability of this proposed AD includes all Boeing Model 747-400, 747-400F, 747-8F, and 747-8 series airplanes. Because the affected software versions are rotatable, the FAA has determined that these software versions could later be installed on airplanes that were initially delivered with acceptable software, thereby subjecting those airplanes to the unsafe condition. We have confirmed with Boeing that the Accomplishment Instructions in Boeing Alert Requirements Bulletin 747-34A3119 RB, dated February 15, 2019, and Boeing Alert Requirements Bulletin 747-34A3125 RB, dated February 15, 2019, are applicable to the affected airplanes.

**Costs of Compliance**

The FAA estimates that this proposed AD affects 115 airplanes of U.S. registry. The agency estimates the following costs to comply with this proposed AD:

**ESTIMATED COSTS FOR REQUIRED ACTIONS**

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Records check or inspection .....	1 work-hour × \$85 per hour = \$85	\$0	\$85 .....	\$9,775.
Software installation and configuration check.	2 work-hours × \$85 per hour = \$170.	(*)	\$170* .....	\$19,550.*
Concurrent actions .....	Up to 119 work-hours × \$85 per hour = \$10,115.	(*)	Up to \$10,115* .....	Up to \$1,163,225.*

\* The FAA has received no definitive data that would enable the agency to provide parts cost-estimates for the software installation or concurrent 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.

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

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**

The FAA has 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) Will not affect intrastate aviation in Alaska, and

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

**List of Subjects in 14 CFR Part 39**

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

**The Proposed Amendment**

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

**PART 39—AIRWORTHINESS DIRECTIVES**

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

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

**§ 39.13 [Amended]**

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

**The Boeing Company:** Docket No. FAA–2019–0576; Product Identifier 2019–NM–049–AD.

**(a) Comments Due Date**

The FAA must receive comments by September 23, 2019.

**(b) Affected ADs**

None.

**(c) Applicability**

This AD applies to all The Boeing Company Model 747–400, 747–400F, 747–8F, and 747–8 series airplanes, certificated in any category.

**(d) Subject**

Air Transport Association (ATA) of America Code 34, Navigation.

**(e) Unsafe Condition**

This AD was prompted by reports of dual flight management computer (FMC) cold starts during a critical flight phase such as takeoff and approach. The FAA is issuing this AD to address dual FMC cold starts, which can result in a loss of flight critical data from flight deck displays during a high workload phase of flight. This condition, if not addressed, could reduce the flightcrew's situational awareness, resulting in a loss of continued safe flight and landing.

**(f) Compliance**

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

**(g) Definition**

For the purposes of this AD, later-approved software versions are only those Boeing software versions that are approved as a replacement for the applicable software identified in Boeing Alert Requirements Bulletin 747–34A3119 RB, dated February 15, 2019; or Boeing Alert Requirements Bulletin 747–34A3125 RB, dated February 15, 2019; and are approved as part of the type design by the FAA or The Boeing Company Organization Designation Authorization (ODA) after February 15, 2019 (the issuance date of Boeing Alert Requirements Bulletin 747–34A3119 RB; and Boeing Alert Requirements Bulletin 747–34A3125 RB).

**(h) Required Actions**

(1) For airplanes that have an original airworthiness certificate or export certificate of airworthiness issued on or before the effective date of this AD: Within 6 months after the effective date of this AD, inspect the FMC left and FMC right to determine if FMC operational program software (OPS) software, part number (P/N) HNP5A–AL11–9008, or later-approved software version, as defined in paragraph (g) of this AD, is installed. A review of airplane maintenance records is acceptable in lieu of this inspection if the part number of the FMC OPS can be conclusively determined from that review.

(2) If, during any inspection or records review required by paragraph (h)(1) of this

AD, FMC OPS, P/N HNP5A–AL11–9008, or later-approved software version, as defined in paragraph (g) of this AD, is not found: Within 6 months after the effective date of this AD, do all applicable actions identified in, and in accordance with, the applicable Concurrent Requirements and Accomplishment Instructions of Boeing Alert Requirements Bulletin 747–34A3119 RB, dated February 15, 2019; or Boeing Alert Requirements Bulletin 747–34A3125 RB, dated February 15, 2019; as applicable.

**Note 1 to paragraph (g):** Guidance for accomplishing the actions required by this AD can be found in Boeing Alert Service Bulletin 747–34A3119, dated February 15, 2019, which is referred to in Boeing Alert Requirements Bulletin 747–34A3119 RB, dated February 15, 2019; and Boeing Alert Service Bulletin 747–34A3125, dated February 15, 2019, which is referred to in Boeing Alert Requirements Bulletin 747–34A3125 RB, dated February 15, 2019.

**(i) Parts Installation Limitation**

As of the effective date of this AD: Do not install FMC software unless it is FMC OPS, P/N HNP5A–AL11–9008 or later-approved software version, as defined in paragraph (g) of this AD.

**(j) Alternative Methods of Compliance (AMOCs)**

(1) The Manager, Seattle ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (k)(1) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov*.

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company ODA that has been authorized by the Manager, Seattle ACO Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

**(k) Related Information**

(1) For more information about this AD, contact Nelson Sanchez, Aerospace Engineer, Systems and Equipment Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; telephone and fax: 206–231–3543; email: *nelson.sanchez@faa.gov*.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminister Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://*

*www.myboeingfleet.com*. You may view this referenced service information 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.

Issued in Des Moines, Washington, on July 29, 2019.

**Dionne Palermo,**

*Acting Director, System Oversight Division, Aircraft Certification Service.*

[FR Doc. 2019–16815 Filed 8–7–19; 8:45 am]

**BILLING CODE 4910–13–P**

**DEPARTMENT OF TRANSPORTATION****Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA–2019–0603; Product Identifier 2019–NM–087–AD]

RIN 2120–AA64

**Airworthiness Directives; The Boeing Company Airplanes**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** The FAA proposes to adopt a new airworthiness directive (AD) for certain The Boeing Company Model 777–300ER and 777F series airplanes. This proposed AD was prompted by an evaluation by the design approval holder (DAH) indicating that the fuselage stringers, stringer splices, and skin splice straps are subject to widespread fatigue damage (WFD). This proposed AD would require repetitive detailed inspections of certain stringer splices and skin splice straps for any cracks, repetitive high frequency eddy current (HFEC) inspections of certain stringers and stringer splices for any cracks, and applicable on-condition actions. The agency is proposing this AD to address the unsafe condition on these products.

**DATES:** The FAA must receive comments on this proposed AD by September 23, 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*: Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminister Blvd., MC 110-SK57, Seal Beach, CA 90740-5600; telephone 562-797-1717; internet <https://www.myboeingfleet.com>. You may view this referenced service information 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 on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2019-0603.

#### 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-2019-0603; 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 is listed above. Comments will be available in the AD docket shortly after receipt.

**FOR FURTHER INFORMATION CONTACT:** Eric Lin, Aerospace Engineer, Airframe Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206-231-3523; email: [eric.lin@faa.gov](mailto:eric.lin@faa.gov).

#### SUPPLEMENTARY INFORMATION:

##### Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA-2019-0603; Product Identifier 2019-NM-087-AD" at the beginning of your comments. The agency specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. The FAA will consider all comments received by the closing date and may amend this NPRM because of those comments.

The FAA will post all comments, without change, to <http://www.regulations.gov>, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this proposed AD.

#### 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 transport category airplanes that had already been certificated by the FAA at the time of that rule's enactment, and all transport-category airplanes to be certificated afterward. The rule requires that DAHs establish a limit of validity (LOV) of the engineering data that support the airplanes' structural maintenance program. Operators affected by the WFD rule may not fly an airplane beyond its LOV, unless the FAA approves an extended LOV.

The WFD rule 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 its LOV. Many LOVs, however, 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.

The FAA has received a report indicating that aluminum chips and conical burr foreign object debris (FOD), were found on in-production model 777-300ER and 777F airplanes in the interfaces beneath stringer splices at station (STA) 825+210, STA 655, and STA 1434+189, and the circumferential splices at STA 1832. FOD has been found in splices that were built using an automated drilling and fastener installation process. This automated process is not always sufficient to close gaps that can occur as a result of the manufacturing build sequence and geometry. This process has also resulted in hole defects at these stations. A product acceptance plan has been inadequate in finding holes that were out of tolerance. FOD and hole defects can reduce the fatigue performance of the splices, and the existing Maintenance Planning Data (MPD) inspections do not provide adequate crack detection for the reduced fatigue thresholds. This could lead to undetected cracking.

This condition, if not addressed, could result in undetected fatigue cracks, which could adversely affect the structural integrity of the airplane.

#### Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing Alert Requirements Bulletin 777-53A0091 RB, dated April 8, 2019. The service information describes procedures for repetitive detailed inspections of certain stringer splices and skin splice straps for any cracks, repetitive HFEC inspections of certain stringers and stringer splices for any cracks, and applicable on-condition actions. On-condition actions include repair.

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

#### FAA's Determination

The FAA is proposing this AD because the agency evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

#### Proposed AD Requirements

This proposed AD would require accomplishment of the actions identified in Boeing Alert Requirements Bulletin 777-53A0091 RB, dated April 8, 2019, described previously, except for any differences identified as exceptions

in the regulatory text of this proposed AD.

For information on the procedures and compliance times, see this service information at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2019-0603.

### Explanation of Requirements Bulletin

The FAA worked in conjunction with industry, under the Airworthiness Directive Implementation Aviation Rulemaking Committee (AD ARC), to

enhance the AD system. One enhancement is a process for annotating which steps in the service information are “required for compliance” (RC) with an AD. Boeing has implemented this RC concept into Boeing service bulletins.

In an effort to further improve the quality of ADs and AD-related Boeing service information, a joint process improvement initiative was worked between the FAA and Boeing. The initiative resulted in the development of a new process in which the service information more clearly identifies the

actions needed to address the unsafe condition in the “Accomplishment Instructions.” The new process results in a Boeing Requirements Bulletin, which contains only the actions needed to address the unsafe condition (*i.e.*, only the RC actions).

### Costs of Compliance

The FAA estimates that this proposed AD affects 12 airplanes of U.S. registry. The agency estimates the following costs to comply with this proposed AD:

### ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Detailed and HFEC Inspections.	Up to 79 work-hours × \$85 per hour = Up to \$6,715 per inspection cycle.	\$0	Up to \$6,715 per inspection cycle.	Up to \$80,580 per inspection cycle.

The FAA has have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this proposed AD.

According to the manufacturer, some or all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage for affected individuals. As a result, the agency has included all known costs in its cost estimate.

### Authority for This Rulemaking

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

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

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

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

For the reasons discussed above, I certify this proposed regulation:

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Will not affect intrastate aviation in Alaska, and
- (3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

### List of Subjects in 14 CFR Part 39

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

### The Proposed Amendment

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

### PART 39—AIRWORTHINESS DIRECTIVES

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

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

#### § 39.13 [Amended]

- 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

**The Boeing Company:** Docket No. FAA-2019-0603; Product Identifier 2019-NM-087-AD.

#### (a) Comments Due Date

The FAA must receive comments by September 23, 2019.

#### (b) Affected ADs

None.

#### (c) Applicability

This AD applies to The Boeing Company Model 777-300ER and 777F series airplanes, certificated in any category, as identified in Boeing Alert Requirements Bulletin 777-53A0091 RB, dated April 8, 2019.

#### (d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

#### (e) Unsafe Condition

This AD was prompted by an evaluation by the design approval holder (DAH) indicating that the fuselage stringers, stringer splices, and skin splice straps are subject to widespread fatigue damage (WFD). The FAA is issuing this AD to address undetected fatigue cracks, which could adversely affect the structural integrity of the airplane.

#### (f) Compliance

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

**(g) Required Actions**

Except as specified by paragraph (h) of this AD: At the applicable times specified in the "Compliance" paragraph of Boeing Alert Requirements Bulletin 777-53A0091 RB, dated April 8, 2019, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin 777-53A0091 RB, dated April 8, 2019.

**Note 1 to paragraph (g):** Guidance for accomplishing the actions required by this AD can be found in Boeing Alert Service Bulletin 777-53A0091, dated April 8, 2019, which is referred to in Boeing Alert Requirements Bulletin 777-53A0091 RB, dated April 8, 2019.

**(h) Exceptions to Service Information Specifications**

(1) For purposes of determining compliance with the requirements of this AD: Where Boeing Alert Requirements Bulletin 777-53A0091 RB, dated April 8, 2019, uses the phrase "the original issue date of Requirements Bulletin 777-53A0091 RB" or "the original issue date of this service bulletin," this AD requires using "the effective date of this AD," except where Boeing Alert Requirements Bulletin 777-53A0091 RB, dated April 8, 2019, uses the phrase "the original issue date of this service bulletin" in a note or flag note.

(2) Where Boeing Alert Requirements Bulletin 777-53A0091 RB, dated April 8, 2019, specifies contacting Boeing for repair instructions: This AD requires doing the repair before further flight using a method approved in accordance with the procedures specified in paragraph (i) of this AD.

**(i) Alternative Methods of Compliance (AMOCs)**

(1) The Manager, Seattle ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j)(1) of this AD. Information may be emailed to: 9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

**(j) Related Information**

(1) For more information about this AD, contact Eric Lin, Aerospace Engineer,

Airframe Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206-231-3523; email: [eric.lin@faa.gov](mailto:eric.lin@faa.gov).

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminister Blvd., MC 110-SK57, Seal Beach, CA 90740-5600; telephone 562-797-1717; internet <https://www.myboeingfleet.com>. You may view this referenced service information 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.

Issued in Des Moines, Washington, on July 26, 2019.

**Dionne Palermo,**

*Acting Director, System Oversight Division, Aircraft Certification Service.*

[FR Doc. 2019-16841 Filed 8-7-19; 8:45 am]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF THE TREASURY****Internal Revenue Service****26 CFR Part 1**

**[REG-106282-18]**

**RIN 1545-BP35**

**Limitation on Deduction for Dividends Received From Certain Foreign Corporations and Amounts Eligible for Section 954 Look-Through Exception; Correction**

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Correction to a notice of proposed rulemaking by cross-reference to temporary regulations.

**SUMMARY:** This document contains a correction to notice of proposed rulemaking by cross-reference to temporary regulations (REG-106282-18) that was published in the **Federal Register** on Tuesday, June 18, 2019.

**DATES:** Written or electronic comments and requests for a public hearing for the notice of proposed rulemaking by cross-reference to temporary regulations at 84 FR 28426, June 18, 2019, are still being accepted and must be received by September 16, 2019.

**ADDRESSES:** Send Submissions to CC:PA:LDP:PR (REG-106282-18), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LDP:PR (REG-106282-18), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC 20224. Alternatively,

taxpayers may submit comments electronically, via the Federal eRulemaking Portal at <http://www.regulations.gov> (IRS REG-106282-18).

**FOR FURTHER INFORMATION CONTACT:**

Concerning the proposed regulations, Logan M. Kincheloe, (202) 317-6937; concerning submission of comments and/or requests for a hearing Regina Johnson at (202) 317-6901 (not toll-free numbers).

**SUPPLEMENTARY INFORMATION:****Background**

This correction to the notice of proposed rulemaking (REG-106282-18) that is the subject of this document is issued under sections 245A, 954, and 6038 of the Internal Revenue Code.

**Need for Correction**

As published, the notice of proposed rulemaking by cross-reference to temporary regulations (REG-106282-18) contains errors that may prove to be misleading and are in need of clarification.

**Correction to Publication**

Accordingly, the notice of proposed rulemaking by cross-reference to temporary regulations, FR 2019-12441, published at 84 FR 28426, June 18, 2019, is corrected as follows:

- 1. On page 28426, the first column, under the caption **SUMMARY**, the third line from the bottom of the last paragraph, the language "controlled foreign that receive certain" is corrected to read "controlled foreign corporations that receive certain".
- 2. On page 28427, in the first column, under the last line of the paragraph before the caption Comments and Request Public Hearing section add the following sections:

**III. Unfunded Mandates Reform Act**

The assessment of costs and benefits under the Unfunded Mandated Reform Act of these proposed regulations are explained in the temporary regulations under 245A, 954(c)(6), and 6038 published in 84 FR 28398 (June 18, 2019).

**IV. Executive Order 13132: Federalism**

The assessment of the federalism implications as required under Executive Order 13132 of these proposed regulations is explained in the temporary regulations under sections 245A, 954(c)(6), and 6038 published in 84 FR 28398 (June 18, 2019).

**§ 1.245A-1 [Corrected]**

- 3. On page 28427, second column, the amendatory instruction Par, 2, the

language “Reserved sections 1.245A–1 through and § 1.245A–5 are added to read as follows:” is corrected to read “Add and reserve §§ 1.245A–1 through 1.245A–4 and add § 1.245A–5 to read as follows:”.

**Martin V. Franks,**

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

[FR Doc. 2019–16632 Filed 8–7–19; 8:45 am]

**BILLING CODE 4830–01–P**

## DEPARTMENT OF DEFENSE

### Department of the Army, Corps of Engineers

#### 33 CFR Part 334

[Docket Number: COE–2019–0010]

#### Washington Channel, Fort McNair, Washington, DC; Restricted Area

**AGENCY:** U.S. Army Corps of Engineers, DoD.

**ACTION:** Notice of proposed rulemaking and request for comments.

**SUMMARY:** The Corps of Engineers is proposing to establish a permanent restricted area in the Washington Channel adjacent to Ft. McNair. Ft. McNair is the headquarters of the Army’s Military District of Washington and home of the National Defense University as well as the official residence of the U.S. Army’s Vice Chief of Staff. Ft. McNair requests the restricted area to fulfill Joint Base Myer-Henderson Hall (JBM–HH) security needs including HMX missions and security needs at Ft. McNair including protection of VIP quarters. The restricted area is also needed to protect public health by preventing vessels from disturbing a planned environmental remediation area located near the Fort.

**DATES:** Written comments must be submitted on or before September 9, 2019.

**ADDRESSES:** You may submit comments, identified by docket number COE–2019–0010, by any of the following methods:

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

*Email:* [david.b.olson@usace.army.mil](mailto:david.b.olson@usace.army.mil). Include the docket number, COE–2019–0010, in the subject line of the message.

*Mail:* U.S. Army Corps of Engineers, Attn: CECW–CO–R (David B. Olson), 441 G Street NW, Washington, DC 20314–1000.

*Hand Delivery/Courier:* Due to security requirements, we cannot

receive comments by hand delivery or courier.

**Instructions:** Direct your comments to docket number COE–2019–0010. All comments received will be included in the public docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the commenter indicates that 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 [regulations.gov](http://www.regulations.gov) or email. The [regulations.gov](http://www.regulations.gov) website is an anonymous access system, which means we will not know your identity or contact information unless you provide it in the body of your comment. If you send an email directly to the Corps without going through [regulations.gov](http://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, we recommend that you include your name and other contact information in the body of your comment and also include your contact information with any compact disc you submit. If we cannot read your comment because of technical difficulties and cannot contact you for clarification, we may not be able to consider your comment. Electronic comments should avoid the use of any special characters, any form of encryption, and be free of any defects or viruses.

**Docket:** For access to the docket to read background documents or comments received, go to [www.regulations.gov](http://www.regulations.gov). All documents in the docket are listed. Although listed in the index, some information is not publicly available, such as CBI 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.

**FOR FURTHER INFORMATION CONTACT:** Mr. David Olson, Headquarters, Operations and Regulatory Division, Washington, DC at 202–761–4922, or Mr. Steve Elinsky, Corps of Engineers, Baltimore District, Regulatory Branch, at 410–962–4503.

**SUPPLEMENTARY INFORMATION:** Pursuant to its authorities in Section 7 of the Rivers and Harbors Act of 1917 (40 Stat. 266; 33 U.S.C. 1) and Chapter XIX of the Army Appropriations Act of 1919 (40 Stat. 892; 33 U.S.C. 3), the Corps of

Engineers is proposing amendments to regulations in 33 CFR part 334 for the establishment of a permanent restricted area in waters of the Washington Channel in Washington, DC. In a memorandum dated September 15, 2017, Ft. McNair requested that the Corps establish this permanent restricted area. The proposed permanent restricted area is necessary to fulfill the current security needs of Ft. McNair and Joint Base Myer-Henderson Hall (JBM–HH) at these facilities. Ft. McNair is the headquarters of the Army’s Military District of Washington and home of the National Defense University as well as the official residence of the U.S. Army’s Vice Chief of Staff.

### Procedural Requirements

#### 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 proposed rule has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, this proposed 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.

The Corps has made a determination this proposed rule is not a significant regulatory action. This regulatory action determination is based on the size, duration, and location of the restricted area. The restricted area occupies only a portion of the waterway and a vessel that needs to transit the restricted area may do so if the operator of the vessel obtains permission from the Commanding Officer, JBM–HH or his/her designated representative. Fishermen may be authorized controlled access to the restricted area after registering with JBM–HH/Ft. McNair officials and following specific access notification procedures.

#### 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 Corps certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities. While some owners or operators of vessels that intend to transit the restricted area may be small entities, for the reasons stated in paragraph (a) above this rule would not have a significant economic impact on any vessel owner or operator. In addition, the restricted area is necessary to address the current security needs at Ft. McNair and JBM–HH Washington, DC. Vessels can utilize navigable waters outside of the restricted area. Vessels may also transit the restricted area as long as they obtain permission from the Commanding Officer, JBM–HH or his/her designated representative. Unless information is obtained to the contrary during the comment period, the Corps expects that the economic impact of the proposed restricted area would have practically no impact on the public, any anticipated navigational hazard or interference with existing waterway traffic. After considering the economic impacts of this restricted area regulation on small entities, I certify that this action will not have a significant impact on a substantial number of small entities.

*c. Review Under the National Environmental Policy Act*

Due to the administrative nature of this action and because there is no intended change in the use of the area, the Corps expects that this regulation, if adopted, will not have a significant impact to the quality of the human environment and, therefore, preparation of an environmental impact statement will not be required. An environmental assessment will be prepared after the public notice period is closed and all comments have been received and considered.

*d. Unfunded Mandates Act*

This proposed rule does not impose an enforceable duty among the private sector and, therefore, it is not a Federal private sector mandate and it is not subject to the requirements of either Section 202 or Section 205 of the Unfunded Mandates Act. We have also found under Section 203 of the Act, that small governments will not be significantly and uniquely affected by this rulemaking.

*e. Congressional Review Act*

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, 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. We will submit a report containing the final rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 33 CFR Part 334**

Danger zones, Marine safety, Navigation (water), Restricted Areas, Waterways.

For the reasons set out in the preamble, the Corps proposes to amend 33 CFR part 334 as follows:

**PART 334—DANGER ZONE AND RESTRICTED AREA REGULATIONS**

■ 1. The authority citation for 33 CFR Part 334 continues to read as follows:

**Authority:** 40 Stat. 266 (33 U.S.C. 1) and 40 Stat. 892 (33 U.S.C. 3).

■ 2. Add § 334.225 to read as follows:

**§ 334.225 Washington Channel, Fort Lesley J. McNair, Washington, DC; Restricted Area.**

(a) *The area.* The restricted area shall encompass all navigable waters of the United States as defined at 33 CFR part 329, within the area bounded by a line connecting the following coordinates: Commencing from the shoreline at latitude 38°52′18.776″ N, longitude –077°1′9.436″ W; thence to latitude 38°52′17.696″ N, longitude –077°1′13.345″ W; thence to latitude 38°52′12.798″ N, longitude –077°1′12.114″ W; thence to latitude 38°52′17.559″ N, longitude –077°1′9.706″ W; thence to latitude 38°51′43.667″ N, longitude –077°1′9.771″ W; thence to latitude 38°51′41.135″ N, longitude 077°1′9.45″ W; thence to latitude 38°51′38.723″ N, longitude –077°1′6.921″ W; thence to latitude 38°51′38.257″ N, longitude –077°1′3.101″ W; thence to latitude 38°51′40.069″ N, longitude –077°0′57.895″ W; thence to latitude 38°51′41.708″ N, longitude –077°0′54.969″ W; thence to latitude 38°51′41.918″ N, longitude –077°0′53.911″ W; thence to latitude 38°51′43.571″ N, longitude –077°0′55.143″ W. The datum for these coordinates is NAD–83.

(b) *The regulations:* (1) Hazardous operations will be in effect on an indefinite 24-hour basis, seven days a week. All persons, vessels or other craft are prohibited from entering, transiting, drifting, dredging, or anchoring within the restricted area except persons,

vessels, or other craft authorized entry by the Commander, JBM–HH or his/her designated representatives.

(2) All persons, vessels or other craft shall clear the area when warned by patrol vessels or on-shore communication.

(3) The boundary of the restricted area will be demarcated with marker buoys and warning signs located at all or some of the coordinates listed in paragraph (a) of this section.

(c) *Enforcement.* Any person or vessel encroaching within the restricted area will be directed to immediately leave the restricted area. Failure to do so could result in forceful removal and/or criminal charges.

(d) *Exceptions.* Fishermen may be authorized controlled access to the restricted area after registering with JBM–HH/Ft. McNair officials and following specific access notification procedures.

Dated: August 1, 2019.

**Thomas P. Smith,**

*Chief, Operations and Regulatory Division, Directorate of Civil Works.*

[FR Doc. 2019–16973 Filed 8–7–19; 8:45 am]

BILLING CODE 3720–58–P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 30**

[FRL–9997–77–OA]

**Strengthening Transparency in Regulatory Science: Notification of a Public Teleconference of the Chartered Science Advisory Board**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Announcement of teleconference.

**SUMMARY:** The Environmental Protection Agency (EPA) Science Advisory Board (SAB) Staff Office announces a public teleconference of the chartered SAB. The SAB will meet to conduct a consultation with the EPA on mechanisms for secure access to personally identifying information (PII) and confidential business information (CBI) as discussed in the proposed rulemaking “Strengthening Transparency in Regulatory Science” (April 30, 2018).

**DATES:** The public teleconference will be held on Tuesday, August 27, 2019, from 1 p.m. to 5 p.m. (Eastern time).

**ADDRESSES:** The public teleconference will be held by telephone only.

**FOR FURTHER INFORMATION CONTACT:** Any member of the public who wants further

information concerning the meeting may contact Dr. Thomas Armitage, Designated Federal Officer (DFO), EPA Science Advisory Board (1400R), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; via telephone/voice mail (202) 564-2155, or email at [armitage.thomas@epa.gov](mailto:armitage.thomas@epa.gov). General information concerning the SAB can be found on the EPA website at <http://www.epa.gov/sab>.

#### SUPPLEMENTARY INFORMATION:

*Background:* The SAB was established pursuant to the Environmental Research, Development, and Demonstration Authorization Act (ERDDAA), codified at 42 U.S.C. 4365, to provide independent scientific and technical advice to the Administrator on the scientific and technical basis for agency positions and regulations. The SAB is a Federal Advisory Committee chartered under the Federal Advisory Committee Act (FACA), 5 U.S.C., App. 2. The SAB will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies. Pursuant to FACA and EPA policy, notice is hereby given that the SAB will hold a public teleconference to conduct a consultation with EPA on mechanisms for secure access to personally identifying information (PII) and confidential business information (CBI) as discussed in the proposed rulemaking “Strengthening Transparency in Regulatory Science.” See (83 FR 18768, April 30, 2018)

EPA’s proposed rulemaking (83 FR 18768, April 30, 2018) contains the following statements: (1) “When promulgating significant regulatory actions, the Agency shall ensure that dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation.” (2) “Information is considered publicly available in a manner sufficient for independent validation when it includes the information necessary for the public to understand, assess, and replicate findings.” (3) “Where the Agency is making data or models publicly available, it shall do so in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security.” Therefore, EPA has requested a consultation with the SAB on mechanisms for secure access to personally identifying information (PII) and confidential business information (CBI) as discussed in the proposed rule consistent with existing laws and policies that protect PII and CBI.

*Availability of Meeting Materials:* A meeting agenda and other materials for the meeting will be placed on the SAB website at <http://epa.gov/sab>.

*Procedures for Providing Public Input:* Public comment for consideration by EPA’s federal advisory committees and panels has a different purpose from public comment provided to EPA program offices. Therefore, the process for submitting comments to a federal advisory committee is different from the process used to submit comments to an EPA program office.

Federal advisory committees and panels, including scientific advisory committees, provide independent advice to the EPA. Members of the public can submit relevant comments pertaining to the EPA’s charge, meeting materials, or the group providing advice. Input from the public to the SAB will have the most impact if it provides specific scientific or technical information or analysis for the SAB to consider or if it relates to the clarity or accuracy of the technical information. Members of the public wishing to provide comment should contact the DFO directly.

*Oral Statements:* In general, individuals or groups requesting an oral presentation at a public teleconference will be limited to three minutes. Persons interested in providing oral statements at the August 27, 2019, teleconference should contact Dr. Thomas Armitage, DFO, in writing (preferably via email) at the contact information noted above by August 20, 2019, to be placed on the list of registered speakers.

*Written Statements:* Written statements for the August 27, 2019, teleconference should be received in the SAB Staff Office by August 20, 2019, so that the information can be made available to the SAB for its consideration prior to the meeting. Written statements should be supplied to the DFO at the contact information above via email (preferred) or in hard copy with original signature. Submitters are requested to provide a signed and unsigned version of each document because the SAB Staff Office does not publish documents with signatures on its websites. Members of the public should be aware that their personal contact information, if included in any written comments, may be posted to the SAB website. Copyrighted material will not be posted without explicit permission of the copyright holder.

*Accessibility:* For information on access or services for individuals with disabilities, please contact Dr. Armitage at the phone number or email address noted above, preferably at least ten days prior to the meeting, to give the EPA as

much time as possible to process your request.

Dated: July 30, 2019.

**Khanna Johnston,**

*Deputy Director, EPA Science Advisory Board Staff Office.*

[FR Doc. 2019-16791 Filed 8-7-19; 8:45 am]

**BILLING CODE 6560-50-P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA-R06-OAR-2019-0438; FRL-9997-72-Region 6]

### Air Plan Approval; Arkansas; Interstate Transport Requirements for the 2010 1-Hour SO<sub>2</sub> NAAQS

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** Pursuant to the Federal Clean Air Act (CAA or the Act), the Environmental Protection Agency (EPA) is proposing to approve the portion of Arkansas’ State Implementation Plan (SIP) submittal addressing the CAA requirements pertaining to the “good neighbor” provision of the CAA for the 2010 Sulfur Dioxide (SO<sub>2</sub>) National Ambient Air Quality Standard (NAAQS). The “good neighbor” provision requires each state’s implementation plan contain adequate provisions prohibiting emissions which will contribute significantly to nonattainment or interfere with maintenance of the 2010 SO<sub>2</sub> NAAQS in other states. EPA is proposing to determine that consistent with the CAA, Arkansas’ SIP contains adequate provisions to ensure that air emissions in Arkansas will not contribute significantly to nonattainment or interfere with maintenance of the 2010 SO<sub>2</sub> NAAQS in any other state.

**DATES:** Written comments must be received on or before September 9, 2019.

**ADDRESSES:** Submit your comments, identified by Docket No. EPA-R06-OAR-2019-0438, at <http://www.regulations.gov> or via email to [salem.nevine@epa.gov](mailto:salem.nevine@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. Nevine Salem, (214) 665-7222, [salem.nevine@epa.gov](mailto:salem.nevine@epa.gov). 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>.

**Docket:** The index to the docket for this action is available electronically at [www.regulations.gov](http://www.regulations.gov) and in hard copy at the EPA Region 6, 1201 Elm Street, Suite 500, 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:** Nevine Salem, EPA Region 6 Office, Infrastructure and Ozone Section, 1201 Elm Street, Suite 500, Dallas, TX 75270, (214) 665-7222, [salem.nevine@epa.gov](mailto:salem.nevine@epa.gov). To inspect the hard copy materials, please schedule an appointment with Ms. Salem or Mr. Bill Deese at (214) 665-7253.

**SUPPLEMENTARY INFORMATION:** Throughout this document “we,” “us,” and “our” means the EPA.

## I. Background

### A. General

On June 2, 2010, the EPA established a new primary 1-hour SO<sub>2</sub> NAAQS of 75 parts per billion (ppb), based on a three-year average of the annual 99th percentile of 1-hour daily maximum concentrations.<sup>1</sup> The CAA requires states to submit, within three years after promulgation of a new or revised NAAQS, SIPs meeting the applicable “infrastructure” elements of sections 110(a)(1) and (2). One of these applicable infrastructure elements, CAA section 110(a)(2)(D)(i), requires SIPs to contain “good neighbor” provisions to prohibit certain adverse air quality effects on neighboring states due to interstate transport of pollution.

### B. EPA’s Infrastructure SIP Requirements

Whenever EPA promulgates a new or revised NAAQS, CAA section 110(a)(1) requires states to make SIP submissions to provide for the implementation, maintenance, and enforcement of the NAAQS. This particular type of SIP submission is commonly referred to as an “infrastructure SIP.” These submissions must meet the various requirements of CAA section 110(a)(2), as applicable.

### C. Interstate Pollution Transport Requirements

Section 110(a)(2)(D)(i)(I) of the CAA requires a state’s SIP to include adequate provisions prohibiting any emissions activity in the state that will contribute significantly to nonattainment, or interferes with maintenance, of the NAAQS in any downwind state. The EPA sometimes refers to these requirements as prong 1 (contribute significantly to nonattainment) and prong 2 (interference with maintenance), or jointly as the “good neighbor” provision of the CAA. Further information can be found in the Technical Support Document (TSD) for this rulemaking action, which is available online at [www.regulations.gov](http://www.regulations.gov), Docket number EPA-R06-OAR-2019-0438.

## II. Summary of Arkansas’ SIP Submittal and EPA’s Evaluation

### A. Arkansas’ SIP Submittal

On March 24, 2017, the Arkansas Department of Environmental Quality (ADEQ) submitted an infrastructure SIP (i-SIP) addressing how the existing Arkansas SIP provides for the implementation, maintenance, and enforcement of the 2010 1-hour SO<sub>2</sub> NAAQS.<sup>2</sup> On February 14, 2018 (83 FR 6470), the EPA approved most elements of Arkansas i-SIP submittal, but we took no action regarding the interstate transport provisions of section 110(a)(2)(D)(i)(I) pertaining to significant contribution to nonattainment (prong 1) and

<sup>2</sup> This proposed approval action is based on the information contained in the administrative record for this action and does not prejudice any other future EPA action that may make other determinations regarding any of the subject state’s air quality status. Any such future actions, such as area designations under any NAAQS, will be based on their own administrative records and the EPA’s analyses of information that becomes available at those times. Future available information may include, and is not limited to, monitoring data and modeling analyses conducted pursuant to the EPA’s SO<sub>2</sub> Data Requirements Rule (80 FR 51052, August 21, 2015) and information submitted to the EPA by states, air agencies, and third-party stakeholders such as citizen groups and industry representatives.

interference with maintenance (prong 2) of the NAAQS in other states.

The portions of Arkansas’ March 24, 2017 SIP submittal addressing interstate transport (for section 110(a)(2)(D)(i)(I)) discuss how Arkansas will not contribute significantly to nonattainment in, or interfere with maintenance by, any other state with respect to the 2010 1-hour SO<sub>2</sub> NAAQS. ADEQ evaluated SO<sub>2</sub> monitoring data within Arkansas and its surrounding states (Oklahoma, Texas, Louisiana, Mississippi, Missouri and Tennessee), and concluded that its emissions will not contribute significantly to nonattainment or interfere with maintenance of the 2010 1-hour SO<sub>2</sub> NAAQS in any other state. In its submittal Arkansas described several existing SIP-approved measures and other federally enforceable source-specific measures, including permitting requirements, that apply to SO<sub>2</sub> sources within the state.

### B. EPA’s Evaluation

For this CAA Section 110(a)(2)(D)(i)(I) evaluation of the 2010 SO<sub>2</sub> NAAQS, EPA conducted a weight of evidence analysis for each prong separately,<sup>3</sup> including available information such as air quality, emission sources, modeling and emission trends in Arkansas and the adjacent nearby states that border Arkansas.

#### 1. EPA’s Prong 1 Evaluation—Contribute Significantly to Nonattainment

Prong 1 of the “good neighbor” provisions requires states’ plans to prohibit emissions that will contribute significantly to nonattainment of the NAAQS in another state. ADEQ confirms in its submission that Arkansas’ SIP contains adequate provisions to prevent sources and other types of emission activities within the State from contributing significantly to nonattainment in other states with respect to the 2010 1-hour SO<sub>2</sub> standard. The EPA’s evaluation<sup>4</sup> of whether Arkansas has met its Prong 1 transport

<sup>3</sup> In *North Carolina v. EPA*, 531 F.3d at 910–911 (D.C. Cir. 2008), the D.C. Circuit explained that the regulating authority must give prong 2 “independent significance” from prong 1 by evaluating the impact of upwind state emissions on downwind areas that, while currently in attainment, are at risk of future nonattainment.

<sup>4</sup> A detailed review of EPA’s evaluation of emissions, air monitoring data, other technical information, and rationale for proposed approval of this SIP revision as meeting CAA section 110(a)(2)(D)(i)(I) for the 2010 1-hour SO<sub>2</sub> NAAQS may be found in the Technical Support Document (TSD) attached to this docket.

<sup>1</sup> 75 FR 35520 (June 22, 2010).

obligations was accomplished by considering these factors:

(1) SO<sub>2</sub> ambient air quality and emissions trends for Arkansas and neighboring states;

(2) Potential ambient impacts of SO<sub>2</sub> emissions from certain facilities<sup>5</sup> in Arkansas on neighboring states based on available air dispersion modeling results of SO<sub>2</sub> sources in Arkansas and surrounding states and proximity analysis;

(3) Analysis of the relationship of Arkansas sources with monitors in adjacent states which have recorded elevated SO<sub>2</sub> concentrations;

(4) Arkansas' SIP-approved regulations specific to SO<sub>2</sub> emissions and permit requirements; and,

(5) Other SIP-approved or federally enforceable regulations which may reduce SO<sub>2</sub> emissions either directly or indirectly.

Based on EPA's analysis and evaluation of Arkansas' March 24, 2017 SIP submittal addressing the requirements of prong 1 of CAA section 110(a)(2)(D)(i)(I) requirement, we agree with Arkansas' conclusion that the existing Arkansas SIP is adequate to prevent sources in the state from contributing significantly to nonattainment in another state with respect to the 2010 1-hour SO<sub>2</sub> NAAQS. EPA proposes to determine that Arkansas' March 24, 2017 SIP submittal satisfies the requirements of Prong 1 of CAA section 110(a)(2)(D)(i)(I). This proposed determination is based on the following considerations:

- There are no monitors recording violations of the 2010 SO<sub>2</sub> NAAQS located in Arkansas or within 50 km of its border. Additionally, all monitors within 50 km of the Arkansas border have design values (DV)<sup>6</sup> that are well below the 75 ppb standard and are unlikely to violate the standard in the future, indicating no potential concern for Prong 1. Current DVs for Arkansas' AQS SO<sub>2</sub> monitors within 50 km of another state's border have remained well below the 2010 1-hour SO<sub>2</sub> NAAQS from 2015–2017; similarly, SO<sub>2</sub> monitors for neighboring states (Oklahoma, Texas, Louisiana, Missouri and Tennessee) within 50 km of Arkansas have 2017 DVs below 2010 1-hour NAAQS standards;

<sup>5</sup> The physical properties of SO<sub>2</sub> result in relatively localized pollutant impacts very near the emissions source. Therefore, the EPA selected a spatial scale with dimensions up to 50 km from point sources.

<sup>6</sup> The design value is the 3-year average of the 99th percentile 1-hour daily maximums at a monitor. A control strategy should be designed to bring the value to attainment of the standard.

- Modeling for the two Arkansas' Data Requirements Rule (DRR) sources<sup>7</sup> within 50 km of an adjacent state's border estimates impacts below the 2010 1-hour SO<sub>2</sub> NAAQS, and modeling for the DRR sources in surrounding states within 50 km of Arkansas indicates that areas around these sources do not violate the 2010 SO<sub>2</sub> NAAQS;

- Significant downward SO<sub>2</sub> emissions trends in Arkansas and its surrounding states (Texas, Oklahoma, Louisiana, Missouri, and Tennessee), when considered together with the other factors discussed as part of EPA's weight of evidence analysis, further decreases the probability that the State's sources are significantly contributing to other states' ability to attain the 2010 1-hour SO<sub>2</sub> NAAQS;

- An analysis of Arkansas sources emitting over 100 tons of SO<sub>2</sub> in 2017 show that these sources will not combine with emissions from the nearby sources in neighboring states to contribute significantly to nonattainment in those states. These analyses show the nearby sources have been modeled to show compliance of the 2010 standard or the modeling of the nearby sources included the Arkansas sources as background concentration or the Arkansas sources were well beyond 50 km from the adjacent states making it unlikely that Arkansas sources will contribute significantly to nonattainment in those states; and

- EPA also evaluated the most recent monitoring data for DRR monitors located in states adjacent to Arkansas and within 50 km of the state's border.<sup>8</sup> There are three monitors that fall into this category, one in Oklahoma and two in Missouri. The Oklahoma monitor's measurements meet the standard by a wide margin. So, Arkansas sources are

<sup>7</sup> On August 21, 2015 (80 FR 51052), EPA promulgated air quality characterization requirements for the 2010 1-hour SO<sub>2</sub> NAAQS in the Data Requirements Rule (DRR). The DRR required state air agencies to characterize air quality, through air dispersion modeling or monitoring, in areas associated with sources that emitted greater than 2,000 tons per year (tpy) of SO<sub>2</sub>, or that have otherwise been listed under the DRR by EPA or state air agencies. In lieu of modeling or monitoring, state air agencies, by specified dates, could elect to impose federally-enforceable emissions limitations on those sources restricting their annual SO<sub>2</sub> emissions to 2,000 tpy or less, or provide documentation that the sources have been shut down.

<sup>8</sup> There are five DRR monitored sources within 50 km of Arkansas the border. Two DRR sources are in Arkansas (Flint Creek Power Plant, in Benton County, Arkansas and Plum Point Energy Station in Mississippi County, Arkansas). Three DRR sources are outside of Arkansas (GRDA Power Plant in Mayes, Oklahoma, Noranda Aluminum Inc and New Madrid Power Plant Marston both in New Madrid, Missouri).

not contributing to nonattainment or interfering with maintenance at that monitor. The monitors in Missouri recorded exceedances of the 2010 SO<sub>2</sub> NAAQS for 2018, the only complete year of data. The nearest Arkansas sources, however, are of relatively small size (less than 300 tpy) and beyond the chosen 50 km spatial scale.

Furthermore, the location of the Arkansas sources relative to Missouri DRR sources and the Missouri monitors that are recording exceedances are such that transport from the Arkansas sources could not significantly contribute to the monitors (or areas around the monitors) at the same time as the DRR sources are having their maximum impact.

Therefore, the Arkansas sources will not have a significant impact on the measured exceedances; and,

- Current Arkansas' statutes, SIP-approved and federal emissions control regulations will continue to adequately control SO<sub>2</sub> emissions from sources within Arkansas.

Based on the analysis provided by Arkansas in its SIP submittal, the summary of EPA's evaluation, and EPA's supplemental Prong 1 analysis given in the TSD for this action, EPA proposes to find that sources within Arkansas will not significantly contribute to nonattainment of the 2010 1-hour SO<sub>2</sub> NAAQS in any other state.

## 2. EPA's Prong 2 Evaluation—Interference With Maintenance

Prong 2 of the “good neighbor” provision requires state plans to prohibit emissions that will interfere with maintenance of a NAAQS in another state. For the Prong 2 analysis, EPA evaluated the SO<sub>2</sub> emissions trends for Arkansas, evaluated air quality data, and assessed how future sources of SO<sub>2</sub> are addressed through existing SIP-approved and federally enforceable regulations. As discussed in more detail in the TSD, current available modeling for areas in other states within 50 km of the Arkansas border show attainment of the 2010 1-hour SO<sub>2</sub> NAAQS supporting that sources within Arkansas will not interfere with neighboring states' ability to maintain the 2010 1-hour SO<sub>2</sub> NAAQS. Emissions over time are not anticipated to increase relative to the baseline emissions modeled. EPA believes that federal and state regulations and statutes directly and indirectly reduced emissions of SO<sub>2</sub> in Arkansas and help to ensure that the State does not interfere with maintenance of the NAAQS in another state. SO<sub>2</sub> emissions from future major modifications and new major sources will be addressed by Arkansas' SIP-approved major NSR regulations

described in more detail in the TSD. In addition, Arkansas has a SIP-approved minor NSR permit program addressing small emission sources of SO<sub>2</sub>. The permitting regulations contained within these programs are designed to ensure that emissions from these activities will not interfere with maintenance of the SO<sub>2</sub> NAAQS in Arkansas or any other state.

EPA proposes to determine that Arkansas' March 24, 2017 SIP submittal satisfies the requirements of Prong 2 of CAA section 110(a)(2)(D)(i)(I). This determination is based on the following considerations:

- Statewide SO<sub>2</sub> emissions from 2000 to 2017 in Arkansas have declined significantly and are expected to continue to decline, tending to reduce background concentrations in neighboring states;
- Current Arkansas statutes and SIP-approved measures and federal emissions control programs adequately control SO<sub>2</sub> emissions from sources within Arkansas;
- Arkansas' SIP-approved PSD and minor source NSR permit programs will address future new and modified SO<sub>2</sub> sources above major and minor permitting thresholds;
- Current 2015–2017 DVs for Air Quality System (AQS)<sup>9</sup> SO<sub>2</sub> monitors both in Arkansas within 50 km of another state's border and in neighboring states (Oklahoma, Texas, Louisiana, Missouri and Tennessee) within 50 km of Arkansas' border are below the 2010 1-hour SO<sub>2</sub> NAAQS; and
- Available modeling for DRR sources within 50 km of Arkansas' border both within the State and in neighboring states demonstrates that Arkansas' larger point sources of SO<sub>2</sub> do not interfere with maintenance of the 2010 1-hour SO<sub>2</sub> NAAQS in another state.

Based on the analysis provided by Arkansas in its SIP submittal, EPA's summary of its evaluation, and EPA's supplemental Prong 2 analysis given in the Technical Support Document (TSD) for this action, EPA proposes to find that sources within Arkansas will not interfere with maintenance of the 2010 1-hour SO<sub>2</sub> NAAQS in any other state.

<sup>9</sup>The Air Quality System (AQS) contains ambient air pollution data collected by EPA, state, local, and tribal air pollution control agencies from over thousands of monitors. AQS also contains meteorological data, descriptive information about each monitoring station (including its geographic location and its operator), and data quality assurance/quality control information. AQS data is used to assess air quality, assist in attainment/non-attainment designations, evaluate State Implementation Plans for non-attainment areas, perform modeling for permit review analysis, and prepare reports for congress as mandated by the Clean Air Act.

### III. Proposed Action

EPA is proposing to approve the remaining portions of the Arkansas' March 24, 2017 SIP submittal addressing interstate transport for the 2010 1-hour SO<sub>2</sub> NAAQS as these portions meet the requirements in section 110(a)(2)(i)(I) of the CAA. Based on the EPA's analysis of the state's submittal and the factors described in this document and the TSD, EPA proposes to determine Arkansas' SIP contains adequate provisions to ensure that air emissions within Arkansas will not contribute significantly to nonattainment or interfere with maintenance of the 2010 1-hour SO<sub>2</sub> NAAQS in any other state.

### IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the 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 CAA. 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, this proposed rule, addressing Arkansas' interstate transport requirements for the 2010 1-hour SO<sub>2</sub> 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, Sulfur oxides.

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

Dated: August 1, 2019.

**David Gray,**

*Acting Regional Administrator, Region 6.*

[FR Doc. 2019–16936 Filed 8–7–19; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA–R01–OAR–2019–0353; FRL–9997–89–Region 1]

#### Air Plan Approval; Massachusetts; Transport Element for the 2010 Sulfur Dioxide National Ambient Air Quality Standard

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to approve the State Implementation Plan (SIP) submission from the Commonwealth of Massachusetts addressing the Clean Air Act (CAA or Act) interstate transport SIP requirements, referred to as the good neighbor provision, for the 2010 sulfur dioxide (SO<sub>2</sub>) national ambient air quality standards (NAAQS). This submission addresses the interstate transport requirements of the CAA that

the SIP contain adequate provisions prohibiting air emissions from Massachusetts from having certain adverse air quality effects in other states. In this action, the EPA is proposing to approve this portion of the infrastructure SIP submission that certifies that the Massachusetts SIP contain adequate provisions to ensure that air emissions in the Commonwealth will not significantly contribute to nonattainment or interfere with maintenance of the 2010 SO<sub>2</sub> NAAQS in any other state.

**DATES:** Written comments must be received on or before September 9, 2019.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-R01-OAR-2019-0353 at <https://www.regulations.gov>, or via email to [hubbard.elizabeth@epa.gov](mailto:hubbard.elizabeth@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, 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 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://www.epa.gov/dockets/commenting-epa-dockets>. Publicly available docket materials are available at <https://www.regulations.gov> or at the U.S. Environmental Protection Agency, EPA Region 1 Regional Office, Air and Radiation Division, 5 Post Office Square—Suite 100, Boston, MA. The EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays. **FOR FURTHER INFORMATION CONTACT:** Elizabeth Hubbard, Air Quality Branch,

U.S. Environmental Protection Agency, EPA Region 1, 5 Post Office Square—Suite 100, (Mail code 05-2), Boston, MA 02109—3912, tel. (617) 918-1614, email [hubbard.elizabeth@epa.gov](mailto:hubbard.elizabeth@epa.gov).

**SUPPLEMENTARY INFORMATION:**

Throughout this document whenever “we,” “us,” or “our” is used, we mean the EPA.

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**I. Background and Purpose**

On June 2, 2010, the EPA established a new primary 1-hour SO<sub>2</sub> NAAQS of 75 parts per billion (ppb), based on the 3-year average of the annual 99th percentile of 1-hour daily maximum concentrations.<sup>1</sup> Whenever the EPA promulgates a new or revised NAAQS, CAA section 110(a)(1) requires states to make SIP submissions to provide for the implementation, maintenance, and enforcement of the NAAQS. This particular type of SIP submission is commonly referred to as an “infrastructure SIP.” These submissions must meet the various requirements of CAA section 110(a)(2), as applicable. Due to ambiguity in some of the language of CAA section 110(a)(2), the EPA believes that it is appropriate to interpret these provisions in the specific context of acting on infrastructure SIP submissions. The 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.<sup>2</sup> Unless otherwise noted below, we are following that existing approach in acting on this submission. In addition, in the context

<sup>1</sup> 75 FR 35520 (June 22, 2010).

<sup>2</sup> The 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](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 the EPA's prior action on Massachusetts's infrastructure SIP to address the 1997 ozone, 2008 lead, 2008 ozone, 2010 NO<sub>2</sub>, and 2010 SO<sub>2</sub> NAAQS (see 81 FR 93627, December 21, 2016).

of acting on such infrastructure submissions, the EPA evaluates the submitting state's SIP for facial compliance with statutory and regulatory requirements, not for the state's implementation of its SIP.<sup>3</sup> The EPA has other authority to address any issues concerning a state's implementation of the rules, regulations, consent orders, etc. that comprise its SIP. One of these applicable infrastructure elements, CAA section 110(a)(2)(D)(i), requires SIPs to contain “good neighbor” provisions to prohibit certain adverse air quality effects on neighboring states due to interstate transport of pollution.

Section 110(a)(2)(D)(i) includes four distinct components, commonly referred to as “prongs,” that must be addressed in infrastructure SIP submissions. The first two prongs, which are codified in section 110(a)(2)(D)(i)(I), require SIPs to contain adequate provisions that prohibit any source or other type of emissions activity in one state from contributing significantly to nonattainment of the NAAQS in another state (prong 1) and from interfering with maintenance of the NAAQS in another state (prong 2). The third and fourth prongs, which are codified in section 110(a)(2)(D)(i)(II), require SIPs to contain adequate provisions that prohibit emissions activity in one state from interfering with measures required to prevent significant deterioration of air quality in another state (prong 3) or from interfering with measures to protect visibility in another state (prong 4).

In this action, the EPA is proposing to approve the February 9, 2018 Massachusetts submission, which certifies that the Commonwealth's infrastructure SIP contains adequate provisions related to prong 1 and prong 2, *i.e.*, to ensure that air emissions in the Commonwealth will not significantly contribute to nonattainment or interfere with maintenance of the 2010 SO<sub>2</sub> NAAQS in any other state. All other applicable infrastructure SIP requirements for the 2010 SO<sub>2</sub> NAAQS have been addressed in a separate rulemaking.<sup>4</sup>

**II. Relevant Factors To Evaluate 2010 SO<sub>2</sub> Interstate Transport SIPs**

Although SO<sub>2</sub> is emitted from a similar universe of point and nonpoint sources as is directly emitted PM<sub>2.5</sub> and the precursors to ozone and PM<sub>2.5</sub>,

<sup>3</sup> See U.S. Court of Appeals for the Ninth Circuit decision in *Montana Environmental Information Center v. EPA*, No. 16-71933 (Aug. 30, 2018).

<sup>4</sup> See the EPA's final action on other elements of Massachusetts's SIP for the 2010 SO<sub>2</sub> NAAQS at 81 FR 93627 (December 21, 2016).

interstate transport of SO<sub>2</sub> is unlike the transport of PM<sub>2.5</sub> or ozone because SO<sub>2</sub> emissions sources usually do not have long range SO<sub>2</sub> impacts. The transport of SO<sub>2</sub> relative to the 1-hour NAAQS is more analogous to the transport of Pb relative to the Pb NAAQS in that emissions of SO<sub>2</sub> typically result in 1-hour pollutant impacts of possible concern only near the emissions source. However, ambient 1-hour concentrations of SO<sub>2</sub> do not decrease as quickly with distance from the source as do 3-month average concentrations of Pb, because SO<sub>2</sub> gas is not removed by deposition as rapidly as are Pb particles and because SO<sub>2</sub> typically has a higher emissions release height than Pb. Emitted SO<sub>2</sub> has wider ranging impacts than emitted Pb, but it does not have such wide-ranging impacts that treatment in a manner similar to ozone or PM<sub>2.5</sub> would be appropriate. Accordingly, while the approaches that the EPA has adopted for ozone or PM<sub>2.5</sub> transport are too regionally focused, the approach for Pb transport is too tightly circumscribed to the source. SO<sub>2</sub> transport is therefore a unique case and requires a different approach.

In SO<sub>2</sub> transport analyses, we focus on a 50 km-wide zone because the physical properties of SO<sub>2</sub> result in relatively localized pollutant impacts near an emissions source that drop off with distance. Given the physical properties of SO<sub>2</sub>, the EPA selected the “urban scale”—a spatial scale with dimensions from 4 to 50 kilometers (km) from point sources—given the usefulness of that range in assessing trends in both area-wide air quality and the effectiveness of large-scale pollution control strategies at such point sources.<sup>5</sup> Furthermore, the American Meteorological Society/ Environmental Protection Agency Regulatory Model (AERMOD) is the EPA’s preferred modeling platform for regulatory purposes for near-field dispersion of emissions for distances up to 50 km (Appendix W to 40 CFR part 51). As such, the EPA utilized an assessment up to 50 km from point sources in order to assess trends in area-wide air quality that might impact downwind states.

<sup>5</sup> For the definition of spatial scales for SO<sub>2</sub>, please see 40 CFR part 58, Appendix D, section 4.4 (“Sulfur Dioxide (SO<sub>2</sub>) Design Criteria”). For further discussion on how the EPA is applying these definitions with respect to interstate transport of SO<sub>2</sub>, see the EPA’s proposal on Connecticut’s SO<sub>2</sub> transport SIP. 82 FR 21351, 21352, and 21354 (May 8, 2017).

As discussed in Section III of this proposed action, the EPA first reviewed Massachusetts’s analysis to assess how the Commonwealth evaluated the transport of SO<sub>2</sub> to other states, the types of information the Commonwealth used in the analysis, and the conclusions drawn by the Commonwealth. The EPA then conducted a weight of evidence analysis, including review of the Massachusetts submission and other available information, including ambient air quality data, data from SO<sub>2</sub> emission sources, and emission trends within the Commonwealth and neighboring states to which it could potentially contribute or interfere.

### III. Massachusetts’s Submission and the EPA’s Analysis

In this section, we provide an overview of Massachusetts’s 2010 SO<sub>2</sub> transport analysis included in its February 9, 2018 submission that addresses the interstate transport requirements of CAA section 110(a)(2)(D)(i)(I), as well as the EPA’s evaluation of prongs 1 and 2.

#### A. Massachusetts’s Analysis

Massachusetts conducted a weight of evidence analysis to examine whether SO<sub>2</sub> emissions from Massachusetts significantly contribute to nonattainment or interfere with maintenance of the 2010 SO<sub>2</sub> NAAQS in neighboring and downwind states. Massachusetts evaluated air monitoring data from ambient air monitoring stations in Massachusetts, as well in neighboring and downwind states. Massachusetts assessed whether SO<sub>2</sub> emissions from sources located within 50 km of Massachusetts’s borders may have contributed significantly to nonattainment or interfered with maintenance in neighboring and downwind states. Massachusetts’s analysis included source-specific SO<sub>2</sub> emissions data from Massachusetts sources located within 50 km of Massachusetts’s border and having SO<sub>2</sub> emissions over 100 tons per year (tpy). Massachusetts included the most recent stationary source SO<sub>2</sub> emissions data, which was from 2015. These sources included: Brayton Point Energy LLC (1446 tpy SO<sub>2</sub>, located 2 km from the Rhode Island border), which shutdown in 2017; Mystic Station (729 tpy SO<sub>2</sub>, located 39 km from the New Hampshire border); Solutia Inc (523 tpy SO<sub>2</sub>, located 13 km from the Connecticut

border), which permanently switched from coal to natural gas in 2016; NRG Canal LLC (492 tpy SO<sub>2</sub>, located 53 km to Rhode Island border); Wheelabrator Millbury Inc (224 tpy SO<sub>2</sub>, located 20 km from the Connecticut border); SEMASS Partnership (192 tpy SO<sub>2</sub>, located 32 km to the Rhode Island border); and Veolia Energy Boston Inc (117 tpy SO<sub>2</sub>, located 43 km from the New Hampshire border).

The largest SO<sub>2</sub> point source in Massachusetts, Brayton Point Energy LLC, permanently ceased operations in 2017. Massachusetts noted that SO<sub>2</sub> emissions have declined in the last 15 years, and that SO<sub>2</sub> levels at all monitors in the Commonwealth are below the 75 ppb SO<sub>2</sub> NAAQS. The Massachusetts Department of Environmental Protection (MassDEP) certifies that sources in Massachusetts do not contribute to nonattainment or interfere with maintenance of attainment of the 2010 SO<sub>2</sub> NAAQS in any neighboring state.

#### B. The EPA’s Prong 1 Evaluation—Significant Contribution to Nonattainment

The EPA has analyzed the ambient air quality data, data from SO<sub>2</sub> emission sources, distance from neighboring states, and emissions trends in Massachusetts and neighboring and downwind states, *i.e.*, Connecticut, Maine, New Hampshire, New York, Rhode Island, and Vermont.<sup>6</sup> Based on that analysis and discussed in greater detail below, the EPA proposes to find that Massachusetts’s SIP meets the interstate transport requirements of CAA section 110(a)(2)(D)(i)(I), prong 1 for the 2010 NAAQS, and Massachusetts will not significantly contribute to nonattainment of the 2010 SO<sub>2</sub> NAAQS in any other state.

Table 1 includes the most recent air quality design value for each active SO<sub>2</sub> monitor in Massachusetts or in a neighboring or downwind state within 50 km of the Massachusetts border. These monitors were reviewed to see if there are any sites that show elevated SO<sub>2</sub> concentrations which may warrant further investigation with respect to interstate transport of SO<sub>2</sub> from Massachusetts emission sources near any given monitor.

<sup>6</sup> For this analysis, though Maine does not share a border with Massachusetts, the EPA is analyzing SO<sub>2</sub> transport impacts of Massachusetts sources on ambient air in Maine, because Maine is located approximately 24 km from Massachusetts at its nearest point.

TABLE 1—SO<sub>2</sub> MONITOR VALUES IN MASSACHUSETTS AND NEIGHBORING AND DOWNWIND STATES

State/city or town	Site ID	Distance to Massachusetts border (km)*	2016–2018 design value (ppb)†
Connecticut/Cornwall	09–005–0005	25	2
Massachusetts/Fall River	25–005–1004	2	7
Massachusetts/Ware	25–015–4002	31	3
Massachusetts/Boston	25–025–0002	41	3
Massachusetts/Boston	25–025–0042	43	4
Massachusetts/Worcester	25–027–0023	26	4
New Hampshire/Peterborough	33–011–5001	18	2
New Hampshire/Suncook	33–013–1006	46	14
New Hampshire/Portsmouth	33–015–0014	24	13
New Hampshire/Londonderry	33–015–0018	17	3
New York/Loudonville	36–001–0012	41	3
New York/Millbrook	36–027–0007	36	2
Rhode Island/East Providence	44–007–1010	2	3

\* All distances throughout this notice are approximations.

† Data retrieved from the EPA’s <https://www.epa.gov/air-trends/air-quality-design-values#report> on July 24, 2019.

As seen in the Table 1, there are no violating monitored design values in Massachusetts or neighboring or downwind states. The data presented in Table 1 show that Massachusetts’s network of SO<sub>2</sub> monitors with data sufficient to produce valid 1-hour SO<sub>2</sub> design values that monitored 1-hour SO<sub>2</sub> levels in Massachusetts range between 4% and 10% of the 75 ppb level of the NAAQS. As shown above, all five Massachusetts SO<sub>2</sub> monitors are located within 50 km of a neighboring state’s border. Seven monitors with data sufficient to calculate a design value for the 2016–2018 period in neighboring or downwind states are located within 50 km of the Massachusetts border, and these monitors recorded SO<sub>2</sub> design

values ranging between 2% and 19% of the 2010 SO<sub>2</sub> NAAQS. Thus, these air quality data do not, by themselves, indicate any particular location that would warrant further investigation with respect to SO<sub>2</sub> emission sources that might significantly contribute to nonattainment in neighboring states. However, the monitoring network is not necessarily designed to find all locations of high SO<sub>2</sub> concentrations. Therefore, this observation indicates an absence of evidence of impact at monitored locations, but is not sufficient evidence by itself of an absence of impact at all locations in the neighboring and downwind states. Given this, the EPA has also conducted a source-oriented analysis.

As mentioned previously, the EPA finds that it is appropriate to examine the impacts of emissions from stationary sources in Massachusetts in distances ranging from 0 km to 50 km from the source. The EPA assessed point sources up to 50 km from state borders to evaluate trends and SO<sub>2</sub> concentrations in area-wide air quality. The list of sources with 2015 emissions equal to or greater than 100 tpy<sup>7</sup> SO<sub>2</sub> within 50 km from Massachusetts borders is shown in Table 2, based on Massachusetts’s submission. The EPA has also included 2017 SO<sub>2</sub> emissions for those sources in the table, which were collected from MassDEP and transmitted to the EPA for incorporation into the National Emissions Inventory (NEI).

TABLE 2—MASSACHUSETTS SO<sub>2</sub> SOURCES GREATER THAN 100 TPY NEAR NEIGHBORING AND DOWNWIND STATES

Massachusetts source	2015 SO <sub>2</sub> emissions (tons)	2017 SO <sub>2</sub> emissions (tons)	Distance to Massachusetts border (km)	Distance (km) to nearest neighboring state SO <sub>2</sub> source emitting over 100 tons in 2017	2017 emissions (tons) for the nearest neighboring or downwind state source emitting over 100 tons*
Brayton Point Energy LLC ( <i>shut down in May 2017</i> ).	1,446	552	2	150 (Public Service of New Hampshire (PSNH) Schiller Station—Portsmouth, New Hampshire).	263
Mystic Station	729	354	39	82 (PSNH Schiller Station—Portsmouth, New Hampshire).	263
SEMASS Partnership	192	301	32	140 (PSNH Schiller Station—Portsmouth, New Hampshire).	263
Solutia Inc ( <i>ceased burning coal as of December 2016</i> ).	523	0	13	104 (Monadnock Paper Mills Inc—Bennington, New Hampshire).	101
Veolia Energy Boston Inc	117	0	43	85 (PSNH Schiller Station—Portsmouth, New Hampshire).	263

<sup>7</sup> Massachusetts limited its analysis to Massachusetts sources of SO<sub>2</sub> emitting at least 100 tpy in 2015. We agree with Massachusetts’s choice to limit its analysis in this way, because in the absence of special factors, for example the presence of a nearby larger source or unusual factors,

Massachusetts sources emitting less than 100 tpy can appropriately be assumed to not be causing or contributing to SO<sub>2</sub> concentrations above the NAAQS. The EPA recognizes that in 2017 Ardagh Glass Inc. emitted 92 tpy SO<sub>2</sub>, with the next highest source (Wheelabrator Saugus Inc) emitting 54 tpy

SO<sub>2</sub>. Ardagh Glass Inc. has permanently ceased operations as of September 26, 2018. Given these facts, the EPA finds MassDEP’s analysis of SO<sub>2</sub> sources above 100 tpy adequate for analysis of SO<sub>2</sub> transport impacts to neighboring and downwind states.

TABLE 2—MASSACHUSETTS SO<sub>2</sub> SOURCES GREATER THAN 100 TPY NEAR NEIGHBORING AND DOWNWIND STATES—Continued

Massachusetts source	2015 SO <sub>2</sub> emissions (tons)	2017 SO <sub>2</sub> emissions (tons)	Distance to Massachusetts border (km)	Distance (km) to nearest neighboring state SO <sub>2</sub> source emitting over 100 tons in 2017	2017 emissions (tons) for the nearest neighboring or downwind state source emitting over 100 tons*
Wheelabrator Millbury Inc .....	224	187	20	88 (PSNH Schiller Station—Portsmouth, New Hampshire).	263

\* Emissions data were obtained using the EPA's 2017 NEI Draft.

Table 2 shows the distance from each Massachusetts source emitting at least 100 tpy SO<sub>2</sub> in 2015 to the nearest out-of-state source emitting at least 100 tpy of SO<sub>2</sub> in 2017. As shown, six facilities in Massachusetts are within 50 km of the border with another state and are at a distance of 82 km or greater from the nearest out-of-state SO<sub>2</sub> source emitting over 100 tpy. The nearest SO<sub>2</sub> source emitting greater than 100 tpy in Massachusetts to a neighboring state, Brayton Point Energy LLC (2 km from Rhode Island), permanently ceased operations on May 31, 2017. Solutia Inc (13 km from Connecticut) converted its coal-fired unit to natural gas in 2016 and is no longer permitted to burn fuels that would result in emissions equal to or greater than 100 tpy. The EPA has reviewed the data Massachusetts submitted and agrees with the determination that the closure of Brayton Point Energy LLC and fuel switching at Solutia Inc have significantly lowered SO<sub>2</sub> emissions in Massachusetts and are not having downwind impacts in violation of prongs 1 and 2.

For the remaining active Massachusetts point sources emitting over 100 tpy of SO<sub>2</sub>, *i.e.*, Mystic Station, SEMASS Partnership, Veolia Energy Boston Inc, and Wheelabrator Millbury Inc, the nearest SO<sub>2</sub> source in a neighboring state is PSNH Schiller Station in Portsmouth, New Hampshire. The EPA has assessed potential SO<sub>2</sub> impacts from Massachusetts sources on the New Hampshire area with SO<sub>2</sub> sources near the Massachusetts border, specifically the Portsmouth, New Hampshire area and the Central New Hampshire nonattainment area, by examining monitoring and modeling information. These assessments are presented as follows for the Central New Hampshire nonattainment area and the Portsmouth, New Hampshire area.

First, the EPA assessed information presented by Massachusetts regarding the State's impacts in the Central New Hampshire nonattainment area.

Massachusetts reviewed potential SO<sub>2</sub> impacts on the Central New Hampshire area, which includes parts of Hillsborough, Merrimack, and Rockingham counties, and was designated as a nonattainment area for the 2010 SO<sub>2</sub> NAAQS on August 5, 2013. The nonattainment designation was related to a monitored violation of the NAAQS at a monitoring station in Pembroke, New Hampshire and caused primarily by SO<sub>2</sub> emissions from nearby Merrimack Generating Station in Bow, New Hampshire.<sup>8</sup> The Merrimack Generating Station facility installed an emissions control system in response to a New Hampshire requirement, and the New Hampshire Department of Environmental Services (NH DES) established stringent emissions limits and other conditions for the facility on September 1, 2016. New Hampshire submitted an attainment plan for the Central New Hampshire area on January 31, 2017, which relied mainly on the emissions limits and other conditions established for the facility, and the EPA approved that plan on June 5, 2018.<sup>9</sup> New Hampshire's attainment plan and demonstration relies on air dispersion modeling of the 1-hour critical emission value shown to be equivalent to the federally-enforceable 7-boiler operating day allowable emissions limit for the Merrimack Generating Station, in addition to monitored background concentrations. These measured background concentrations account for contributions from Massachusetts. The New Hampshire modeling analysis demonstrated that allowable emissions from Merrimack Generating Station, in addition to the background levels, will not cause a violation of the 1-hour SO<sub>2</sub> NAAQS. The attainment plan did not require any reductions from

<sup>8</sup> 40 CFR part 81 Air Quality Designations for the 2010 Sulfur Dioxide (SO<sub>2</sub>) Primary National Ambient Air Quality Standard (78 FR 47191, August 5, 2013).

<sup>9</sup> See the EPA's final action on the Central New Hampshire Nonattainment Area Plan for the 2010 SO<sub>2</sub> NAAQS at 83 FR 25922 (June 5, 2018).

Massachusetts sources, and relied solely on controls and limits at Merrimack Generating Station to address the nonattainment. Therefore, the EPA concludes that sources in Massachusetts do not contribute significantly to SO<sub>2</sub> nonattainment in the Central New Hampshire area.<sup>10</sup>

Second, the EPA has assessed information, including both monitoring and modeling information, for the area around Portsmouth, New Hampshire during the third round of SO<sub>2</sub> designations.<sup>11</sup> For monitoring information, the EPA reviewed available monitoring data in the Portsmouth, New Hampshire area. There is one SO<sub>2</sub> monitor (Site ID 33-015-0014—See Table 1) in the area, located 4 km southeast of PSNH Schiller Station. As shown, this monitor recorded a design value of 13 ppb from 2016–2018. This design value indicates that SO<sub>2</sub> levels are low (17% of the NAAQS) in areas of Portsmouth. An additional monitor sited at Sawgrass Lane in Eliot, Maine (Site ID 23-031-0009), was located 1.1 miles to the northeast of PSNH Schiller Station and collected ambient SO<sub>2</sub> data from October 24, 2014 to April 1, 2016. The maximum 1-hour SO<sub>2</sub> concentration observed from this monitor was 37.7 ppb on January 8, 2015, when winds came from the direction of PSNH Schiller Station and the power plant was operating at near-maximum capacity.<sup>12</sup> While the

<sup>10</sup> On July 31, 2019, the EPA published a proposal to formally redesignate the Central New Hampshire SO<sub>2</sub> Nonattainment Area to attainment for the 2010 SO<sub>2</sub> NAAQS (84 FR 37187).

<sup>11</sup> A full assessment of New Hampshire's modeling for the Portsmouth, New Hampshire area is provided in the technical support document for the EPA's intended Round 3 air quality designations for the 2010 SO<sub>2</sub> NAAQS (82 FR 41903, September 5, 2017).

<sup>12</sup> The Sawgrass Lane monitor was sited in an area expected to experience peak SO<sub>2</sub> impacts from PSNH Schiller Station based on modeling information submitted by the Town of Eliot. Additional background and results of the Sawgrass Lane monitoring study are described in the report, "Review of 2014–2016 Eliot, Maine Air Quality Monitoring Study," EPA, the Maine Department of

Portsmouth SO<sub>2</sub> monitor is not sited to determine maximum impacts from PSNH Schiller Station, the Sawgrass Lane monitor measured combined impacts from PSNH Schiller Station and background concentrations for the area that generally include contributions from sources emitting upwind in Massachusetts. Additionally, Massachusetts noted air quality modeling by the State of New Hampshire. New Hampshire’s air quality modeling indicates that allowable emissions from PSNH Schiller Station combined with background levels that include contributions from sources emitting SO<sub>2</sub> in Massachusetts

will not cause a violation of the 2010 SO<sub>2</sub> NAAQS.<sup>13</sup> The EPA has previously evaluated that modeling and agrees that the modeling supports Massachusetts’s conclusion. Therefore, the EPA concludes that sources in Massachusetts would not contribute significantly to SO<sub>2</sub> nonattainment in the Portsmouth, New Hampshire area.

The EPA also reviewed sources in neighboring and downwind states emitting more than 100 tpy of SO<sub>2</sub> and located within 50 km of the Massachusetts border (see Table 3). This is because elevated SO<sub>2</sub> levels, to which an SO<sub>2</sub> source in Massachusetts may contribute, are most likely to be found

near such sources. Massachusetts based its analysis on 2015 SO<sub>2</sub> emissions, and the EPA has included updated 2017 emissions as part of the weight of evidence analysis. As shown in Table 3, the shortest distance between a source emitting at least 100 tpy SO<sub>2</sub> in Massachusetts and one in another state is 82 km. Given the localized range of potential 1-hour SO<sub>2</sub> impacts, this indicates that there are no additional locations in neighboring and downwind states that would warrant further investigation with respect to Massachusetts SO<sub>2</sub> emission sources that might contribute to problems with attainment of the 2010 SO<sub>2</sub> NAAQS.

TABLE 3—NEIGHBORING AND DOWNWIND STATE SO<sub>2</sub> SOURCES GREATER THAN 100 TPY AND WITHIN 50 KM OF MASSACHUSETTS

Source	2015 SO <sub>2</sub> emissions (tons) *	2017 SO <sub>2</sub> emissions (tons)	Distance to Massachusetts border (km)	Distance to nearest Massachusetts SO <sub>2</sub> source greater than 100 tpy (km)	Massachusetts source 2015 emissions (tons)
Lafarge North America—Ravena (Ravena, New York).	4,806	63	36	107 (Solutia Inc—Springfield) .....	523
Monadnock Paper Mills Inc (Bennington, New Hampshire).	†80	101	36	88 (Wheelabrator Millbury Inc—Millbury).	224
Norlite Corp (Cohoes, New York) .....	††117	60	34	117 (Solutia Inc—Springfield) .....	523
Northeast Solite Corporation (Glasco, New York).	††222	303	39	121 (Solutia Inc—Springfield) .....	523
PSNH—Merrimack Station (Bow, New Hampshire).	636	144	49	90 (Mystic Station—Everett) .....	729
PSNH—Newington Station (Newington, New Hampshire).	294	41	25	82 (Mystic Station—Everett) .....	729
PSNH—Schiller Station (Portsmouth, New Hampshire).	858	263	26	82 (Mystic Station—Everett) .....	729

\* Data retrieved, unless otherwise noted, by the EPA from its Emissions Inventory System gateway, available at <https://www.epa.gov/air-emissions-inventories/emissions-inventory-system-eis-gateway>, on July 22, 2019 for 2015 emissions as submitted by MassDEP, New York Department of Environmental Conservation (NYDEC), New Hampshire Department of Environmental Services (NHDES), and Connecticut Department of Energy and Environmental Protection.

† Emissions data reported by NHDES.  
 †† Emissions data reported by NYDEC.

The EPA also assessed previous modeling information available for the Lafarge North America—Ravena facility in Ravena, New York. This modeling information was available based on the technical support document for the EPA’s intended Round 3 air quality designations for the 2010 SO<sub>2</sub> NAAQS (82 FR 41903, September 5, 2017). The Lafarge North America—Ravena facility had its kiln replaced in 2016, resulting in considerably lower emissions than those emitted prior to the kiln replacement. The Lafarge North America—Ravena facility was modeled using new allowable emissions rather than previous actual emissions and the modeling indicated the area around the facility would not violate the NAAQS. New York’s modeling, which the EPA found accurately characterized air

quality in the area of analysis, included monitored background concentrations for the area. Based on this information, the EPA concludes that combined impacts from Lafarge North America—Ravena and background levels will not cause a violation of the NAAQS.

Massachusetts asserted that because there are no large sources of SO<sub>2</sub> emissions that significantly affect any neighboring state, and because monitored SO<sub>2</sub> levels in Massachusetts and adjacent states are substantially below the 2010 SO<sub>2</sub> NAAQS, sources in Massachusetts do not significantly contribute to nonattainment areas in any neighboring states. The EPA agrees with this conclusion.

In conclusion, for interstate transport prong 1, the EPA reviewed ambient SO<sub>2</sub> monitoring data and SO<sub>2</sub> emission

sources both within Massachusetts and in neighboring and downwind states. Based on this analysis, the EPA proposes to determine that Massachusetts will not significantly contribute to nonattainment of the 2010 SO<sub>2</sub> NAAQS in any other state, per the requirements of CAA section 110(a)(2)(D)(i)(I).

*C. The EPA’s Prong 2 Evaluation—Interference With Maintenance of the NAAQS*

The EPA has reviewed available information on SO<sub>2</sub> air quality and emission trends to evaluate the Commonwealth’s conclusion that Massachusetts will not interfere with maintenance of the 2010 SO<sub>2</sub> NAAQS in downwind states.

The EPA interprets CAA section 110(a)(2)(D)(i)(I) prong 2 to require an

<sup>13</sup> See EPA’s final action of New Hampshire’s SIP revision at 83 FR 64470 (December 17, 2018).

evaluation of the potential impact of a state’s emissions on areas that are currently measuring clean data, but that may have issues maintaining that air quality, rather than only former nonattainment areas (and thus current maintenance areas). Therefore, in addition to the analysis presented by Massachusetts, the EPA has also reviewed additional information on SO<sub>2</sub> air quality and emission trends to evaluate the Commonwealth’s conclusion that Massachusetts will not interfere with maintenance of the 2010

SO<sub>2</sub> NAAQS in downwind states. This evaluation builds on the analysis regarding significant contribution to nonattainment (prong 1). Specifically, because of the low monitored ambient concentrations of SO<sub>2</sub> in Massachusetts and neighboring and downwind states, the EPA is proposing to find that SO<sub>2</sub> levels in neighboring states near the Massachusetts border do not indicate any inability to maintain the SO<sub>2</sub> NAAQS that could be attributed in part to sources in Massachusetts.

As shown in Table 1 in section III.B. of this notice, the EPA reviewed 2016–2018 SO<sub>2</sub> design value concentrations at monitors with data sufficient to produce valid 1-hour SO<sub>2</sub> design values in Massachusetts and neighboring states. There are no violating monitored design values in Massachusetts or neighboring or downwind states.

Table 4 shows emission trends for Massachusetts along with neighboring and downwind states (Connecticut, Maine, New Hampshire, New York, Rhode Island, and Vermont).

TABLE 4—STATEWIDE SO<sub>2</sub> DATA (tpy) FOR MASSACHUSETTS AND NEIGHBORING AND DOWNWIND STATES

State	2000	2005	2010	2017	SO <sub>2</sub> reduction, 2000–2017 (%)
Massachusetts .....	208,146	139,937	57,892	15,100	93
Connecticut .....	60,309	34,638	16,319	11,379	81
Maine .....	57,906	32,397	17,020	10,447	82
New Hampshire .....	68,768	63,634	35,716	6,401	91
New York .....	543,868	386,568	170,247	38,641	93
Rhode Island .....	8,976	7,356	4,416	3,399	62
Vermont .....	9,438	7,038	3,659	1,512	84

As shown in Table 4, the statewide SO<sub>2</sub> emissions from Massachusetts and neighboring and downwind states have decreased substantially over time, per the EPA’s review of emissions trends data for these states.<sup>14</sup> From 2000 to 2017, total statewide SO<sub>2</sub> emissions decreased by the following proportions: Massachusetts (93% decrease), Connecticut (81% decrease), Maine (82% decrease), New Hampshire (91% decrease), New York (93% decrease), Rhode Island (62% decrease), and Vermont (84%). This trend of decreasing SO<sub>2</sub> emissions does not by itself demonstrate that areas in Massachusetts and neighboring states will not have issues maintaining the 2010 SO<sub>2</sub> NAAQS. However, as a piece of this weight of evidence analysis for prong 2, it provides further indication (when considered alongside low monitor values in neighboring states) that such maintenance issues are unlikely. This is because the geographic scope of these reductions and their large sizes strongly suggest that they are not transient effects from reversible causes, and thus these reductions suggest there is very low likelihood that a strong upward trend in emissions will occur that might cause areas presently in attainment to violate the NAAQS.

As noted in Massachusetts’s submission, sources of SO<sub>2</sub> emissions will be addressed by Massachusetts’s

SIP-approved SO<sub>2</sub> control programs. These programs include the low sulfur fuel rule, emissions standards for power plants, SO<sub>2</sub> limits on municipal waste combustors, and a statewide permitting program. The low sulfur fuel rule reduces the sulfur content of oil combusted in stationary sources and requires the use of low sulfur fuel for large stationary engines and turbines based on EPA requirements for diesel fuel.<sup>15</sup> Massachusetts notes in the submission that sulfur emissions from stationary sources will continue to decrease over time due to MassDEP’s fuel rule. The State’s Emissions Standards for Power Plants regulation establishes a facility-wide rolling 12-month SO<sub>2</sub> emissions rate of 3.0 pounds per megawatt-hour and a monthly average emissions rate of 6.0 pounds per megawatt-hour.<sup>16</sup> The State’s 310 CMR 7.08 regulations establish limits on municipal waste combustors and requires such facilities to establish emission control plans and places limits on SO<sub>2</sub>.<sup>17</sup> MassDEP’s statewide permitting program establishes a pre-construction Plan Approval for sources that require Best Available Control Technology for pollutants will be emitted, including SO<sub>2</sub>, and ensures that

projects requiring Plan Approvals will limit SO<sub>2</sub> emissions.<sup>18</sup> These regulations will help ensure that sulfur emissions from stationary sources will continue to decrease over time, and that new or modified stationary sources in Massachusetts will not cause exceedances of the SO<sub>2</sub> NAAQS in neighboring states.

In conclusion, for interstate transport prong 2, the EPA reviewed additional information about emissions trends, Massachusetts regulations that limit SO<sub>2</sub> sources, and the technical information considered for interstate transport prong 1. The EPA finds that the combination of low ambient concentrations of SO<sub>2</sub> in Massachusetts and neighboring and downwind states, the distances between cross-state SO<sub>2</sub> sources, the downward trend in SO<sub>2</sub> emissions from Massachusetts and neighboring and downwind states, and Massachusetts regulations that limit SO<sub>2</sub> sources indicate no interference with maintenance of the 2010 SO<sub>2</sub> NAAQS from Massachusetts. Accordingly, the EPA proposes to determine that Massachusetts SO<sub>2</sub> emissions sources will not interfere with maintenance of the 2010 SO<sub>2</sub> NAAQS in any other state, per the requirements of CAA section 110(a)(2)(D)(i)(I).

<sup>14</sup> Additional emissions trends data are available at: <https://www.epa.gov/air-emissions-inventories/airpollutant-emissions-trends-data>.

<sup>15</sup> See the EPA’s final action of the regional haze portions in Massachusetts’s SIP, at 78 FR 57487 (September 21, 2013).

<sup>16</sup> Id.

<sup>17</sup> See the EPA’s final action of the reasonably available control technology (RACT) of nitrous oxides in Massachusetts’s SIP, at 64 FR 48095, September 13, 1999.

<sup>18</sup> See the EPA’s final action of the Massachusetts “U Restricted Emission Status” regulation into the SIP, at 60 FR 17226, April 5, 1995. Massachusetts has delegation of the Federal Prevention of Significant Deterioration program (See CFR 40 52.1165).

#### IV. Proposed Action

The EPA is proposing to approve Massachusetts's February 9, 2018 submission of the 2010 SO<sub>2</sub> NAAQS as meeting the interstate transport requirements of CAA section 110(a)(2)(D)(i)(I). The EPA is soliciting public comments on the issues discussed in this notice or on other relevant matters. These comments will be considered before taking final action. Interested parties may participate in the Federal rulemaking procedure by submitting written comments to this proposed rule by following the instructions listed in the **ADDRESSES** section of this **Federal Register**.

#### V. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not expected to be an Executive Order 13771 regulatory action because this action is not significant 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 Clean Air Act; 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 the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications 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, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: August 5, 2019.

**Deborah Szaro,**

*Acting Regional Administrator, EPA Region 1.*

[FR Doc. 2019-17000 Filed 8-7-19; 8:45 am]

**BILLING CODE 6560-50-P**

#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 300

[EPA-HQ-SFUND-1989-0011; FRL-9997-99-Region 3]

#### National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Partial Deletion of the Novak Sanitary Landfill Superfund Site

**AGENCY:** Environmental Protection Agency.

**ACTION:** Proposed rule; notice of intent.

**SUMMARY:** The Environmental Protection Agency (EPA) Region 3 is issuing a Notice of Intent to Delete the groundwater portion of the Novak Sanitary Landfill Superfund Site (Site) located in South Whitehall Township, Pennsylvania, from the National Priorities List (NPL) and requests public comments on this proposed action. The

NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The EPA and the Commonwealth of Pennsylvania, through the Pennsylvania Department of Environmental Protection (PADEP), have determined that all appropriate response actions to address the groundwater portion of the Site, other than monitoring, operations and maintenance and Five-Year Reviews (FYRs), have been completed. However, this deletion does not preclude future actions under Superfund.

This partial deletion pertains only to the groundwater portion of the Site. The landfill and landfill gas components of the Site will remain on the NPL and are not being considered for deletion as part of this action.

**DATES:** Comments must be received by September 9, 2019.

**ADDRESSES:** Submit your comments, identified by Docket ID no. EPA-HQ-SFUND-1989-0011, by one of the following methods:

- <http://www.regulations.gov>. Follow on-line instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

- **Email:** Remedial Project Manager: [arquines.rombel@epa.gov](mailto:arquines.rombel@epa.gov).

- **Mail:** Community Involvement Coordinator: [mandell.alexander@epa.gov](mailto:mandell.alexander@epa.gov).

Rombel Arquines (3SD21), U.S. Environmental Protection Agency, Region 3, 1650 Arch Street, Philadelphia, PA 19103-2029.

Alexander Mandell (3RA22), U.S. Environmental Protection Agency, Region 3, 1650 Arch Street, Philadelphia, PA 19103–2029.

- *Hand delivery:* U.S. Environmental Protection Agency, Region 3, 1650 Arch Street, Philadelphia, Pennsylvania 19103–2029. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

*Instructions:* Direct your comments to Docket ID no. EPA–HQ–SFUND–1989–0011. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential 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 <http://www.regulations.gov> or email. The <http://www.regulations.gov> website is an "anonymous access" system, which means 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 EPA without going through <http://www.regulations.gov>, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, 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 EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, 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.

*Docket:* All documents in the docket are listed in the <http://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 the hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at: U.S. Environmental Protection Agency, Region 3 Records Center, 1650 Arch

Street, Philadelphia, Pennsylvania 19103–2029. Business Hours: 8 a.m.–5 p.m. (by appointment only), Monday–Friday excluding federal holidays (215) 814–3157.

Parkland Community Library, 4422 Walbert Ave., Allentown, PA 18104, Business Hours: Monday–Thursday 9 a.m.–9 p.m.; Friday 9 a.m.–6 p.m.; Saturday 9 a.m.–1 p.m.; closed Sunday. (610) 398–1361.

**FOR FURTHER INFORMATION CONTACT:** Rombel Arquines, Remedial Project Manager, U.S. Environmental Protection Agency, Region 3, (3SD21), U.S. Environmental Protection Agency, Region 3, 1650 Arch Street, Philadelphia, Pennsylvania 19103–2029, (215) 814–3182, [arquines.rombel@epa.gov](mailto:arquines.rombel@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### Table of Contents

- I. Introduction
- II. NPL Deletion Criteria
- III. Deletion Procedures
- IV. Basis for Intended Partial Site Deletion

#### I. Introduction

EPA announces its intent to delete the groundwater portion of the Novak Sanitary Landfill Superfund Site (Site), from the National Priorities List (NPL) and requests public comment on this proposed action. The NPL constitutes Appendix B of 40 CFR part 300 which is the NCP, which EPA promulgated pursuant to section 105 of the CERCLA of 1980, as amended. EPA maintains the NPL as those sites that appear to present a significant risk to public health, welfare, or the environment. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund (Fund). This deletion of the groundwater portion of the Site is proposed in accordance with 40 CFR 300.425(e) and is consistent with the Notice of Policy Change: Partial Deletion of Sites Listed on the National Priorities List. 60 FR 55466 (Nov. 1, 1995). As described in 300.425(e)(3) of the NCP, a portion of a site deleted from the NPL remains eligible for Fund-financed remedial action if future conditions warrant such actions.

EPA will accept comments on the proposal to partially delete this Site for thirty (30) days after publication of this document in the **Federal Register**.

Section II of this document explains the criteria for deleting sites from the NPL. Section III discusses procedures that EPA is using for this action. Section IV discusses the groundwater portion of the Site and demonstrates how it meets the deletion criteria.

#### II. NPL Deletion Criteria

The NCP establishes the criteria that EPA uses to delete sites from the NPL. In accordance with 40 CFR 300.425(e), sites may be deleted from the NPL where no further response is appropriate. In making such a determination pursuant to 40 CFR 300.425(e), EPA will consider, in consultation with the Commonwealth, whether any of the following criteria have been met:

- i. Responsible parties or other persons have implemented all appropriate response actions required;
- ii. All appropriate Fund-financed response under CERCLA has been implemented, and no further response action by responsible parties is appropriate; or
- iii. The remedial investigation has shown that the release poses no significant threat to public health or the environment and, therefore, the taking of remedial measures is not appropriate.

Pursuant to CERCLA section 121(c) and the NCP, EPA conducts FYRs to ensure the continued protectiveness of remedial actions where hazardous substances, pollutants, or contaminants remain at a site above levels that allow for unlimited use and unrestricted exposure. EPA conducts such FYRs even if a site is deleted from the NPL. EPA may initiate further action to ensure continued protectiveness at a deleted site if new information becomes available that indicates it is appropriate. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system.

#### III. Deletion Procedures

The following procedures apply to deletion of the groundwater portion of the Site:

- (1) EPA consulted with the Commonwealth of Pennsylvania before developing this Notice of Intent for Partial Deletion.
- (2) EPA provided the Commonwealth of Pennsylvania thirty (30) working days for review of this notice prior to publication of it today.
- (3) In accordance with the criteria discussed above, EPA has determined that no further response is appropriate.
- (4) The Commonwealth of Pennsylvania, through the Pennsylvania Department of Environmental Protection (PADEP), has concurred with the deletion of the groundwater portion of the Site, from the NPL.
- (5) Concurrently, with the publication of this Notice of Intent for Partial Deletion in the **Federal Register**, a

notice is being published in a major local newspaper, the Parkland Press. The newspaper announces the 30-day public comment period concerning the Notice of Intent for Partial Deletion of the Site from the NPL.

(6) EPA placed copies of documents supporting the proposed partial deletion in the deletion docket, made these items available for public inspection, and copying at the Site information repositories identified above.

If comments are received within the 30-day comment period on this document, EPA will evaluate and respond accordingly to the comments before making a final decision to delete the groundwater portion of the Site. If necessary, EPA will prepare a Responsiveness Summary to address any significant public comments received. After the public comment period, if EPA determines it is still appropriate to delete the groundwater portion of the Site, the Regional Administrator will publish a final Notice of Partial Deletion in the **Federal Register**. Public notices, public submissions and copies of the Responsiveness Summary, if prepared, will be made available to interested parties and included in the site information repositories listed above.

Deletion of a portion of a site from the NPL does not itself create, alter, or revoke any individual's rights or obligations. Deletion of a portion of a site from the NPL does not in any way alter EPA's right to take enforcement actions, as appropriate. The NPL is designed primarily for informational purposes and to assist EPA management. Section 300.425(e)(3) of the NCP states that the deletion of a site from the NPL does not preclude eligibility for future response actions, should future conditions warrant such actions.

#### IV. Basis for Intended Partial Site Deletion

The following information provides EPA's rationale for deleting the groundwater portion of the Site from the NPL:

##### *Site Background and History*

The Site (EPA ID: PAD079160842) is located in the northern portion of South Whitehall Township in Lehigh County, Pennsylvania. The approximately 65-acre parcel is situated on a hillside north of Jordan Creek and south of Orefield Road. The Site is separated from neighboring properties by a steep drop in elevation to the south and southwest due to natural topography and to the buildup of the landfill disposal areas and storm-water

management berms. The Beekmantown Group and Allentown Formation comprise the aquifer that underlies the Site. Groundwater mounds in the bedrock beneath the landfill waste, and water within the landfill flows radially.

From the mid-1950's until May 1990, Novak Sanitary Landfill, Inc. operated the Site as a landfill for municipal, commercial, and industrial solid waste. Alleged permit violations discovered by the Pennsylvania Department of Environmental Protection (PADEP) in 1984, then known as the Pennsylvania Department of Environmental Resources (PADER), led to a Site Investigation (SI) by EPA in 1985. The SI identified Site-related hazardous substances in the groundwater in proximity to private residential wells and a public supply well. Based on the information gathered in the SI, the Site was proposed to the National Priorities List (NPL) on January 22, 1987 (52 FR 2492) and added as final on October 4, 1989 (54 FR 41000).

The historical waste disposal areas of the landfill include:

- An old surface iron mine excavation (Old Mine Area) in the north-central area (approximately 9 acres) containing municipal, commercial and industrial waste;
- A demolition debris fill area (Demolition Fill Area) in the northeast area (approximately 2 acres) containing municipal and commercial solid waste;
- A Surface Fill Area (including the East, West and Southwest Trenches) containing municipal and commercial solid waste which extends across the northwestern and central part of the Site property (approximately 14 acres); and,
- A Trench Fill Area occupying the southern portion of the Site property (approximately 9 acres) also containing municipal and commercial solid waste.

##### *Remedial Investigation and Feasibility Study (RI/FS)*

On January 11, 1989, sixteen Potentially Responsible Parties (PRPs) entered into an Administrative Order on Consent with EPA to perform the Remedial Investigation (RI) and to prepare the Feasibility Study (FS) for the Site. The RI/FS report was approved by EPA on September 30, 1993.

##### *Selected Remedy*

The Selected Remedy for the Site was documented in a September 30, 1993 Record of Decision (1993 ROD) and modified in a March 13, 2015 Explanation of Significant Differences (2015 ESD). The Selected Remedy identified in the 1993 ROD was comprised of the following components:

- Installation of a perimeter fence around the Site boundaries;

- Implementation of deed restrictions within the Site boundaries;

- Removal of contaminated landfill surface water and sediments based on the results of additional sampling and environmental risk assessments to be conducted;

- Installation of landfill surface water control systems to provide drainage and to minimize soil erosion throughout the Site;

- Containment of the landfill contents by construction of a cap over the entire waste area, including the Surface Fill, Trench Fill, Old Surface Iron Mine Excavation and Demolition Debris Fill Areas; the constructed cap is a multilayer, impermeable soil cap with a geo-synthetic layer.

- Site restoration to promote wildlife habitat diversity without jeopardizing the integrity of the cap;

- Installation and monitoring of a gas collection system that is compatible with an active gas collection and treatment system;

- Ongoing leachate collection and monitoring throughout the Site and transport of leachate to an approved wastewater treatment facility by tanker for disposal;

- Preparation of a contingency method for on-site leachate treatment and disposal to surface water if approval for disposal at an approved wastewater treatment facility was not obtained;

- Long-term groundwater monitoring in the vicinity of the Site. Achievement of background levels or maximum contaminant levels (MCLs), whichever is lower, in groundwater. Create a contingency plan for provision of drinking water (via residential treatment units or waterline hookups) to affected residences. Delineation of the source of groundwater contamination in the vicinity of RW-13;

- Operation and Maintenance (O&M) of the vegetative soil cover, the cap and the treatment systems (gas venting system and leachate collection system) on-site.

The 2015 ESD modified the Selected Remedy as follows:

- It eliminated the requirement to continuously remove leachate from the landfill. Monitoring of the leachate system will continue and provisions for removing and treating additional leachate, if determined to be necessary by EPA, will remain.

- It eliminated the performance standard that required continuous removal of leachate to ensure that leachate depth in the waste disposal areas does not exceed one (1) foot.

- It changed the groundwater performance standard to the lower of either the MCL codified at 40 CFR part

141 and promulgated pursuant to the Safe Drinking Water Act, 42 U.S.C. 300f, *et seq.* or the non-zero maximum contaminant level goal (MCLG) for that contaminant. The ESD also modified the groundwater performance standard by including the requirement that, in addition to MCLs and non-zero MCLGs being achieved, the cumulative risk presented by all remaining Site-related compounds in the groundwater at the conclusion of the Selected Remedy must be at or below the  $1 \times 10^{-4}$  cancer risk level, and the non-cancer Hazard Index (HI) must be less than or equal to 1 for four consecutive quarters.

The Remedial Action Objectives (RAOs) for the Site as established in the 1993 ROD were as follows:

- Landfill Contents
  - Prevent direct contact to exposed landfill contents;
- Leachate
  - Prevent direct contact to the leachate seeps on the landfill surface;
  - Reduce the leaching of constituents from the landfill contents to the groundwater;
- Landfill Gas
  - Control subsurface off-site migration of landfill gas;
  - Control combustible gas concentrations;
- Groundwater
  - Prevent human ingestion and inhalation of groundwater containing Site-related constituents in excess of federal MCLs or Pennsylvania Water Quality Criteria;
  - Prevent human ingestion and inhalation of groundwater which would present excess lifetime cancer risks greater than  $1 \times 10^{-4}$  or hazard indices greater than one (1);
  - Remediate groundwater to background levels;
- On-Site Surface Water
  - Remediate altered surface water quality exhibiting excess lifetime cancer risks greater than  $1 \times 10^{-4}$  or hazard indices greater than one (1);
  - Prevent contact of surface water with landfill contents;
  - Control surface water runoff and erosion;

- Ecological Receptors
  - Conduct chronic toxicity studies (through environmental risk assessments) to determine if low levels of contamination may cause ecological impairment; and,
- Jordan Creek
  - Based upon the analytical results of sediment samples taken from Jordan Creek, and an evaluation of groundwater and surface flow characteristics, it was determined that the conditions of Jordan Creek downstream of the landfill are consistent with conditions upstream of the landfill, or background conditions. Since inorganic sediment samples did not indicate that the creek was altered by surface water run-off from the Site, a determination was made that no further investigation of the creek was necessary.

*Response Actions*

Pursuant to a June 30, 1995 Unilateral Administrative Order for Remedial Design/Remedial Action (Docket No. III-95-52-DC), the PRP group developed a Remedial Design Report that was approved by EPA on July 16, 1999. The PRPs initiated construction of the Selected Remedy on June 5, 2000. The final inspection was completed on August 29, 2002 and construction completion for the Site was documented in the Preliminary Close-Out Report (PCOR), dated September 17, 2002. EPA approved the PRP Remedial Action Completion Report on July 13, 2004. The following Remedial Action (RA) activities were implemented by the PRP group according to the EPA-approved RD specifications:

- Installation of a perimeter fence around the Site boundaries;
- Installation of a multi-layered impermeable cap over the entire waste area;
- Removal of contaminated on-site surface water and sediments based on results of additional sampling and environmental risk assessments;
- Installation of surface water control systems to provide drainage and to minimize soil erosion throughout the Site which includes four sediment ponds, spillways, drainage swales,

diversion berms, and a discharge line for surface waters to Jordan Creek;

- Site restoration to promote wildlife habitat diversity including planting wetland plant species within and around the sediment ponds;
- Installation and monitoring of a passive gas collection system that is compatible with an active gas collection and treatment system (if future data indicates it is needed); and
- Ongoing leachate collection and monitoring throughout the Site and transport of leachate through a series of sixteen extraction wells and three main leachate collection lines to a 100,000-gallon collection tank, and a pump house and tanker truck pad for transportation of the collected leachate to the Allentown wastewater treatment facility for disposal.

As required by the 1993 ROD, an investigation of the former well RW-13 was performed by the PRP group in March 1999 as part of a pre-design investigation to determine the source of contamination in groundwater. A soil vapor contamination assessment was conducted to assess the potential source of constituents detected in the former well RW-13, as well as to aid in locating additional monitoring wells. Two new monitoring wells, MW-24 and MW-25, were installed and analyzed after the soil vapor contamination assessment. These wells were placed to hydrogeologically isolate the maintenance area, a potential source area of contamination. It was concluded that the type and concentrations of constituents found in the bedrock wells MW-24 and MW-25 are consistent with the nature of impacted groundwater historically found in well RW-13, as well as other monitoring wells. No additional source area was identified. Long-term monitoring of Site monitoring wells and nearby residential wells has been performed since 2000.

*Cleanup Levels*

The 1993 ROD performance standard requiring continuous removal of leachate from the landfill to a depth of one foot was eliminated by the 2015 ESD. The groundwater cleanup levels for the COCs identified in the 1993 ROD, as modified in the 2015 ESD, are identified below in Table 1.

TABLE 1—GROUNDWATER CLEANUP LEVELS FOR SITE CONTAMINANTS OF CONCERN

Contaminant of concern	MCL (ug/L) *	Non-zero MCLG (ug/L) *
Organics:		
benzene .....	5	.....
bromodichloromethane .....	80	.....
chlorobenzene .....	100	100

TABLE 1—GROUNDWATER CLEANUP LEVELS FOR SITE CONTAMINANTS OF CONCERN—Continued

Contaminant of concern	MCL (ug/L) *	Non-zero MCLG (ug/L) *
chloroform .....	80	<b>70</b>
dibromochloromethane .....	80	<b>60</b>
1,4-dichlorobenzene .....	<b>75</b>	75
1,1-dichloroethane .....	(**)	(**)
1,2-dichloroethane .....	<b>5</b>	.....
1,1-dichloroethene .....	7	7
1,2-dichloroethene (cis) .....	<b>70</b>	70
1,2-dichloroethene (trans) .....	<b>100</b>	100
1,2-dichloropropane .....	<b>5</b>	.....
1,3-dichloropropene (trans) .....	(**)	(**)
ethyl benzene .....	<b>700</b>	700
toluene .....	<b>1,000</b>	1,000
tetrachloroethene .....	<b>5</b>	.....
1,1,1-trichloroethane .....	<b>200</b>	200
trichloroethylene .....	<b>5</b>	.....
vinyl chloride .....	<b>2</b>	.....
xylene (total) .....	<b>10,000</b>	10,000
Inorganics:		
Cadmium .....	<b>5</b>	5
Beryllium .....	<b>4</b>	4

“.....” Non-zero MCLGs are not available for these site-related compounds.

\* Values in **bold** are the selected performance standard.

\*\* These site-related compounds do not have MCLs or non-zero MCLGs but were included in the cumulative risk assessment.

The PRP group samples 13 monitoring wells on an annual basis for the compounds listed in Table 1, above. Groundwater COC concentrations at all sampling locations have been below the cleanup levels for all COCs since 2004. Additionally, in accordance with the 2015 ESD, EPA performed a cumulative risk assessment using the four most recent annual groundwater sampling results from 2015 through 2018. The 2015 ESD specifies that the cumulative risk assessment be performed using data from four consecutive quarters. Since groundwater at the Site is monitored annually, rather than quarterly, EPA conservatively performed the risk assessment based upon four years, rather than four quarters, of monitoring data. Groundwater COC concentrations were compared to EPA Tap Water Risk Screening Level (RSLs) and if the RSL was exceeded, a risk assessment was performed. Chlorobenzene, 1,2-dichloroethane, TCE, and vinyl chloride exceeded their respective RSLs in the 2015–2018 dataset at a limited number of wells. However, when risks were calculated for these chemicals assuming a conservative default future residential exposure (ingestion, dermal exposure, and inhalation from showering exposure routes), the cumulative non-cancer HIs were below 1 and the cumulative cancer risks were below  $1 \times 10^{-4}$  at each monitoring well.

Based on the results of the annual groundwater monitoring and the cumulative risk assessment, the groundwater cleanup levels and performance standards have been

achieved and the groundwater portion of the Site is eligible for deletion from the NPL.

*Operation and Maintenance*

O&M activities of the remediation system are being performed by the PRP group in accordance with the requirements of the 1995 UAO. Ongoing O&M activities include operation, maintenance, and monitoring of the Landfill cap and passive gas vent system, groundwater and residential well monitoring, and stormwater management. The PRP group also historically performed O&M of the leachate extraction system before it was decommissioned in 2011.

*Landfill Cap*

Vegetative cover at the Landfill is maintained by a cutting program. The entire Site is mowed three times per year. Wetland areas, vegetated with the specified wetland seed, are not mowed. Other cover vegetation maintenance measures include removal of trees, saplings, shrubs, weeds, and other plants that may cause damage to the cap system. The cap is also re-seeded where bare spots occur. Soil ruts, channels, washouts, animal burrows or other erosion greater than six inches deep are repaired. Repairs to the cap geosynthetics and the on-site gravel road are completed, as necessary. Landfill cap maintenance is documented in monthly progress reports to EPA.

*Landfill Gas Monitoring System*

Quarterly gas monitoring is performed at 14 gas monitoring points located outside the perimeter of the Landfill cap, and 12 residences to ensure that measured concentrations of combustible gases remain below the lower explosive limit (LEL). The collected information includes flow, percent LEL, percent oxygen, and concentrations of VOCs, methane, carbon monoxide, and hydrogen sulfide in parts per million. Since the leachate extraction system was decommissioned, including the pump house electrical systems, the pump house is primarily used as storage and gas monitoring in the pump house is unnecessary.

The basements of 12 residences adjacent to the Site are monitored on a quarterly basis for the percent LEL and percent oxygen as well as total VOCs (TVOCs). Because the sampling method cannot distinguish specific VOCs, it cannot be the sole line of evidence used to determine if the measured TVOCs are from the Landfill or from household chemicals/solvents being used in the residences. In 2007–2008, a three-phase investigation addressed the concern that TVOCs detections in the monitoring results could be caused by gas migration from the Site. EPA concluded that the occasional TVOC results in the residential sampling were not Site-related and that further vapor intrusion mitigation action was not warranted at the Site. In the past five years, there have been no detections above the LEL and no detections of TVOC COCs above

screening levels in any of the quarterly residential air monitoring samples.

A passive gas collection system was installed within the Landfill limits to collect and vent accumulated gases in the Surface Fill, Trench Fill, Demolition Fill, and Old Mine areas and to control gas migration. Additionally, 14 gas monitoring points (GMPs) were installed along the perimeter of the Landfill boundary. These passive gas points were installed to serve two purposes: (1) To intercept the potential migration of subsurface Landfill gas off-site, and (2) to monitor the effectiveness of the Landfill gas venting system. In addition, residential indoor air monitoring occurs quarterly. Since the installation of two pairs of passive gas vents in 2007, only three GMPs, GMP-3, GMP-7, and GMP-8, have had detections above the LEL of methane.

Quarterly monitoring of the on-site GMPs and residential properties will continue to be performed by the PRP group.

#### Leachate Extraction Wells

As indicated above, the leachate collection system was decommissioned in 2011. The leachate collection system was intended to remove accumulated leachate present beneath the Landfill as a singular event, prior to the construction of the cap. It accommodated leachate extraction from 21 pumping leachate extraction/gas venting wells (eventually optimized down to eight producing wells) at a combined maximum design flow rate of 63 gallons per minute. Extracted leachate was temporarily stored in an aboveground 100,000-gallon tank within a lined containment berm prior to transfer to the local Publicly Owned Treatment Works for disposal via tanker trucks. No leachate was pumped during the second leachate pilot (2009–2011), which tested the effects of shutting down the entire leachate system, or after EPA determined that the pilot provided sufficient evidence to discontinue pumping. The total cumulative volume of leachate that was removed from the Landfill since the leachate collection system's construction in 2002 was 304,481 gallons, including the final shipment in December 2011 of 72,000 gallons remaining in the tank before it was decommissioned.

#### Groundwater and Residential Well Monitoring

Designated Landfill monitoring wells are monitored annually to evaluate concentrations of the Landfill-related contaminants of concern relative to the performance standards specified in the 1993 ROD. Various residential wells in

close proximity to the Site are sampled quarterly and one community supply well is sampled annually to confirm that the drinking water quality at the point of use remains below MCLs for drinking water. No groundwater COCs have been detected in site monitoring wells or residential wells since 2004. The monitoring wells and residential wells will continue to be monitored on an annual basis by the PRP group.

#### Storm-Water Management

The Site is graded to provide drainage off the cap, and to minimize soil erosion in accordance with the 1993 ROD requirements. The final design for the Site included a conversion of three existing sedimentation ponds into storm-water management basins. In addition to their dewatering devices, the basins have an overflow outlet structure or spillway, which helps dissipate any flow that leaves the basin through these structures. Additional storm-water management components include diversion berms and rip-rap lined drainage swales. Quarterly inspections are performed to evaluate the performance and maintenance needs of the storm-water management system.

#### Institutional Controls

Institutional Controls (ICs) were required by the 1993 ROD to prohibit: (1) The use of the land for residential or agricultural purposes; and (2) the use of on-site ground water for domestic purposes, including drinking water. The purpose of these restrictions is to prevent excavation or construction on the capped and closed Landfill, and to prevent the risks associated with human exposure to landfill contents, leachate and groundwater.

To fulfill the IC requirements in the 1993 ROD, a Uniform Environmental Covenant Act (UECA) covenant was recorded with the Lehigh County Recorder of Deeds on July 28, 2011. The Site property is currently owned by Novak Sanitary Landfill, Inc. Pursuant to the 2011 UECA Covenant, the PRP group has the authority to enforce the ICs at the Site property. The PRP group is responsible for monitoring compliance with the ICs, in accordance with the requirements of the 1995 UAO.

#### Five-Year Review

Pursuant to CERCLA section 121(c) and as provided in the current guidance on FYRs *Comprehensive Five-Year Review Guidance, OSWER Directive 9355.7-03B-P, June 2001*, EPA must conduct a statutory FYR if hazardous substances remain on-site above levels that would not allow for unlimited use and unrestricted exposure. EPA has

performed three FYRs at the Site in 2006, 2011, and 2016 and statutory FYRs will continue to be performed because waste is left in place at the Site. The next FYR will be completed by May 16, 2021.

The Third FYR (signed May 16, 2016) concluded that the Site is protective of human health and the environment but identified one issue and recommendation that does not impact current or future protectiveness. The FYR recommended that an ecological investigation of the Site be performed to modify the O&M plan to meet the 1993 ROD's goal of promoting wildlife diversity.

The recommended ecological inspection was conducted on June 12, 2017 and potential solutions to promote wildlife habitat diversity were explored. Minor revisions to the O&M plan were completed in September 2018.

#### Community Involvement

In accordance with the requirements of 40 CFR 300.425(e)(4), EPA's community involvement activities associated with this partial deletion will consist of information supporting the deletion docket in the local Site information repository and placing a public notice of EPA's intent to delete the groundwater portion of the Site from the NPL in the *Parkland Press*, a major, local newspaper of general circulation.

#### Determination That the Site Meets the Criteria for Deletion in the NCP

Construction of the Selected Remedy for groundwater at the Site has been completed and O&M has been performed and is still ongoing in accordance with the EPA-approved O&M Plans. All RAOs, performance standards, and cleanup levels established for groundwater at the Site in the 1993 ROD, as amended by the 2015 ESD, have been achieved and the Selected Remedy for groundwater is protective of human health and the environment. No further Superfund response actions for the groundwater portion of the Site, other than O&M, monitoring, and FYRs, are necessary to protect human health and the environment. The Landfill and Landfill gas components of the Site will be considered for deletion from the NPL when all RAOs, performance standards, and cleanup levels have been achieved for those components.

The procedures specified in 40 CFR 300.425(e) have been followed for the deletion of the groundwater portion of the Site. EPA, with concurrence of the Commonwealth of Pennsylvania through PADEP, has determined that all appropriate response actions under

CERCLA have been completed for the groundwater portion of the Site. Therefore, EPA proposes to delete the groundwater portion of the Site from the NPL.

#### List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

**Authority:** 33 U.S.C. 1321(d); 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3 CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Dated: July 31, 2019.

#### Cosmo Servidio,

Regional Administrator, EPA Region 3.

[FR Doc. 2019–17017 Filed 8–7–19; 8:45 am]

BILLING CODE 6560–50–P

## DEPARTMENT OF TRANSPORTATION

### National Highway Traffic Safety Administration

#### 49 CFR Part 576

[Docket No. NHTSA–2019–0035]

RIN 2127–AL81

#### Record Retention Requirement; Proposed Rule; Correction

**AGENCY:** National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

**ACTION:** Proposed rule; correction

**SUMMARY:** The National Highway Traffic Safety Administration (NHTSA) published a document in the **Federal Register** of May 15, 2019, proposing changes to NHTSA’s records retention requirements. The document contained outdated information that is now being updated along with other minor corrections.

**DATES:** August 8, 2019.

**ADDRESSES:** You may submit written comments to the docket number identified in the heading of this document by any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- *Mail:* Docket Management Facility, U.S. Department of Transportation, West Building Ground Floor, Rm. W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

- *Hand Delivery or Courier:* U.S. Department of Transportation, West Building Ground Floor, Rm. W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590 between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

- *Fax:* (202) 493–2251.

Regardless of how you submit your comments, please be sure you mention the docket number of this document located at the top of this notice in your correspondence.

You may call the Docket at 202–366–9826.

Note that all comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. Please see the Privacy Act discussion below.

**Privacy Act:** Anyone is able to search the electronic form of all comments received into our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT’s complete Privacy Act Statement, in the **Federal Register** published on April 11, 2000. 65 FR 19477–78.

**Confidential Information:** If you wish to submit any information under a claim of confidentiality, you should submit two copies of your complete submission, including the information you claim to be confidential business information, and one copy with the claimed confidential business information deleted from the document, to the Chief Counsel, NHTSA, at the address given below under **FOR FURTHER INFORMATION CONTACT**. In addition, you should submit two copies, from which you have deleted the claimed confidential business information, to Docket Management at the address given above under **ADDRESSES**. When you send a comment containing information claimed to be confidential business information, you should follow the procedures set forth in 49 CFR part 512 and include a cover letter setting forth the information specified in our confidential business information regulation. 49 CFR part 512.

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

**FOR FURTHER INFORMATION CONTACT:** Thomas Healy, Trial Attorney, Office of the Chief Counsel, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590 (telephone: 202–366–2992).

#### SUPPLEMENTARY INFORMATION:

##### Correction

This notice is to correct citations included in a notice of proposed rulemaking published in the **Federal Register** on May 15, 2019, on amendments to the record retention requirements (84 FR 21741). NHTSA is correcting the following text in the **Federal Register** Document Number 2019–09844.

On page 21741, in first paragraph of the third column, correct “we have determined that a ten-year records retention requirement would ensure that the agency’s investigative needs are met without unnecessarily burdening manufacturers of motor vehicles and equipment.” to “we have determined that a ten-year records retention requirement would ensure that the agency’s investigative needs are met without unnecessarily burdening manufacturers of motor vehicles and equipment.”

On page 21742, in the third paragraph of the second column, correct “The average age of the United States light vehicle fleet has been trending upward reaching 11.6 years in 2016” to “The average age of the United States light vehicle fleet has been trending upward reaching 11.7 years in 2017.”

Again on page 21742, correct corresponding footnote 2 “Vehicles Getting Older: Average Age of Light Cars and Trucks in U.S. Rises Again in 2016 to 11.6 Years, HIS Markit Says, IHS Markit (Nov. 22, 2016), <https://news.ihsmarkit.com/press-release/automotive/vehicles-getting-older-average-age-lightcars-and-trucks-us-rises-again-2016> (last visited Sept. 19, 2018)” to “America’s Cars and Trucks are Getting Older, Business Insider (Aug. 22, 2018), <https://www.businessinsider.com/americas-cars-and-trucks-are-getting-older-2018-8> (last visited April 26, 2019).”

Yet again on page 21742, correct footnote 3, “Average Age of Automobiles and Trucks in Use, 1970–1999, Fed. Highway Admin., <https://www.fhwa.dot.gov/ohim/onh00/line3.htm> (last visited Sept. 19, 2018). From 1977 to 2017 the average of medium and heavy duty trucks increased from 11.6 years to 17.3 years and the average age of recreational vehicles increased from 4.5 years to 15.8 years. See Average Age of Automobiles and Trucks in Operation in the United States, Bureau of Transp. Statistics, <https://www.bts.gov/content/average-age-automobiles-and-trucks-operation-united-states> (last visited Sept. 19, 2018).” to “Average Age of Automobiles and Trucks in Use, 1970–1999, Fed.

Highway Admin., <https://www.fhwa.dot.gov/ohim/onh00/line3.htm> (last visited April 26, 2019). From 1977 to 2017, the average of medium and heavy duty trucks increased from 11.6 years to 17.3 years and the average age of recreational vehicles increased from 4.5 years to 15.8 years. See Average Age of Automobiles and Trucks in Operation in the United States, Bureau of Transp. Statistics, <https://www.bts.gov/content/average-age-automobiles-and-trucks-operation-united-states> (last visited April 26, 2019)."

Again on page 21742, correct footnote 4, "Average age of cars on U.S. roads breaks record, USA Today (July 29, 2015), <http://www.usatoday.com/story/money/2015/07/29/new-car-sales-soaring-but-cars-getting-older-too/30821191/> (last visited May 11, 2018) (citing an IHS Automotive study)." to "Average age of cars on U.S. roads breaks record, USA Today (July 29, 2015), <http://www.usatoday.com/story/money/2015/07/29/new-car-sales-soaring-but-cars-getting-older-too/30821191/> (last visited April 26, 2019) (citing an IHS Automotive study)."

On page 21743, in the first column, correct "At the time, NHTSA determined that the costs of extending the records requirement to eight years outweigh the benefits" to "At the time, NHTSA determined that the costs of extending the records requirement to eight years outweighed the benefits."

Again on page 21743, correct footnote 13, "Child restraint system manufacturers are not required to report property the number of damage claims they received and tire manufacturers are only required to report the number of property damage claims and warranty adjustments." to "Child restraint system manufacturers are not required to report the number of property damage claims they received and tire manufacturers are only required to report the number of property damage claims and warranty adjustments."

Issued in Washington, DC, under authority delegated in 49 CFR 1.95 and 501.5.

**Heidi Renate King,**

*Deputy Administrator.*

[FR Doc. 2019-16844 Filed 8-7-19; 8:45 am]

**BILLING CODE 4910-59-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Parts 300 and 679

[Docket No. 190802-0009]

RIN 0648-BH94

#### Pacific Halibut Fisheries; Revisions To Catch Sharing Plan and Domestic Management Measures in Alaska

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

**ACTION:** Proposed rule; request for comments.

**SUMMARY:** NMFS proposes regulations that would require Charter Halibut Permits (CHPs) to be registered annually with NMFS. In 2010, NMFS implemented a Charter Halibut Limited Access Program that issued a limited number of CHPs to persons who operate in the guided sport (charter) halibut fishery on the waters of International Pacific Halibut Commission Regulatory Areas 2C and 3A. The proposed annual registration of CHPs is intended to improve the enforcement of CHP transfer limitations and ownership caps, as well as provide additional information to NMFS and the North Pacific Fishery Management Council on any changes in CHP ownership and participation.

**DATES:** Comments must be received no later than September 9, 2019.

**ADDRESSES:** You may submit comments, identified by FDMS Docket Number NOAA-NMFS-2018-0076, by any of the following methods:

- *Federal eRulemaking Portal:* Go to [www.regulations.gov/#/docketDetail;D=NOAA-NMFS-2018-0076](http://www.regulations.gov/#/docketDetail;D=NOAA-NMFS-2018-0076), click the "Comment Now!" icon, complete the required fields, and enter or attach your comments.

- *Mail:* Submit written comments to Glenn Merrill, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: James Bruschi. Mail comments to P.O. Box 21668, Juneau, AK 99802-1668.

*Instructions:* NMFS may not consider comments sent by any other method, to any other address or individual, or received after the end of the comment period. All comments received are a part of the public record and will generally be posted for public viewing on <http://www.regulations.gov> without change. All personal identifying information (e.g., name, address), confidential business information, or

otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter N/A in the required fields if you wish to remain anonymous).

Electronic copies of the Categorical Exclusion and the Regulatory Impact Review (RIR) prepared for this action are available from <http://www.regulations.gov> or from the NMFS Alaska Region website at <http://alaskafisheries.noaa.gov>.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this rule may be submitted to NMFS at the above address and by email to [OIRA\\_Submission@omb.eop.gov](mailto:OIRA_Submission@omb.eop.gov) or fax to 202-395-5806.

**FOR FURTHER INFORMATION CONTACT:** Doug Duncan, 907-586-7228.

#### SUPPLEMENTARY INFORMATION:

##### Authority for Action

The International Pacific Halibut Commission (IPHC) and NMFS manage fishing for Pacific halibut (*Hippoglossus stenolepis*) through regulations established under authority of the Northern Pacific Halibut Act of 1982 (Halibut Act). The IPHC adopts regulations governing the Pacific halibut fishery under the Convention between the United States and Canada for the Preservation of the Halibut Fishery of the North Pacific Ocean and Bering Sea (Convention), signed at Ottawa, Ontario, on March 2, 1953, as amended by a Protocol Amending the Convention (signed at Washington, DC, on March 29, 1979). For the United States, regulations developed by the IPHC are subject to acceptance by the Secretary of State with concurrence by the Secretary of Commerce. After acceptance by the Secretary of State and the Secretary of Commerce, NMFS publishes the IPHC regulations in the **Federal Register** as annual management measures pursuant to 50 CFR 300.62.

The Halibut Act, at sections 773c(a) and (b), provides the Secretary of Commerce with general responsibility to carry out the Convention and the Halibut Act. In adopting regulations that may be necessary to carry out the purposes and objectives of the Convention and the Halibut Act, the Secretary of Commerce is directed to consult with the Secretary of the department in which the U.S. Coast Guard is operating, currently the Department of Homeland Security.

The Halibut Act, at section 773c(c), also provides the North Pacific Fishery Management Council (Council) with

authority to develop regulations, including limited access regulations, that are in addition to, and not in conflict with, approved IPHC regulations. Regulations developed by the Council may be implemented by NMFS only after approval by the Secretary of Commerce. The Council has exercised this authority in the development of subsistence halibut fishery management measures, the Charter Halibut Limited Access Program (CHLAP), and a catch sharing plan and domestic management measures in waters in and off Alaska, codified at 50 CFR parts 300.61, 300.65, 300.66, and 300.67. The Council also developed the Individual Fishing Quota (IFQ) Program for the commercial halibut and sablefish fisheries, codified at 50 CFR part 679, under the authority of section 773 of the Halibut Act and section 303(b) of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*).

### Management of the Halibut Fishery

#### *Description of the Action Area*

This proposed action would change regulations for the management of the sport halibut fishery in IPHC Regulatory Areas 2C (Southeast Alaska) and 3A (Southcentral Alaska). These regulatory areas are referred to as “IFQ regulatory areas” throughout the IFQ Program regulations at 50 CFR part 679 and as “Commission regulatory areas” throughout the halibut management regulations at 50 CFR parts 300.61, 300.65, 300.66, and 300.67. These terms are synonymous with “IPHC regulatory areas” and may be used interchangeably throughout this document. This preamble uses the term “Area 2C” and “Area 3A” to refer to IPHC Regulatory Areas 2C and 3A, respectively.

#### *Background on the Halibut Fishery*

The harvest of halibut in Alaska occurs in three fisheries—the commercial, sport, and subsistence fisheries. The commercial halibut fishery is managed under the IFQ Program. The sport fishery includes guided and unguided anglers. Guided anglers are commonly called “charter” anglers because they fish from chartered vessels. Throughout this preamble, the term “charter fishery” is used to refer to the fishery prosecuted by guided anglers. The subsistence fishery provides an opportunity for rural residents and members of an Alaska Native tribe to retain halibut for personal use or customary trade.

The following sections of the preamble summarize charter fishery management. Sections 3.1 and 3.2 of the

RIR prepared for this action provides additional detail on charter halibut management programs that have been implemented in Areas 2C and 3A.

### Charter Halibut Fishery

Sport fishing activities for halibut in Areas 2C and 3A are subject to different regulations, depending on whether those activities are guided or unguided. Guided sport fishing (charter fishing) for halibut is subject to charter restrictions under Federal regulations that are generally more restrictive than the regulations for unguided anglers. Charter fishery regulations apply if a charter vessel guide is providing assistance, for compensation, to a person who is sport fishing, to take or attempt to take fish during any part of a charter vessel fishing trip. Unguided anglers typically use their own vessels and equipment, or they may rent a vessel and fish with no assistance from a guide.

Over the years, the Council and NMFS have developed specific management programs for the charter fishery to achieve allocation and conservation objectives. These management programs maintain stability and economic viability in the charter fishery by (1) limiting the number of charter vessel operators, (2) allocating halibut to the charter fishery that varies with abundance, and (3) establishing a process for determining harvest restrictions for charter vessel anglers to keep the charter halibut fishery harvest within its allocations.

The charter fisheries in Areas 2C and 3A are currently managed under the CHLAP and the Catch Sharing Plan (CSP). The CHLAP limits the number of operators in the charter fishery, while the CSP establishes annual allocations to the charter and commercial fisheries and describes a process for determining annual management measures to limit charter harvest to the allocations in each management area. The CHLAP and the CSP are summarized below.

### Description of the CHLAP

The CHLAP established Federal charter halibut permits (throughout this preamble, “CHP” and “permit” are used synonymously) for operators in the charter halibut fisheries in Areas 2C and 3A (75 FR 554, January 5, 2010). Since 2011, all vessel operators in Areas 2C and 3A with charter anglers on board must have an original, valid permit on board during every charter vessel fishing trip on which Pacific halibut are caught and retained. CHPs are endorsed for the appropriate regulatory area and the number of charter anglers that may catch and retain halibut on a trip.

NMFS implemented this program, based on recommendations by the Council, to meet allocation objectives in the charter halibut fishery. The program provides stability in the fishery by limiting the number of charter vessels that may participate in Areas 2C and 3A. Several basic standards were required to initially receive a CHP. They included (1) a timely application for a permit; (2) documentation of participation in the charter vessel fishery during the qualifying and recent participation periods by Alaska Department of Fish and Game (ADF&G) logbooks; and (3) ownership of a business that was licensed by ADF&G to conduct the guided sport fishing that was reported in the logbooks. Licensed business owners that qualified for CHPs included individuals, corporations, firms, or associations (50 CFR 300.61). NMFS issued both transferable and nontransferable CHPs depending on specific qualifying criteria detailed in the final rule implementing the CHLAP (75 FR 554, January 5, 2010), and summarized in this preamble.

To receive an initial issuance of a CHP, vessel operators had to meet minimum participation requirements. The basic unit of participation for receiving a CHP was a logbook fishing trip. A logbook fishing trip is an event that was reported in the ADF&G logbooks within a requisite period of time. The minimum participation qualifications included documentation of at least five logbook fishing trips during one of the qualifying years of 2004 or 2005, and at least five logbook fishing trips during 2008. Meeting the minimum participation qualifications could qualify an applicant for a nontransferable CHP. To qualify for a transferable CHP, the minimum participation qualifications included documentation of at least 15 logbook fishing trips during one of the qualifying years—2004 or 2005—and at least 15 logbook fishing trips during 2008.

At initial issuance, each CHP was endorsed with a maximum number of anglers authorized to catch and retain halibut onboard the charter vessel. The assigned number of anglers on a CHP was based on the highest number of anglers that the applicant reported on any logbook fishing trip in 2004 or 2005, subject to a minimum endorsement of four. Vessel operators are allowed to stack CHPs to increase the number of charter vessel anglers on board.

### *Special Military and Community Permits*

In addition to transferable and nontransferable CHPs, the CHLAP also authorizes NMFS to issue Military

Charter Halibut Permits (Military CHPs). These permits are available for any U.S. Military Morale, Welfare, and Recreation program in Alaska operating a halibut charter vessel. To obtain a Military CHP, the military program may apply through NMFS at no cost. Military CHPs are nontransferable, issued without angler endorsements, and may be used only in the regulatory area designated on the permit. NMFS reserves the right to limit the number of Military CHPs. Additional detail on Military CHPs is provided in the final rule implementing the CHLAP (75 FR 554, January 5, 2010).

Specific small rural communities in Areas 2C and 3A are eligible to form a Community Quota Entity (CQE) to provide additional harvesting opportunities for residents. Regulations at 50 CFR 679.1 describe the specific communities eligible to form CQEs and apply for Community Charter Halibut Permits (Community CHPs). Similar to Military CHPs, qualifying CQEs may obtain a limited number of Community CHPs at no cost by applying to NMFS. A charter vessel operator who is using a Community CHP is required to either begin or end the charter vessel fishing trip within the community designated on the permit. In addition, a CQE may also obtain and hold transferable CHPs that are separate from their Community CHPs. Operators using either a CHP held by a CQE or a Community CHP must have a current ADF&G Saltwater Sport Fishing Charter Trip Logbook. An eligible CQE in Area 2C may receive a maximum of four Community CHPs and an eligible CQE in Area 3A may receive a maximum of seven Community CHPs from NMFS. All Community CHPs issued to a CQE are nontransferable, designated for either Area 2C or 3A, and endorsed for six anglers. CQEs may not hold more than a maximum of eight permits in total, including both CHPs and Community CHPs, in Area 2C, or 14 permits in total (CHPs and Community CHPs) in Area 3A (50 CFR 300.67(k)).

#### *Transferable and Nontransferable CHPs*

The issuance of transferable CHPs establishes a market-based system of access to the halibut charter fishery after the initial allocation of permits. It also provides a means to freely transfer the halibut charter fishing privilege to persons who have a close association to the current permit holder, such as family members or business associates. A person holding a transferable CHP may transfer the permit to another person (individual or non-individual entity) by submitting to NMFS an Application for Transfer of Charter Halibut Permit. NMFS approves the

transfer if (1) the receiver is a U.S. citizen or 75-percent-owned U.S. business; (2) either party does not owe NMFS any fines, civil penalties, or other payments; and (3) the receiver would not exceed the excessive share limit (five CHPs). A formal CHP transfer is a change of CHP holder as named on the permit and must be approved by NMFS. All CHP transfers are considered permanent; NMFS does not approve limited-duration transfers.

Nontransferable CHPs were authorized as a means to allow a business with relatively low participation in the qualifying years established by the CHLAP to continue to operate, while reducing the size of the charter fleet over time. Nontransferable CHPs may not be transferred to another individual or business entity, and the permits are invalidated when a permit holder dies, or the business entity that holds the permit dissolves. Nontransferable CHPs are also invalidated when new shareholders or partners are added to a business, which, under the CHLAP regulations, creates a new business entity and would otherwise require the permit to be transferred. Business entities that hold nontransferable CHPs may continue to hold the permit if they reduce the number of individuals who were listed as owners of the permit at initial issuance; however, no new individuals may be added to the ownership structure. Regulations describing CHP limitations, including ownership changes, are located at § 300.67(j).

#### *Ownership Caps*

The CHLAP included regulations that prohibit a person or entity from holding more than five CHPs (under most conditions) to limit potential consolidation in the charter fishery and provide continuing opportunities to access the fishery. Existing businesses that initially qualified for more than five permits were allowed to continue their business at levels above this excessive share standard; however, they are prevented from acquiring more permits than their initial allocation. Permit transfers that will result in a person, business, or other entity receiving more than five permits are only approved by NMFS under limited exceptions. This preamble uses the term “ownership cap” to describe the limit on the number of CHPs that a person or entity is eligible to hold because it is commonly used by participants in the charter halibut fishery. The final rule implementing the CHLAP describes the factors that the Council and NMFS considered when establishing ownership caps. Regulations at 50 CFR

300.67 describe the limitations on the use of CHPs.

To implement the ownership cap for corporations or other business entities, NMFS adopted a 10 percent ownership criterion that prevents a corporation from exceeding the excessive share standard by owning or controlling subsidiary businesses where the sum of CHPs held by the businesses exceed the maximum number of allowable permits. Under this definition, two entities are considered the same entity if one owns or controls 10 percent or more of the other. Ownership shares were initially accounted for on the applications for CHPs. If the initial applicant was not a sole individual, then the corporation, partnership, or other business entity that made the application was required to submit the names of all the individual owners of the business entity, together with the percent of the business ownership for each individual.

If there is a change in the ownership of either transferable or nontransferable CHPs, the owner is required to notify NMFS. For an individual, a “change” might mean that the person has died, in which case, NMFS must be notified within 30 days of the individual’s death (§ 300.67(j)(5)(i)). For corporations, partnerships, or other non-individual entities, a “change” occurs when a new partner is added, unless it is a court appointed trustee acting on behalf of an incapacitated partner (§ 679.42(j)(4)(i)). Business entity changes must be registered with NMFS within 15 days of the effective date of the change. Many ownership changes occur when a CHP is transferred; however, other changes occur when a business entity simply adds partners or shareholders or an individual dies. In either case, whether there is a CHP transfer or not, CHP owners are required to notify NMFS if changes are made to the ownership structure of the permit.

Monitoring the ownership structure of CHPs is necessary for NMFS to implement and enforce features of the CHLAP, such as transfer provisions, ownership caps, and the retirement of nontransferable CHPs.

Complete regulations for the CHLAP are published at 50 CFR 300.65, 300.66, and 300.67.

#### *NMFS Administration of CHPs*

Currently, CHPs are indefinitely valid for the initial recipient or transferee until the permit is transferred, reissued, or subject to a qualifying change of ownership. Reissues most commonly occur when a CHP is lost or destroyed. To obtain a replacement CHP, the CHP holder must submit an Application for Replacement of Certificates or Permits

to NMFS or submit a written request that is signed by the CHP holder or an authorized representative. Upon transfer or reissuance, NMFS issues a different version of the CHP. Each CHP has a unique and ongoing serial number with a character to identify the version of the CHP that is currently in use. Initial permits were issued as version "A," while subsequent versions are identified with sequential characters (e.g., "B," "C," "D"). In this respect, the character version of the CHP approximates the number of times the permit has been transferred or reissued. If a permit is not lost, destroyed, transferred, or subject to a reported change in ownership, then holder and contact information may fall out of date because there is no regular reporting requirement to NMFS.

### Need for This Action

This proposed rule would address the Council's intent to advance several of the Council's goals under the CHLAP. This rule would aid in the enforcement of CHP ownership caps and help ensure compliance through the annual registration and issuance of valid permits. By annually documenting the ownership structure of active CHPs, this proposed rule would also facilitate the retirement of nontransferable permits, and address the Council's intent to collect information on the use of CHPs by identifying whether the CHP holder received financial compensation for use of the permit in previous years.

The Council's intent was reflected in the purpose and need statement adopted at final action in April 2018. The Council's purpose and need, and final motion is available at: [http://legistar2.granicus.com/npfmc/meetings/2018/4/977\\_A\\_North\\_Pacific\\_Council\\_18-04-02\\_Meeting\\_Agenda.pdf](http://legistar2.granicus.com/npfmc/meetings/2018/4/977_A_North_Pacific_Council_18-04-02_Meeting_Agenda.pdf).

Section 1.2 of the RIR also provides a summary of the history of this action.

### This Proposed Rule

This proposed rule would implement an annual registration requirement for CHPs. To be valid, a CHP would need to be registered with NMFS each calendar year before use. This annual registration requirement would not apply to Military CHPs or Community CHPs, but would apply to CHPs held by CQEs. In determining whether to implement an annual registration requirement, and what information would be collected during registration, the Council and NMFS considered two alternatives, described in Sections 2.1 and 2.2 of the RIR prepared for this action. Under the preferred alternative (Alternative 2), the registration process would require submission of CHP holder name, CHP number, CHP holder

address, CHP holder phone number and/or email address, CHP ownership holdings including all partners and corporate entities, and a "yes" or "no" question that asks whether financial compensation for the use of the CHP was received in the preceding year. After approval of a CHP annual registration, NMFS would issue a new, original valid CHP to the permit holder and update the published list of CHP information. A CHP would be valid for the remainder of the calendar year in which it is registered and issued, unless it is transferred. Previous versions of the CHP would not be valid. Consistent with existing regulations at § 300.67, a charter vessel guide must have an original valid CHP onboard when catching and retaining halibut during a charter vessel fishing trip.

Under this proposed rule, the transfer of a CHP would be a separate process from the annual registration of a CHP. As noted above, if a CHP is not registered in a calendar year, it would not be valid for use until a complete registration form is submitted to and approved by NMFS. In a situation where a registered CHP is transferred in a year, if the new owner also intends to use that CHP in that year, they would also be required to submit a complete CHP registration form to be issued an original valid CHP. A new CHP would then be issued and imprinted with the new owner's information. The RIR indicates that, on average, there have been 41 transfers of CHPs each year.

This proposed rule would not require Community CHPs and Military CHPs to be annually registered. Community CHPs and Military CHPs are issued by NMFS to eligible entities and are nontransferable. Although the CHLAP defines Community and Military CHPs as nontransferable, these permits were issued not based on specific charter halibut landings during a qualifying period, but to provide access opportunities for military personnel and economic benefits to small rural communities. An annual registration process that could result in limiting the use of Community and Military CHPs would be inconsistent with the purpose of these special permits. Additional information on the rationale for issuing Community and Military CHPs is provided in the final rule implementing the CHLAP (75 FR 554, January 5, 2010). The RIR prepared for this rule indicates that there are a limited number of these special permits; 48 Community CHPs and one Military CHP have been issued for Area 2C, and 63 Community CHPs and 7 Military CHPs have been issued for Area 3A. Overall, this represents approximately 10 percent of the total

number of CHPs in Areas 2C and 3A (Section 3.2.1 of the RIR). Additionally, Community CHPs are subject to an annual reporting requirement where CQEs must report ownership and use information. Adding an annual registration to collect information similar to the existing annual report could create unnecessary duplication.

Currently, NMFS may receive updated CHP ownership and contact information when a transfer occurs, or when the death of the permit holder or an ownership change is reported. Implementing an annual registration requirement in § 300.67(a) would ensure annual reporting of active CHP holder information to NMFS, which would improve enforcement of these provisions and ensure that this information is updated annually for active CHPs. This is particularly important for nontransferable CHPs, which are no longer valid upon the holder's death or when a CHP holding entity dissolves, or when there is a change in ownership, as defined in § 300.67(j)(5). The annual registration and issuance of CHPs would simplify enforcement and reduce unintentional and intentional violations arising from unreported nontransferable CHP ownership changes.

The Council and NMFS considered two other options for annual registration information collections; one requiring submission of the natural person(s) and vessel(s) that would use the CHP during a fishing year, and the other requiring submission of where a nontransferable permit would be used during the fishing year. The Council and NMFS decided against implementing these registration information collections because a CHP holder may not know the specific person who will be harvesting charter halibut under that CHP, which vessel will be using that specific CHP, and specifically where a CHP would be used at the time of registration. Among other things, the Council wanted to avoid the possibility of limiting the operational flexibility of CHP holders.

CHP holders would be required to indicate whether they had received financial compensation for use of their CHP in the preceding year on their annual registration application. There is no requirement that a CHP holder be present when the CHP is being used on a charter vessel, which effectively allows the leasing or lending of CHPs. Although this was a deliberate feature of the CHLAP, and this proposed regulation would not restrict lending or leasing, by collecting information on financial compensation, the Council and NMFS will be better informed about charter vessel operations, which would

serve to inform program evaluations and decisions on potential future management actions.

The Council and NMFS considered another option that would have provided information about CHP leasing. The Council and NMFS considered one option that would have asked the annual applicant if a CHP was used by an operator who was not part of the CHP ownership structure; whether the owner of the CHP received compensation for the use of the CHP, and if so, to provide the details of compensation. The Council and NMFS recognized the diversity in potential leasing structures and compensation terms, and the possibility of significant confusion among annual registration applicants if detailed information was requested. Therefore, the Council recommended and this proposed rule would require only that the annual registration applicant indicate if financial compensation was received for use of the CHP in the preceding year, with a “yes” or “no” answer.

This proposed rule also establishes a standard process in the event a CHP annual registration is denied. A denial could occur due to an incomplete or inaccurate registration application, registration of a non-transferable permit by a non-eligible holder, violation of a CHP holding limitation, or other reasons. If this occurs, NMFS would inform the applicant why the annual registration was denied and begin a 30 day period in which the applicant can correct the application. If NMFS determines that there is still sufficient reason to deny the application after corrections and evidence are received during the 30 day period, an Initial Administrative Determination (IAD) detailing the problems would be issued to the applicant. An applicant that has received an IAD could appeal the denial to the Office of Administrative Appeals. This is consistent with the process relating to the denial and appeal of other NMFS fishing permits.

Finally, this proposed rule makes a non-substantive update to the appeal process for a CHP application. It would revise the outdated reference for the Office of Administrative Appeals in order to bring it up to date with current regulations. This would not change how appeals are currently made or handled.

#### **Proposed Revisions to §§ 300.67 and 679.4**

This proposed rule would add new paragraph to § 300.67(a)(4) that would require annual registration of CHPs, describe the registration process, define what constitutes a complete annual registration, and identify an appeal

process. Section 300.67(h)(6) would be revised to correct the reference to the appeals process.

The table in § 679.4(a)(1) would be revised to indicate that CHPs would be in effect until the expiration date shown on the permit, rather than indefinitely.

#### **Classification**

Regulations governing the U.S. fisheries for Pacific halibut are developed by the IPHC, the Pacific Fishery Management Council, the North Pacific Fishery Management Council, and the Secretary of Commerce. Section 5 of the Halibut Act (16 U.S.C. 773c) allows the Regional Council having authority for a particular geographical area to develop regulations governing fishing for halibut in U.S. Convention waters as long as those regulations do not conflict with IPHC regulations. The Halibut Act at section 773c(a) and (b) provides the Secretary of Commerce with the general responsibility to carry out the Convention with the authority to, in consultation with the Secretary of the department in which the U.S. Coast Guard is operating, adopt such regulations as may be necessary to carry out the purposes and objectives of the Convention and the Halibut Act. This proposed rule is consistent with the Halibut Act and other applicable laws.

#### *Executive Order 12866*

This proposed rule has been determined to be not significant for purposes of Executive Order 12866. This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866. This proposed rule also complies with the Secretary of Commerce’s authority under the Halibut Act to implement management measures for the halibut fishery.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration (SBA) that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. NMFS requests comments on the decision to certify this proposed rule. The factual basis for this determination is as follows:

This proposed rule would directly regulate (1) individuals and entities holding CHPs, and (2) Community Quota Entities that hold CHPs. As of 2017, there were approximately 550 CHP holders. It is unlikely that the largest of the affected CHP holders would be considered large entities under SBA standards; however, that cannot be confirmed because NMFS does not have or collect economic data

on permit holders necessary to definitively determine total annual receipts. Thus, all CHP holders are considered small entities, based on SBA criteria.

Eligible CQEs may obtain CHPs; therefore, this proposed rule may directly regulate entities representing small, remote communities in Areas 2C and 3A. There are 34 communities in Area 2C and 14 in Area 3A eligible to obtain CHPs. Of these, all have populations less than 50,000 and are considered to be small government jurisdictions.

The proposed annual registration of CHPs is intended to improve the enforcement of existing permit transfer limitations, ownership caps, and provide additional information to NMFS and the North Pacific Fishery Management Council on any changes in permit ownership and participation in the charter halibut sector. The estimated annual cost burden is less than \$20 per application. This proposed action, therefore, is not expected to have a significant economic impact on a substantial number of the small entities directly regulated by this proposed action. As a result, an initial regulatory flexibility analysis is not required, and none has been prepared.

#### *Regulatory Impact Review*

An RIR was prepared to assess all costs and benefits of available regulatory alternatives. A copy of the RIR is available from NMFS (see **ADDRESSES**). The Council recommended this proposed action based on those measures that maximized net benefits to the Nation.

#### *Collection-of-Information Requirements*

This proposed rule mentions but would not change the following collection-of-information-requirements: ADF&G Saltwater Sport Fishing Charter Trip Logbook (OMB Control Number 0648–0575); Application for Replacement of Certificates or Permits (OMB Control Number 0648–0272); the CQE Annual Report (OMB Control Number 0648–0665); and the Application for Transfer of CHP and the Application for Transfer Between IFQ and GAF (OMB Control Number 0648–0592).

This proposed rule contains collection-of-information requirements subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA). NMFS has submitted these requirements to OMB for approval under OMB Control Number 0648–0592, Pacific Halibut Fisheries: Charter Permits. Public reporting burden is

estimated to average 15 minutes per response for the application for annual registration of a CHP and 4 hours per response for appeal of a denied application. These estimates include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection information.

Public comment is sought regarding whether these proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collections of information, including through the use of automated collection techniques or other forms of information technology. Send comments on these or any other aspects of the collections of information to NMFS (see ADDRESSES), and by email to OIRA\_Submission@omb.eop.gov, or fax to (202) 395-5806.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number. All currently approved NOAA collections of information may be viewed at http://www.cio.noaa.gov/services\_programs/prasubs.html.

List of Subjects

50 CFR Part 300

Administrative practice and procedure, Antarctica, Canada, Exports, Fish, Fisheries, Fishing, Imports, Indians, Labeling, Marine resources, Reporting and recordkeeping requirements, Russian Federation, Transportation, Treaties, Wildlife.

50 CFR Part 679

Alaska, Fisheries, Reporting and recordkeeping requirements.

Dated: August 2, 2019.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, NMFS proposes to amend 50 CFR parts 300 and 679 as follows:

PART 300—INTERNATIONAL FISHERIES REGULATIONS

Subpart E—Pacific Halibut Fisheries

1. The authority citation for part 300, subpart E, continues to read as follows:

Authority: 16 U.S.C. 773–773k.

2. In § 300.67:

a. Add paragraph (a)(4); and

b. Revise paragraph (h)(6) introductory text to read as follows:

§ 300.67 Charter halibut limited access program.

\* \* \* \* \*

(a) \* \* \*

(4) Annual registration. A charter halibut permit holder must register a charter halibut permit with NMFS during the calendar year when it will be used to be valid.

(i) Application and submittal. An application for a charter halibut permit annual registration will be made available by NMFS. A completed registration application may be submitted using the NMFS-approved electronic reporting system on the Alaska Region website at http://alaskafisheries.noaa.gov. Completed applications may also be submitted by mail, hand delivery, or facsimile at any time to the address(s) listed on the application.

(ii) Complete annual registration. To be complete, a charter halibut permit registration application must have all

required fields accurately completed and be signed and dated by the applicant.

(iii) Denied registration applications. If NMFS does not approve an annual charter halibut permit registration application, NMFS will inform the applicant of the basis for its disapproval and provide the applicant with a 30-day evidentiary period in which to correct any application deficiencies.

(A) Initial Administration Determination (IAD). NMFS will send an IAD to the applicant following the expiration of the 30-day evidentiary period if NMFS determines there is sufficient reason to deny the application. The IAD will indicate the deficiencies in the application and the deficiencies with the information submitted by the applicant in support of its claim.

(B) Appeal. An applicant that receives an IAD may appeal to the Office of Administrative Appeals (OAA) pursuant to 15 CFR part 906.

\* \* \* \* \*

(h) \* \* \*

(6) Appeal. An applicant that receives an IAD may appeal to the Office of Administrative Appeals (OAA) pursuant to 15 CFR part 906.

\* \* \* \* \*

PART 679—FISHERIES OF THE EXCLUSIVE ECONOMIC ZONE OFF ALASKA

3. The authority citation for part 679 continues to read as follows:

Authority: 16 U.S.C. 773 et seq.; 1801 et seq.; 3631 et seq.; Pub. L. 108–447; Pub. L. 111–281.

4. In § 679.4, revise paragraph (a)(1)(xv)(A) as follows:

§ 679.4 Permits.

(a) \* \* \*

(1) \* \* \*

If program permit or card type is: Permit is in effect from issue date through the end of: For more information, see . . .

Table with 3 columns: If program permit or card type is, Permit is in effect from issue date through the end of, For more information, see. Row 1: (xv) \* \* \*, (A) Charter halibut permit, Until expiration date shown on permit, § 300.67 of this title.

\* \* \* \* \*

[FR Doc. 2019-16979 Filed 8-7-19; 8:45 am]

BILLING CODE 3510-22-P

**DEPARTMENT OF COMMERCE****National Oceanic and Atmospheric Administration****50 CFR Part 635**

[Docket No. 190214111-9513-01]

RIN 0648-BI51

**Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries; Pelagic Longline Fishery Management; Correction**

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

**ACTION:** Proposed rule; correction.

**SUMMARY:** The National Marine Fisheries Service is correcting an error in the alternatives section of a proposed rule that published on July 12, 2019. In that proposed rule, NMFS proposes to adjust regulatory measures that reduce bluefin tuna bycatch in the pelagic longline fishery for Atlantic highly migratory species (HMS). The preferred alternative for the Spring Gulf of Mexico Gear Restricted Area includes an evaluation period to determine whether current area-based management measures remain necessary to reduce and/or maintain low numbers of bluefin tuna discards and interactions in the pelagic longline fishery. The description of this alternative included two timing errors, one about the evaluation period and one about the applicable months for actions within the alternative. This action corrects the errors.

**DATES:** Comments on the proposed rule must be submitted on or before September 30, 2019.

**ADDRESSES:** You may submit comments on this document, identified by NOAA-NMFS-2018-0035, by any one of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to [www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2018-0035](http://www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2018-0035), click the "Comment Now" icon, complete the required fields, and enter or attach your comments.

- *Mail:* Submit written comments to Craig Cockrell, NMFS/SF1, 1315 East-West Highway, National Marine Fisheries Service, SSMC3, Silver Spring, MD 20910.

*Instructions:* Please include the identifier NOAA-NMFS-2018-0035

when submitting comments. Comments sent by any other method, to any other address or individual, or received after the close of the comment period, may not be considered by NMFS. All comments received are a part of the public record and generally will be posted for public viewing on [www.regulations.gov](http://www.regulations.gov) without change. All personal identifying information (*e.g.*, name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter "N/A" in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

**FOR FURTHER INFORMATION CONTACT:** Jennifer Cudney, 727-824-5399 or Craig Cockrell, 301-427-8503.

**SUPPLEMENTARY INFORMATION:****Need for Correction**

On July 12, 2019, NMFS published a proposed rule in the **Federal Register** (84 FR 33205) that would adjust regulatory measures put in place to reduce bluefin tuna bycatch in the pelagic longline fishery for Atlantic highly migratory species (HMS). Specifically, the proposed measures address the Northeastern United States Closed Area, the Cape Hatteras Gear Restricted Area, and the Spring Gulf of Mexico Gear Restricted Area as well as the weak hook requirement in the Gulf of Mexico. As described in the proposed rule, the preferred alternative for the Spring Gulf of Mexico Gear Restricted Area included an evaluation period to determine whether the current area-based management measure remains necessary to reduce and/or maintain low numbers of bluefin tuna discards and interactions in the pelagic longline fishery. The description of this alternative cited both incorrect timing for the three-year evaluation period and incorrect timing for the months during which the pelagic longline fishery would be allowed to fish within a previously closed area under specific conditions. Corrections are necessary to provide an accurate description of this preferred alternative, which will be useful to the public as they prepare comment on the proposed rule.

The proposed rule provides a summary of how the Spring Gulf of Mexico Gear Restricted Area would be managed under the preferred alternative, appearing in bullet form on page 33208 of the **Federal Register**. The sentence preceding the bullets states

that "This alternative would have a three-year evaluation period (January 1, 2010 through December 31, 2022) for the Monitoring Area . . .". The parenthetical is incorrect and should instead read that the three-year evaluation period would be from "(January 1, 2020 through December 31, 2022)." The first bullet under this sentence incorrectly states that "The Monitoring Area would initially remain open to pelagic longline fishing from June 1 through June 30". This bullet should instead note that the Monitoring Area would initially remain open to pelagic longline fishing from April 1 through May 31. The fourth bullet under this sentence states that "On or after the effective date of the notice, the Monitoring Area would be closed to pelagic longline fishing each year from June 1 through June 30, unless NMFS takes further action." This bullet should instead state that "On or after the effective date of the notice, the Monitoring Area would be closed to pelagic longline fishing each year from April 1 through May 31, unless NMFS takes further action," to correct the dates.

The same corrections need to be made in the IRFA that was prepared to meet requirements of Section 603 of the Regulatory Flexibility Act (RFA). Column 3 of page 33212 of the **Federal Register** provides a summary of how the Spring Gulf of Mexico Gear Restricted Area would be managed under the preferred alternative in bullet form. The sentence preceding the bullets states that "This alternative would have a three-year evaluation period (January 1, 2010 through December 31, 2022) for the Monitoring Area . . .". The parenthetical is incorrect and should instead read that the three-year evaluation period would be from "(January 1, 2020 through December 31, 2022)." The first bullet under this sentence incorrectly states that "The Monitoring Area would initially remain open to pelagic longline fishing from June 1 through June 30". This bullet should instead note that the Monitoring Area would initially remain open to pelagic longline fishing from April 1 through May 31. The fourth bullet under this sentence states that "On or after the effective date of the notice, the Monitoring Area would be closed to pelagic longline fishing each year from June 1 through June 30, unless NMFS takes further action." This bullet should instead state that "On or after the effective date of the notice, the Monitoring Area would be closed to pelagic longline fishing each year from April 1 through May 31, unless NMFS

takes further action,” to correct the dates.

Dated: August 5, 2019.

**Samuel D. Rauch III,**

*Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.*

[FR Doc. 2019-16996 Filed 8-7-19; 8:45 am]

**BILLING CODE 3510-22-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 648

[Docket No. 190802-0010]

RIN 0648-BI93

#### Fisheries of the Northeastern United States; Summer Flounder, Scup, and Black Sea Bass Fisheries; Framework Adjustment 14

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

**ACTION:** Proposed rule; request for comments.

**SUMMARY:** NMFS proposes modifications to aspects of the commercial and recreational summer flounder, scup, and black sea bass management program, as recommended by the Mid-Atlantic Fishery Management Council. NMFS proposes these management measure adjustments to provide an opportunity for public comment. The intent of this action is to allow for more flexibility in the management of these species.

**DATES:** Comments must be received by September 9, 2019.

**ADDRESSES:** You may submit comments on this document, identified by NOAA-NMFS-2019-0049, by either of the following methods:

*Electronic submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal.

- Go to [www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2019-0049](http://www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2019-0049),

- Click the “Comment Now!” icon, complete the required fields
- Enter or attach your comments.

OR

*Mail:* Submit written comments to Michael Pentony, Regional Administrator, Greater Atlantic Region, 55 Great Republic Drive, Gloucester, MA 01930.

*Instructions:* Comments sent by any other method, to any other address or

individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on [www.regulations.gov](http://www.regulations.gov) without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter “N/A” in the required fields if you wish to remain anonymous).

An environmental assessment (EA) was prepared for this action that describes the proposed measures and other considered alternatives, and provides an analysis of the impacts of the proposed measures and alternatives. Copies of the EA are available on request from Dr. Christopher M. Moore, Executive Director, Mid-Atlantic Fishery Management Council, Suite 201, 800 North State Street, Dover, DE 19901. These documents are also accessible via the internet at [http://www.mafmc.org/s/SFSBSB\\_Framework14\\_EA.pdf](http://www.mafmc.org/s/SFSBSB_Framework14_EA.pdf).

**FOR FURTHER INFORMATION CONTACT:** Emily Gilbert, Fishery Policy Analyst, (978) 281-9244.

#### SUPPLEMENTARY INFORMATION:

##### General Background

The summer flounder, scup, and black sea bass fisheries are managed cooperatively under the provisions of the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan (FMP) developed by the Mid-Atlantic Fishery Management Council and the Atlantic States Marine Fisheries Commission, in consultation with the New England and South Atlantic Fishery Management Councils. The management units specified in the FMP include summer flounder (*Paralichthys dentatus*) in U.S. waters of the Atlantic Ocean from the southern border of North Carolina northward to the U.S./Canada border, and scup (*Stenotomus chrysops*) and black sea bass (*Centropristis striata*) in U.S. waters of the Atlantic Ocean from 35°13.3' N lat. (the approximate latitude of Cape Hatteras, North Carolina). States manage these three species within 3 nautical miles (4.83 km) of their coasts, under the Commission's management plan for summer flounder, scup, and black sea bass. The applicable species-specific Federal regulations govern vessels and individual fishermen commercially fishing in Federal waters of the exclusive economic zone, as well as vessels possessing a summer flounder, scup, or black sea bass Federal charter/

party vessel permit, regardless of where they fish. This rule proposes management measures intended to provide more flexibility in the commercial and recreational fisheries for these species and includes the following modifications to the FMP:

- Include conservation equivalency as an annual management consideration for the black sea bass recreational fishery;

- Create a Federal waters transit zone for non-federally permitted vessels fishing in state waters around Block Island Sound; and

- Incorporate a maximum recreational size limit in the list of potential specification measures for summer flounder and black sea bass.

These measures, which are further explained below, are consistent with the recommendations of the Council and the Commission's Summer Flounder, Scup, and Black Sea Bass Management Board for this action.

#### Proposed Management Measures

##### Black Sea Bass Conservation Equivalency

This action proposes to allow conservation equivalency for future use in the recreational black sea bass fishery based on the process currently used for summer flounder. Under conservation equivalency, the Council and Board would decide each year whether to use Federal coastwide measures or conservation equivalency to manage the recreational black sea bass fishery. Conservation equivalency would waive Federal measures so long as the states implement appropriate measures. If they agree to use conservation equivalency, they must also develop a set of non-preferred coastwide measures (minimum and/or maximum fish size limit, possession limit, and season) that would be expected to prevent harvest from exceeding the annual recreational harvest limit. The Council and Board must also recommend a suite of precautionary default measures that would apply to all recreational anglers and Federal party/charter permit holders fishing in Federal waters and landing black sea bass in states that do not develop and implement Commission-approved conservationally equivalent measures.

If the Council and Board agree to use conservation equivalency in a given year, the Board would determine the states' management program to implement conservation equivalency for black sea bass in any given year through a separate action. After reviewing and approving the state/regional proposals, the Commission would submit a letter

to us certifying that the combination of state and regional measures is expected to prevent black sea bass harvest from exceeding that year's recreational harvest limit. Based on the Commission's certification, we would be able to approve conservation equivalency and waive Federal measures for the remainder of the calendar year in favor of the state or regional conservation equivalency measures. Federally-permitted vessels and vessels fishing in Federal waters would then be subject to the regulations in the states where they land their catch. If the Commission submits a letter to us

announcing that a state or states have not implemented appropriate measures, the state(s) would be required to implement precautionary default measures in state waters through the Commission, and we would similarly apply those precautionary default measures to recreational anglers and Federal party/charter permit holders landing black sea bass in applicable states. If a state or region implements measures which are not approved, the Commission would require the precautionary default measures to be enforced in that state or region and would request NMFS to apply those

measures to recreational anglers and federally permitted party/charter vessels fishing in Federal waters and landing black sea bass in those states as well. Table 1 outlines the conservation equivalency timeline for management decisions, based on the current process for summer flounder. Non-preferred coastwide measures would be implemented (1) if we do not approve conservation equivalency, or (2) at the start of the next fishing year (i.e., when conservation equivalency for a given year has expired).

TABLE 1—APPROXIMATE TIMELINE FOR IMPLEMENTING CONSERVATION EQUIVALENCY

- August:*
- Council recommends the recreational harvest limit to NMFS. Board takes final action on recreational harvest limit for state waters.
- October:*
- Preliminary Marine Recreational Information Program (MRIP) data for waves 1–4 (i.e., January–August) of the current year are available.
- November:*
- Monitoring Committee reviews MRIP data through wave 4 and recommends overall percent reduction required or liberalization allowed and use of coastwide measures or conservation equivalency (including non-preferred coastwide and precautionary default measures).
- December:*
- Council/Board recommend conservation equivalency or coastwide measures for the following year. If they select conservation equivalency, they also recommend non-preferred coastwide and precautionary default measures.
  - NMFS publishes final rule announcing subsequent year's recreational harvest limit.

If conservation equivalency is recommended	If coastwide measures are recommended
<p><i>January:</i></p> <ul style="list-style-type: none"> <li>• States/regions submit conservation equivalency proposals to Commission staff.</li> <li>• Technical Committee evaluates proposals.</li> </ul> <p><i>February:</i></p> <ul style="list-style-type: none"> <li>• Board reviews and approves/disapproves proposals.</li> </ul> <p><i>February/March:</i></p> <ul style="list-style-type: none"> <li>• Council staff submits recreational measure package to NMFS. Package includes:                             <ul style="list-style-type: none"> <li>○ Overall percent reduction required or liberalization allowed;</li> <li>○ Non-preferred coastwide and precautionary default measures; and</li> <li>○ Recommendation to implement conservation equivalency.</li> </ul> </li> </ul> <p><i>April:</i></p> <ul style="list-style-type: none"> <li>• NMFS publishes proposed rule for recreational measures announcing the overall percent reduction required or liberalization allowed and the non-preferred coastwide and precautionary default measures.</li> <li>• Board submits letter to NMFS certifying that the combination of state/regional measures is not expected to result in harvest exceeding the recreational harvest limit.</li> </ul> <p><i>May:</i></p> <ul style="list-style-type: none"> <li>• NMFS publishes final rule announcing overall percent reduction required or liberalization allowed and coastwide measures.</li> </ul>	<p><i>February/March:</i></p> <ul style="list-style-type: none"> <li>• Council staff submits recreational measure package to NMFS. Package includes:                             <ul style="list-style-type: none"> <li>○ Overall percent reduction required or liberalization allowed; and</li> <li>○ Coastwide measures.</li> </ul> </li> </ul> <p><i>April:</i></p> <ul style="list-style-type: none"> <li>• NMFS publishes proposed rule for recreational measures announcing the overall percent reduction required or liberalization allowed and coastwide measures.</li> </ul> <p><i>May:</i></p> <ul style="list-style-type: none"> <li>• NMFS publishes final rule announcing overall percent reduction required or liberalization allowed and approval of conservation equivalency; or coastwide measures.</li> </ul>

### Block Island Sound Transit Zone

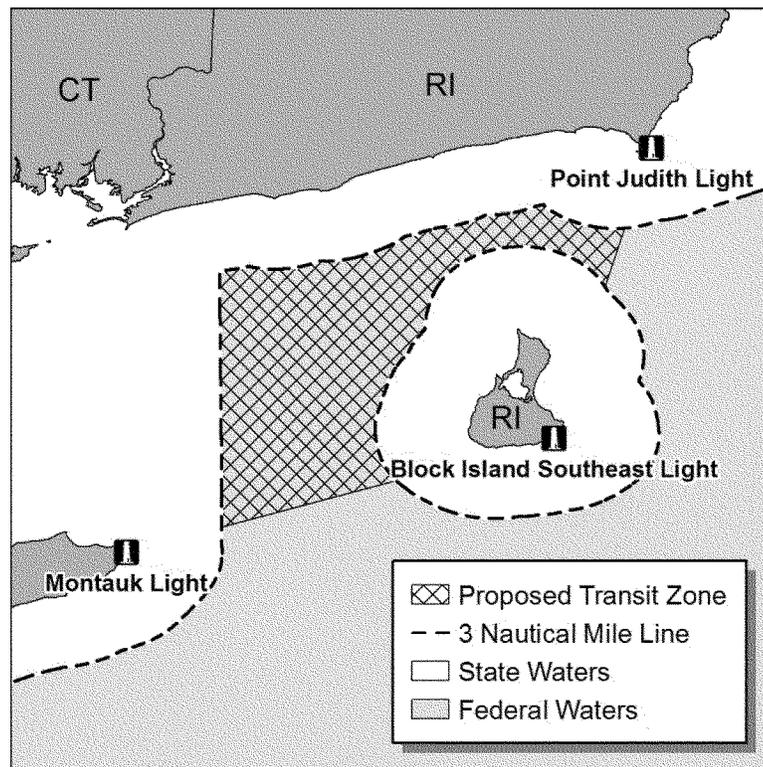
This action also proposes a transit area for state-only permitted vessels fishing around Block Island to address issues when Federal and state management measures differ. The transit zone would mirror the current transit area for striped bass and allow for transit by state-only permitted commercial and party/charter vessels and private recreational anglers with summer flounder, scup, and black sea

bass on board that were legally harvested in state waters (Figure 1). These vessels could transit between the Rhode Island state waters surrounding Block Island and the coastal state waters of Rhode Island, New York, Connecticut, or Massachusetts while complying with the state waters measures for those species. Transit through the defined area would be allowed, provided that fishermen and harvest are compliant with all applicable state regulations, gear is

stowed in accordance with Federal regulations, no fishing takes place from the vessel while in Federal waters, and the vessel is in continuous transit.

This transit provision does not apply to federally permitted vessels. There would be no change to current Federal regulations requiring all federally permitted vessels to abide by the measures of the state(s) in which they harvest or land their catch, or the Federal waters measures, whichever are more restrictive.

Figure 1 -- Proposed Block Island Sound Transit Area



### Inclusion of Maximum Size Limit

Although the states are able to set a maximum size limit for fish caught in state waters, only a minimum size can be specified in the current Federal regulations. By including a maximum size, the Council could recommend both a minimum and maximum recreational size limit to allow for consideration of regular slot limits, split slot limits, and trophy fish when setting recreational measures each year. The proposed measure would only be for summer flounder and black sea bass. The Commission already has the flexibility to develop slot limits in state waters. This measure does not make any immediate adjustments to any current Federal recreational measures, but would add flexibility in specifying

recreational management measures and would allow for future consideration by the Council.

### Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the Assistant Administrator has determined that this proposed rule is consistent with the Summer Flounder, Scup, and Black Sea Bass FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

The Council reviewed the proposed regulations for this action and deemed them necessary and appropriate to implement consistent with section 303(c) of the Magnuson-Stevens Conservation and Management Act.

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

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The Council conducted an evaluation of the potential socioeconomic impacts of the proposed measures. According to the commercial ownership database, 869 for-hire affiliate firms generated revenues from recreational fishing for various species during the 2015–2017 period. All of those business affiliates are categorized as small businesses. A similar affiliate database is not available

for non-federally permitted vessels. As previously stated, the transit provision for Block Island Sound applies only to non-federally permitted commercial and recreational vessels. The number of commercial and recreational affiliates which are legally authorized to fish in Rhode Island state waters and do not hold Federal commercial or party/charter permits for summer flounder, scup, and black sea bass has not been assessed. However, based on the federally permitted recreational fishing fleet, it is expected that most, if not all, of these entities would be classified as small businesses.

This action would include conservation equivalency as an annual management consideration for the black sea bass fishery, incorporate a maximum recreational size limit in the list of potential specifications measures for summer flounder and black sea bass, and create a Federal water transit area for non-federally permitted vessels fishing in state waters around Block Island Sound. The first two management measures are administrative in nature and make no immediate changes to the fisheries, but are expected to result in increased angler satisfaction by allowing for consistency of measures in state and Federal waters. If the Council and Board utilize these provisions when setting recreational specifications in the future, those impacts will be evaluated. The last management measure, which would allow non-federally permitted recreational and commercial vessels to transit a defined area in Block Island Sound while complying with the state regulations for summer flounder, scup, and black sea bass, only applies to state-only permitted vessels and does not impact federally permitted vessels. This transit area would likely result in a slight increase in fishing activity in Rhode Island state waters around Block Island by state-only permitted commercial and recreational vessels, but landings will still be constrained by annual harvest limits.

Because this action would either implement administrative measures or allow for a slight increase in fishing opportunities and revenues, this rule will not have a significant economic impact on a substantial number of small entities. Therefore, an initial regulatory flexibility analysis is not required and none has been prepared.

There are no new reporting or recordkeeping requirements contained in this action.

**List of Subjects in 50 CFR Part 648**

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: August 8, 2019.

**Samuel D. Rauch III,**  
*Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.*

For the reasons set out in the preamble, 50 CFR part 648 is proposed to be amended as follows:

**PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES**

■ 1. The authority citation for part 648 continues to read as follows:

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

■ 2. In § 648.14, revise paragraphs (n)(1)(i), (o)(1) introductory text, (p)(1) introductory text, (p)(1)(i) and (v), and (p)(2) introductory text, to read as follows:

**§ 648.14 Prohibitions.**

\* \* \* \* \*

(n) \* \* \*  
(1) \* \* \*

(i) *Permit requirement.* Possess summer flounder in or harvested from the EEZ, either in excess of the possession limit specified in § 648.106, or before or after the time period specified in § 648.105, unless the vessel was issued a summer flounder moratorium permit and the moratorium permit is on board the vessel and has not been surrendered, revoked, or suspended. However, possession of summer flounder harvested from state waters is allowed for state-only permitted vessels when transiting Federal waters within the Block Island Sound Transit Area provided they follow the provisions at § 648.111.

\* \* \* \* \*

(o) \* \* \*

(1) *All persons.* Unless a vessel is participating in a research activity as described in § 648.122(e) or unless a vessel has no Federal scup permit, possesses scup caught exclusively in state waters, and is transiting Federal waters within the Block Island Sound Transit Area in accordance with the provisions at § 648.131, it is unlawful for any person to do any of the following:

\* \* \* \* \*

(p) \* \* \*

(1) *All persons.* Unless participating in a research activity as described in § 648.142(e), it is unlawful for any person to do any of the following:

(i) *Permit requirement.* Possess black sea bass in or harvested from the EEZ north of 35°15.3' N lat., either in excess of the possession limit established pursuant to § 648.145, or before or after the time period established pursuant to § 648.146, unless the person is operating

a vessel issued a moratorium permit under § 648.4 and the moratorium permit is on board the vessel. However, possession of black sea bass harvested from state waters is allowed for state-only permitted vessels when transiting Federal waters within the Block Island Sound Transit Area provided they follow the provisions at § 648.151.

\* \* \* \* \*

(v) *Size limits.* Fish for, possess, land, or retain black sea bass in or from the EEZ that does not comply with the minimum or maximum (as applicable) fish size specified in § 648.147.

\* \* \* \* \*

(2) *Vessel and operator permit holders.* Unless participating in a research activity as described in § 648.142(e), it is unlawful for any person owning or operating a vessel issued a black sea bass permit (including a moratorium permit) to do any of the following:

\* \* \* \* \*

■ 3. In § 648.102, revise paragraphs (a)(7), and (d)(2)(ii) through (iv) to read as follows:

**§ 648.102 Summer flounder specifications.**

(a) \* \* \*

(7) Recreational minimum and/or maximum fish size.

\* \* \* \* \*

(d) \* \* \*  
(2) \* \* \*

(ii) The ASMFC will review conservation equivalency proposals and determine whether or not they achieve the necessary adjustment to recreational landings. The ASMFC will provide the Regional Administrator with the individual state and/or multi-state region conservation measures for the approved state and/or multi-state region proposals and, in the case of disapproved state and/or multi-state region proposals, the precautionary default measures that should be applied to a state or region. At the request of the ASMFC, precautionary default measures would apply to federally permitted party/charter vessels and other recreational fishing vessels harvesting summer flounder in or from the EEZ when landing in a state that implements measures not approved by the ASMFC.

(iii) After considering public comment, the Regional Administrator will publish a final rule in the **Federal Register** to implement either the state specific conservation equivalency measures or coastwide measures to ensure that the applicable specified target is not exceeded.

(iv) The ASMFC may allow states assigned the precautionary default measures to resubmit revised

management measures. The ASMFC will detail the procedures by which the state can develop alternate measures. The ASMFC will notify the Regional Administrator of any resubmitted state proposals approved subsequent to publication of the final rule and the Regional Administrator will publish a notice in the **Federal Register** to notify the public.

\* \* \* \* \*

■ 4. In § 648.104, revise the section heading and paragraphs (b) and (c) to read as follows:

**§ 648.104 Summer flounder size requirements.**

\* \* \* \* \*

(b) *Party/charter permitted vessels and recreational fishery participants.* The minimum size for summer flounder is 19 inches (48.3 cm) TL for all vessels that do not qualify for a moratorium permit under § 648.4(a)(3), and charter boats holding a moratorium permit if fishing with more than three crew members, or party boats holding a moratorium permit if fishing with passengers for hire or carrying more than five crew members, unless otherwise specified in the conservation equivalency regulations at § 648.107. If conservation equivalency is not in effect in any given year, possession of smaller (or larger, if applicable) summer flounder harvested from state waters is allowed for state-only permitted vessels when transiting Federal waters within the Block Island Sound Transit Area provided they follow the provisions at § 648.111 and abide by state regulations.

(c) The size limits in this section apply to whole fish or to any part of a fish found in possession, *e.g.*, fillets, except that party and charter vessels possessing valid state permits authorizing filleting at sea may possess fillets smaller than the size specified if all state requirements are met.

■ 5. Revise § 648.105 to read as follows:

**§ 648.105 Summer flounder recreational fishing season.**

No person may fish for summer flounder in the EEZ from May 15 through September 15 unless that person is the owner or operator of a fishing vessel issued a commercial summer flounder moratorium permit, or is issued a summer flounder dealer permit, or unless otherwise specified in the conservation equivalency measures at § 648.107. Persons aboard a commercial vessel that is not eligible for a summer flounder moratorium permit are subject to this recreational fishing season. This time period may be adjusted pursuant to the procedures in § 648.102. Possession of summer

flounder harvested from state waters during this time is allowed for state-only permitted vessels when transiting Federal waters within the Block Island Sound Transit Area provided they follow the provisions at § 648.111 and abide by state regulations.

■ 6. In § 648.106, revise paragraph (a) to read as follows:

**§ 648.106 Summer flounder possession restrictions.**

(a) *Party/charter and recreational possession limits.* No person shall possess more than four summer flounder in, or harvested from, the EEZ, per trip unless that person is the owner or operator of a fishing vessel issued a summer flounder moratorium permit, or is issued a summer flounder dealer permit, or unless otherwise specified in the conservation equivalency measures at § 648.107. Persons aboard a commercial vessel that is not eligible for a summer flounder moratorium permit are subject to this possession limit. The owner, operator, and crew of a charter or party boat issued a summer flounder moratorium permit are subject to the possession limit when carrying passengers for hire or when carrying more than five crew members for a party boat, or more than three crew members for a charter boat. This possession limit may be adjusted pursuant to the procedures in § 648.102. Possession of summer flounder harvested from state waters above this possession limit is allowed for state-only permitted vessels when transiting Federal waters within the Block Island Sound Transit Area provided they follow the provisions at § 648.111 and abide by state regulations.

\* \* \* \* \*

■ 7. In § 648.107, revise paragraph (a) introductory text and paragraph (b) to read as follows:

**§ 648.107 Conservation equivalent measures for the summer flounder fishery.**

(a) The Regional Administrator has determined that the recreational fishing measures proposed to be implemented by the states of Maine through North Carolina for 2019 are the conservation equivalent of the season, size limits, and possession limit prescribed in §§ 648.104(b), 648.105, and 648.106. This determination is based on a recommendation from the Summer Flounder Board of the Atlantic States Marine Fisheries Commission.

\* \* \* \* \*

(b) Federally permitted vessels subject to the recreational fishing measures of this part, and other recreational fishing vessels registered in states and subject to the recreational fishing measures of this part, whose fishery management

measures are not determined by the Regional Administrator to be the conservation equivalent of the season, size limits and possession limit prescribed in §§ 648.102, 648.103(b), and 648.105(a), respectively, due to the lack of, or the reversal of, a conservation equivalent recommendation from the Summer Flounder Board of the Atlantic States Marine Fisheries Commission shall be subject to the following precautionary default measures: Season—July 1 through August 31; minimum size—20 inches (50.8 cm); and possession limit—two fish.

■ 8. Add § 648.111 to read as follows:

**§ 648.111 Block Island Sound Transit Area.**

(a) Vessels not issued a Federal moratorium or party/charter permit, and recreational fishing participants fishing exclusively in state waters may transit with summer flounder harvested from state waters on board through Federal waters of the EEZ within Block Island Sound, north of a line connecting Montauk Light, Montauk Point, NY, and Block Island Southeast Light, Block Island, RI; and west of a line connecting Point Judith Light, Point Judith, RI, and Block Island Southeast Light, Block Island, RI. Within this area, possession of summer flounder is permitted regardless of the minimum or maximum size (as applicable), possession limit, and seasons outlined in §§ 648.104, 648.105, and 648.106, provided no fishing takes place from the vessel while in Federal waters of the EEZ, the vessel complies with state regulations, and is in continuous transit. During such transit through this area, commercial gear must be stowed in accordance with the definition of “not available for immediate use” found at § 648.2, and party/charter vessels and recreational participants must have all bait and hooks removed from fishing rods, and any summer flounder on board must be stored in a cooler or container.

(b) The requirements of this transit zone are not necessary or applicable for recreational fishery participants during years when conservation equivalency has been adopted under § 648.107 conservation equivalency measures and recreational Federal measures are waived.

■ 9. In § 648.126, revise paragraph (b) to read as follows:

**§ 648.126 Scup minimum fish sizes.**

\* \* \* \* \*

(b) *Party/Charter permitted vessels and recreational fishery participants.* The minimum size for scup is 9 inches (22.9 cm) TL for all vessels that do not have a moratorium permit, or for party and charter vessels that are issued a

moratorium permit but are fishing with passengers for hire, or carrying more than three crew members if a charter boat, or more than five crew members if a party boat. However, possession of smaller scup harvested from state waters is allowed for state-only permitted vessels when transiting Federal waters within the Block Island Sound Transit Area provided they follow the provisions at § 648.131 and abide by state regulations.

\* \* \* \* \*

■ 10. Revise § 648.127 to read as follows:

**§ 648.127 Scup recreational fishing season.**

Fishermen and vessels that are not eligible for a moratorium permit under § 648.4(a)(6), may possess scup year-round, subject to the possession limit specified in § 648.128(a). The recreational fishing season may be adjusted pursuant to the procedures in § 648.122. Should the recreational fishing season be modified, non-federally permitted vessels abiding by state regulations may transit with scup harvested from state waters on board through the Block Island Sound Transit Area following the provisions outlined in § 648.131.

■ 11. In § 648.128, revise paragraph (a) to read as follows:

**§ 648.128 Scup possession restrictions.**

(a) *Party/Charter and recreational possession limits.* No person shall possess more than 50 scup in, or harvested from, per trip the EEZ unless that person is the owner or operator of a fishing vessel issued a scup moratorium permit, or is issued a scup dealer permit. Persons aboard a commercial vessel that is not eligible for a scup moratorium permit are subject to this possession limit. The owner, operator, and crew of a charter or party boat issued a scup moratorium permit are subject to the possession limit when carrying passengers for hire or when carrying more than five crew members for a party boat, or more than three crew members for a charter boat. This possession limit may be adjusted pursuant to the procedures in § 648.122. However, possession of scup harvested from state waters above this possession limit is allowed for state-only permitted vessels when transiting Federal waters within the Block Island Sound Transit Area provided they follow the provisions at § 648.131 and abide by state regulations.

\* \* \* \* \*

■ 12. Add § 648.131 to read as follows:

**§ 648.131 Block Island Sound Transit Area.**

(a) Vessels not issued a Federal moratorium or party/charter permit, and recreational fishing participants fishing exclusively in state waters may transit with scup harvested from state waters on board through Federal waters of the EEZ within Block Island Sound, north of a line connecting Montauk Light, Montauk Point, NY, and Block Island Southeast Light, Block Island, RI; and west of a line connecting Point Judith Light, Point Judith, RI, and Block Island Southeast Light, Block Island, RI. Within this area, possession of scup is permitted regardless of the minimum size, possession limit, and seasons outlined in §§ 648.126, 648.127, and 648.128, provided no fishing takes place from the vessel while in Federal waters of the EEZ, the vessel complies with state regulations, and is in continuous transit. During such transit through this area, commercial gear must be stowed in accordance with the definition of “not available for immediate use” found at § 648.2, and party/charter vessels and recreational participants must have all bait and hooks removed from fishing rods, and any scup on board must be stored in a cooler or container.

■ 13. Revise § 648.142 to read as follows:

**§ 648.142 Black sea bass specifications.**

(a) *Commercial quota, recreational landing limit, research set-aside, and other specification measures.* The Black Sea Bass Monitoring Committee will recommend to the Demersal Species Committee of the MAFMC and the ASMFC, through the specification process, for use in conjunction with the ACL and ACT, sector-specific research set-asides, estimates of the sector-related discards, a recreational harvest limit, a commercial quota, along with other measures, as needed, that are projected to ensure the sector-specific ACL for an upcoming year or years will not be exceeded. The following measures are to be considered by the Black Sea Bass Monitoring Committee:

(1) Research quota set from a range of 0 to 3 percent of the maximum allowed.

(2) A commercial quota, allocated annually.

(3) A commercial possession limit for all moratorium vessels, with the provision that these quantities be the maximum allowed to be landed within a 24-hour period (calendar day).

(4) Commercial minimum fish size.

(5) Minimum mesh size in the codend or throughout the net and the catch threshold that will require compliance with the minimum mesh requirement.

(6) Escape vent size.

(7) A recreational possession limit set after the reduction for research quota.

(8) Recreational minimum and/or maximum fish size.

(9) Recreational season.

(10) Recreational state conservation equivalent and precautionary default measures utilizing possession limits, minimum fish sizes, and/or seasons set after reductions for research quota.

(11) Restrictions on gear other than other trawls and pots or traps.

(12) Total allowable landings on an annual basis for a period not to exceed 3 years.

(13) Changes, as appropriate, to the SBRM, including the CV-based performance standard, the means by which discard data are collected/obtained, fishery stratification, the process for prioritizing observer sea-day allocations, reports, and/or industry-funded observers or observer set aside programs.

(14) Modification of the existing AM measures and ACT control rules utilized by the Black Sea Bass Monitoring Committee.

(b) *Specification fishing measures.* The Demersal Species Committee shall review the recommendations of the Black Sea Bass Monitoring Committee. Based on these recommendations and any public comment, the Demersal Species Committee shall make its recommendations to the MAFMC with respect to the measures necessary to assure that the sector-specific ACLs for an upcoming fishing year or years will not be exceeded. The MAFMC shall review these recommendations and, based on the recommendations and public comment, make recommendations to the Regional Administrator with respect to the measures necessary to assure that sector ACLs are not exceeded. Included in the recommendation will be supporting documents, as appropriate, concerning the environmental and economic impacts of the final rule. The Regional Administrator will review these recommendations and any recommendations of the ASMFC. After such review, the Regional Administrator will publish a proposed rule in the **Federal Register** to implement a commercial quota, a recreational harvest limit, and additional management measures for the commercial fishery.

(c) *Distribution of annual commercial quota.* The black sea bass commercial quota will be allocated on a coastwide basis.

(d) *Recreational specification measures.* The Demersal Species Committee shall review the recommendations of the Black Sea Bass Monitoring Committee. Based on these

recommendations and any public comment, the Demersal Species Committee shall recommend to the MAFMC and ASMFC measures that are projected to ensure the recreational ACL for an upcoming fishing year or years will not be exceeded. The MAFMC shall review these recommendations and, based on the recommendations and any public comment, recommend to the Regional Administrator measures that are projected to ensure the recreational ACL for an upcoming fishing year or years will not be exceeded. The MAFMC's recommendations must include supporting documentation, as appropriate, concerning the environmental and economic impacts of the recommendations. The MAFMC and the ASMFC will recommend that the Regional Administrator implement either:

(1) *Coastwide measures.* Annual coastwide management measures that constrain the recreational black sea bass fishery to the recreational harvest limit, or

(2) *Conservation equivalent measures.* Individual states, or regions formed voluntarily by adjacent states (*i.e.*, multi-state conservation equivalency regions), may implement different combinations of minimum and/or maximum fish sizes, possession limits, and closed seasons that achieve equivalent conservation as the coastwide measures established under paragraph (e)(1) of this section. Each state or multi-state conservation equivalency region may implement measures by mode or area only if the proportional standard error of recreational landing estimates by mode or area for that state is less than 30 percent.

(i) After review of the recommendations, the Regional Administrator will publish a proposed rule in the **Federal Register** as soon as possible to implement the overall percent adjustment in recreational landings required for the fishing year, and the ASMFC's recommendation concerning conservation equivalency, the precautionary default measures, and coastwide measures.

(ii) The ASMFC will review conservation equivalency proposals and determine whether or not they achieve the necessary adjustment to recreational landings. The ASMFC will provide the Regional Administrator with the individual state and/or multi-state region conservation measures for the approved state and/or multi-state region proposals and, in the case of disapproved state and/or multi-state region proposals, the precautionary default measures that should be applied

to a state or region. At the request of the ASMFC, precautionary default measures would apply to federally permitted party/charter vessels and other recreational fishing vessels harvesting summer flounder in or from the EEZ when landing in a state that implements measures not approved by the ASMFC.

(iii) After considering public comment, the Regional Administrator will publish a final rule in the **Federal Register** to implement either the state specific conservation equivalency measures or coastwide measures to ensure that the applicable specified target is not exceeded.

(iv) The ASMFC may allow states assigned the precautionary default measures to resubmit revised management measures. The ASMFC will detail the procedures by which the state can develop alternate measures. The ASMFC will notify the Regional Administrator of any resubmitted state proposals approved subsequent to publication of the final rule and the Regional Administrator will publish a notice in the **Federal Register** to notify the public.

(e) *Research quota.* See § 648.22(g).

■ 14. In § 648.144, revise paragraph (a)(1)(ii) to read as follows:

**§ 648.144 Black sea bass gear restrictions.**

(a) \* \* \*

(1) \* \* \*

(ii) Mesh sizes shall be measured pursuant to the procedure specified in § 648.108(a)(2).

\* \* \* \* \*

■ 15. In § 648.145, revise paragraph (a) to read as follows:

**§ 648.145 Black sea bass possession limit.**

(a) During the recreational fishing season specified at § 648.146, no person shall possess more than 15 black sea bass in, or harvested from, per trip the EEZ unless that person is the owner or operator of a fishing vessel issued a black sea bass moratorium permit, or is issued a black sea bass dealer permit, unless otherwise specified in the conservation equivalent measures at § 648.150. Persons aboard a commercial vessel that is not eligible for a black sea bass moratorium permit may not retain more than 15 black sea bass during the recreational fishing season specified at § 648.146. The owner, operator, and crew of a charter or party boat issued a black sea bass moratorium permit are subject to the possession limit when carrying passengers for hire or when carrying more than five crew members for a party boat, or more than three crew members for a charter boat. This possession limit may be adjusted pursuant to the procedures in § 648.142.

However, possession of black sea bass harvested from state waters above this possession limit is allowed for state-only permitted vessels when transiting Federal waters within the Block Island Sound Transit Area provided they follow the provisions at § 648.151 and abide by state regulations.

\* \* \* \* \*

■ 16. Revise § 648.146 to read as follows:

**§ 648.146 Black sea bass recreational fishing season.**

Vessels that are not eligible for a moratorium permit under § 648.4(a)(7), and fishermen subject to the possession limit specified in § 648.145(a), may only possess black sea bass from February 1 through February 28, May 15 through December 31, unless otherwise specified in the conservation equivalent measures at § 648.150 or unless this time period is adjusted pursuant to the procedures in § 648.142. However, possession of black sea bass harvested from state waters outside of this season is allowed for state-only permitted vessels when transiting Federal waters within the Block Island Sound Transit Area provided they follow the provisions at § 648.151 and abide by state regulations.

■ 17. In § 648.147, revise the section heading and paragraphs (b) and (c) to read as follows:

**§ 648.147 Black sea bass size requirements.**

\* \* \* \* \*

(b) *Party/Charter permitted vessels and recreational fishery participants.* The minimum fish size for black sea bass is 12.5 inches (31.75 cm) TL for all vessels that do not qualify for a moratorium permit, and for party boats holding a moratorium permit, if fishing with passengers for hire or carrying more than five crew members, and for charter boats holding a moratorium permit, if fishing with more than three crew members, unless otherwise specified in the conservation equivalent measures at § 648.150. However, possession of smaller black sea bass harvested from state waters is allowed for state-only permitted vessels when transiting Federal waters within the Block Island Sound Transit Area provided they follow the provisions at § 648.151 and abide by state regulations.

(c) The size limits in this section applies to the whole fish or any part of a fish found in possession (*e.g.*, fillets), except that party or charter vessels possessing valid state permits authorizing filleting at sea may possess fillets smaller than the size specified if skin remains on the fillet and all other state requirements are met.

**§ 648.150 [Reserved]**

- 18. Add and reserve § 648.150.
- 19. Add § 648.151 to read as follows:

**§ 648.151 Block Island Sound Transit Zone.**

(a) Vessels not issued a Federal moratorium or party/charter permit, and recreational fishing participants fishing exclusively in state waters may transit with black sea bass harvested from state waters on board through Federal waters of the EEZ within Block Island Sound, north of a line connecting Montauk Light, Montauk Point, NY, and Block Island Southeast Light, Block Island, RI;

and west of a line connecting Point Judith Light, Point Judith, RI, and Block Island Southeast Light, Block Island, RI. Within this area, possession of black sea bass is permitted regardless of the minimum and/or maximum (as applicable) size, possession limit, and seasons outlined in §§ 648.145, 648.146, and 648.147, provided no fishing takes place from the vessel while in Federal waters of the EEZ, the vessel complies with state regulations, and is in continuous transit. During such transit through this area, commercial gear must be stowed in accordance with the definition of “not available for

immediate use” found at § 648.2, and party/charter vessels and recreational participants must have all bait and hooks removed from fishing rods, and any black sea bass on board must be stored in a cooler or container.

(b) The requirements of this transit zone are not necessary or applicable for recreational fishery participants during years when conservation equivalency has been adopted under § 648.150 conservation equivalency measures and recreational Federal measures are waived.

[FR Doc. 2019-16980 Filed 8-7-19; 8:45 am]

**BILLING CODE 3510-22-P**

# Notices

Federal Register

Vol. 84, No. 153

Thursday, August 8, 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.

## ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

### Adoption of Recommendations

**AGENCY:** Administrative Conference of the United States.

**ACTION:** Notice.

**SUMMARY:** The Administrative Conference of the United States adopted four recommendations at its Seventy-first Plenary Session. The appended recommendations address Agency Guidance Through Interpretive Rules, Agency Recruitment and Selection of Administrative Law Judges, Public Availability of Agency Guidance Documents, and Revised Model Rules for Implementation of the Equal Access to Justice Act.

**FOR FURTHER INFORMATION CONTACT:** For Recommendation 2019–1, Todd Rubin; for Recommendations 2019–2 and 2019–4, Alexandria Tindall Webb; and for Recommendation 2019–3, Todd Phillips. For each of these actions the address and telephone number are: Administrative Conference of the United States, Suite 706 South, 1120 20th Street NW, Washington, DC 20036; Telephone 202–480–2080.

**SUPPLEMENTARY INFORMATION:** The Administrative Conference Act, 5 U.S.C. 591–596, established the Administrative Conference of the United States. The Conference studies the efficiency, adequacy, and fairness of the administrative procedures used by Federal agencies and makes recommendations to agencies, the President, Congress, and the Judicial Conference of the United States for procedural improvements (5 U.S.C. 594(1)). For further information about the Conference and its activities, see [www.acus.gov](http://www.acus.gov). At its Seventy-first Plenary Session, held on June 13, 2019, the Assembly of the Conference adopted four recommendations.

Recommendation 2019–1, *Agency Guidance Through Interpretive Rules*

identifies ways agencies can offer the public the opportunity to propose alternative approaches to those presented in an interpretive rule and to encourage, when appropriate, public participation in the adoption or modification of interpretive rules. It largely extends the best practices for statements of policy adopted in Recommendation 2017–5, *Agency Guidance Through Policy Statements*, to interpretive rules, with appropriate modifications to account for differences between interpretive rules and policy statements.

Recommendation 2019–2, *Agency Recruitment and Selection of Administrative Law Judges* addresses the processes and procedures agencies should establish for exercising their authority under Executive Order 13,843 (2018) to hire administrative law judges (ALJs). It encourages agencies to advertise ALJ positions in order to reach a wide pool of applicants, to publish minimum qualifications and selection criteria for ALJ hiring, and to develop policies for the review of ALJ applications.

Recommendation 2019–3, *Public Availability of Agency Guidance Documents* offers best practices for promoting widespread availability of guidance documents on agency websites. It urges agencies to develop and disseminate internal policies for publishing, tracking, and obtaining input on guidance documents; post guidance documents online in a manner that facilitates public access; and undertake affirmative outreach to notify members of the public of new or updated guidance documents.

Recommendation 2019–4, *Revised Model Rules for Implementation of the Equal Access to Justice Act* revises the Conference's 1986 model agency procedural rules for addressing claims under the Act, which provides for the award of attorney fees to individuals and small businesses that prevail against the government in certain agency adjudications. The revisions reflect, among other things, changes in law and agency practice since 1986.

The Appendix below sets forth the full texts of these four recommendations. In addition, a Notice of Availability, containing the *Revised Model Rules* referenced in Recommendation 2019–4, is published elsewhere in this issue of the **Federal**

**Register.** The Conference will transmit the recommendations to affected agencies, Congress, and the Judicial Conference of the United States, as appropriate. The recommendations are not binding, so the entities to which they are addressed will make decisions on their implementation.

The Conference based these recommendations on research reports that are posted at: <https://www.acus.gov/meetings-and-events/plenary-meeting/71st-plenary-session>.

Dated: August 2, 2019.

**Shawne C. McGibbon,**  
General Counsel.

### Appendix—Recommendations of the Administrative Conference of the United States

#### Administrative Conference Recommendation 2019–1

##### Agency Guidance Through Interpretive Rules

*Adopted June 13, 2019*

The Administrative Procedure Act (APA) exempts policy statements and interpretive<sup>1</sup> rules from its requirements for the issuance of legislative rules, including notice and comment.<sup>2</sup> The *Attorney General's Manual on the Administrative Procedure Act* defines “general statements of policy” as agency statements “issued . . . to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power.”<sup>3</sup> The *Manual* similarly defines “interpretive rules” as “rules or statements issued by an agency to advise the public of the agency’s construction of the statutes and rules which it administers.”<sup>4</sup> Because of the commonalities between policy statements and interpretive rules, including their advisory function, many scholars and government agencies have more recently adopted the umbrella term “guidance” to refer to both interpretive rules and policy statements.<sup>5</sup>

The Administrative Conference has issued several recommendations on policy statements.<sup>6</sup> The latest one, Recommendation

<sup>1</sup> In accordance with standard parlance, this Recommendation uses the term “interpretive” in place of the APA’s word “interpretative.”

<sup>2</sup> 5 U.S.C. 553(b)(A).

<sup>3</sup> *Attorney General's Manual on the Administrative Procedure Act* 30 n.3 (1947).

<sup>4</sup> *Id.*

<sup>5</sup> See, e.g., Nicholas R. Parrillo, *Federal Agency Guidance: An Institutional Perspective* (Oct. 12, 2017) (report to the Admin. Conf. of the U.S.), <https://www.acus.gov/report/agency-guidance-final-report>.

<sup>6</sup> See, e.g., Admin. Conf. of the U.S., *Recommendation 2017–5, Agency Guidance*

2017–5, *Agency Guidance Through Policy Statements*, offers best practices to agencies regarding policy statements. The Recommendation advises agencies not to treat policy statements as binding on the public and to take steps to make clear to the public that policy statements are nonbinding. It also suggests measures agencies could take to allow the public to propose alternative approaches to those contained in a policy statement and offers suggestions on how agencies can involve the public in adopting and modifying policy statements.<sup>7</sup>

During the discussion of Recommendation 2017–5, the Assembly considered whether to extend the recommendations therein to interpretive rules. The Assembly decided against doing so, but it expressed its views that a follow-on study addressing interpretive rules would be valuable.

This project takes up that charge. Policy statements and interpretive rules are similar in that they lack the force of law<sup>8</sup> and are often issued without notice-and-comment proceedings, as the APA permits. This similarity suggests that, as a matter of best practice, when interested persons disagree with the views expressed in an interpretive rule, the agency should allow them a fair opportunity to try to persuade the agency to revise or reconsider its interpretation. That is the practice that Recommendation 2017–5 already prescribes in the case of policy statements.<sup>9</sup> The benefits to the public of according such treatment, as well as the potential costs to agencies of according it, are largely the same regardless of whether a given guidance document is concerned with law, policy, or a combination of both.<sup>10</sup>

Recommendation 2017–5 provided that “[a]n agency should not use a policy statement to create a standard binding on the public, that is, as a standard with which noncompliance may form an independent basis for action in matters that determine the rights and obligations of any member of the public.”<sup>11</sup> Although the same basic idea should apply to interpretive rules, the concept of “binding” effect can give rise to misunderstanding in the context of those rules, for several reasons.

First, interpretive rules often use mandatory language when the agency is describing an existing statutory or regulatory requirement. Recommendation 2017–5 itself

*Through Policy Statements*, 82 FR 61,734 (Dec. 29, 2017); Admin. Conf. of the U.S., Recommendation 1992–2, *Agency Policy Statements*, 57 FR 30,103 (July 8, 1992); Admin. Conf. of the U.S., Recommendation 1976–5, *Interpretive Rules of General Applicability and Statements of General Policy*, 41 FR 56,769 (Dec. 30, 1976).

<sup>7</sup> See Recommendation 2017–5, *supra* note 6, ¶ 9.

<sup>8</sup> *Perez v. Mortg. Bankers Ass’n*, 135 S. Ct. 1199, 1208 (2015) (citing *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 n.31 (1979) (citing the Attorney General’s Manual, *supra* note 3)).

<sup>9</sup> Recommendation 2017–5, *supra* note 6, ¶ 2; see also Recommendation 1992–2, *supra* note 6, ¶ II.B.

<sup>10</sup> See Blake Emerson & Ronald M. Levin, *Agency Guidance Through Interpretive Rules: Research and Analysis 33–34* (May 28, 2019) (report to the Admin. Conf. of the U.S.), <https://www.acus.gov/report/agency-guidance-through-interpretive-rules-final-report>.

<sup>11</sup> Recommendation 2017–5, *supra* note 6, ¶ 1.

recognized the legitimacy of such phrasing.<sup>12</sup> For this reason, administrative lawyers sometimes describe such rules as “binding.” That common usage of words, however, can lead to confusion: It can impede efforts to make clear that interpretive rules should remain nonbinding in a different sense, *i.e.*, that members of the public should be accorded a fair opportunity to request that such rules be modified, rescinded, or waived.

Second, discussions of the circumstances in which interpretive rules may or may not be “binding” bring to mind assumptions that stem from the case law construing the rulemaking exemption in the APA.<sup>13</sup> Courts and commentators have disagreed about whether, under that case law, interpretive rules may be binding on the agency that issues them.<sup>14</sup> Despite this diversity of views, officials interviewed for this project did not express the view that they would categorically deny private parties the opportunity to seek modification, rescission, or waiver of an interpretive rule. In this Recommendation, the Administrative Conference addresses only best practices and expresses no opinions about how the APA rulemaking exemption should be construed. Nevertheless, assumptions derived from the APA background can divert attention from consideration of what sound principles of administration require, which this Recommendation does address.

Third, administrative lawyers currently differ on the question of whether interpretive rules are effectively rendered “binding” when they are reviewed in court under the *Auer v. Robbins*<sup>15</sup> standard of review, which provides that an agency’s interpretation of its own regulation becomes of “controlling weight” if it is not “plainly erroneous or inconsistent with the regulation.”<sup>16</sup> The question of whether interested persons should be able to ask an agency to modify, rescind, or waive an interpretive rule does not intrinsically have to turn on what level of deference the courts would later accord to the agency’s interpretation. Indeed, the possibility of judicial deference at the appellate level (under *Auer* or any other standard of review) may augment the

<sup>12</sup> *Id.* ¶ 5; accord Office of Mgmt. & Budget, Exec. Office of the President, Final Bulletin for Agency Good Guidance Practices, 72 FR 3,432, 3,440 (Jan. 25, 2007).

<sup>13</sup> See 5 U.S.C. 553(b)(A).

<sup>14</sup> Emerson & Levin, *supra* note 10, at 20–23; Parrillo, *supra* note 5, at 23–25; see also Ronald M. Levin, *Rulemaking and the Guidance Exemption*, 70 Admin. L. Rev. 263, 317–19, 346–53 (2018).

<sup>15</sup> 519 U.S. 452 (1997).

<sup>16</sup> *Id.* at 461; compare *Perez*, 135 S. Ct. at 1211–12 (Scalia, J., concurring in the judgment) (stating that because of “judge-made doctrines of deference . . . [a]gencies may now use [interpretive] rules not just to advise the public, but also to bind them”), with *id.* at 1208 n.4 (opinion of the Court) (“Even in cases where an agency’s interpretation receives *Auer* deference, however, it is the court that ultimately decides whether a given regulation means what the agency says.”). The Supreme Court is currently considering whether to overrule *Auer* in *Kisor v. Wilkie*, 139 S. Ct. 657 (2018) (granting certiorari). For reasons explained in the text, the present recommendations do not depend on which view of *Auer* one favors, or on what the Court may decide in *Kisor*.

challenger’s interest in raising this interpretive issue at the agency level.<sup>17</sup> Even so, the doctrinal debate over whether an interpretive rule is or is not “binding” under *Auer* can direct attention away from these practical considerations.

For these reasons, the Administrative Conference has worded the initial operative provisions of the Recommendation so that it avoids using the phrase “binding on the public.” Instead it urges that agencies not treat interpretive rules as setting independent standards for action and that interested persons should have a fair opportunity to seek modification, rescission, or waiver of an interpretive rule. In substance, this formulation expresses positions that largely correspond with prescriptions that Recommendation 2017–5 made regarding policy statements, but it does so without implicating unintended associations that the word “binding” might otherwise evoke.

What constitutes a fair opportunity to contest an interpretive rule will depend on the circumstances. Research conducted for Recommendation 2017–5 indicated that a variety of factors can deter affected persons from contesting guidance documents with which they disagree; these factors operate in approximately the same manner regardless of whether a policy statement or interpretive rule is involved.<sup>18</sup> Agencies that design procedures for requesting reconsideration or modification of both types of guidance should be attentive to circumstances that affect the practical ability of members of the public to avail themselves of the opportunity to be heard. The mere existence of an opportunity to contest an interpretive rule through an internal appeal may not be enough to afford a “fair opportunity” because of the very high process costs that pursuing such an appeal could entail.

At the same time, agencies should also consider governmental interests such as the agency’s resource constraints and need for centralization.<sup>19</sup> For example, an agency should be able to deal summarily with requests that it finds to be obstructive, dilatory, or otherwise tendered in apparent bad faith. It should not be expected to entertain and respond in detail to repetitive or frivolous challenges to the agency’s position. Additionally, Paragraph 3 recognizes that the need for coordination of multiple decision makers in a given program may justify requiring lower-level employees to adhere to the agency’s interpretive rules.

The recommendations below pertaining to public participation in the formulation of interpretive rules closely track the public participation provisions of Recommendation 2017–5. The recommendations here have been modified to reflect differences between interpretive rules and statements of policy.

Paragraphs 12 through 15 set forth principles that agencies should consider in determining whether and how to invite members of the public to suggest alternative approaches or analyses to those spelled out in interpretive rules. These paragraphs are largely drawn from corresponding provisions

<sup>17</sup> See Emerson & Levin, *supra* note 10, at 25.

<sup>18</sup> Parrillo, *supra* note 5, at 25.

<sup>19</sup> See Emerson & Levin, *supra* note 10, at 38–41.

in Recommendation 2017–5. Interpretive rules that lend themselves to alternative approaches include those that lay out several lawful options for the public but do not purport to be exhaustive. They may also include rules that, in setting forth decisional factors that are relevant to the meaning of a statute or regulation, leave open the possibility that other decisional factors might also be relevant. Typically, such rules speak at a general level, leaving space for informal adjustments and negotiation between the agency and interested persons<sup>20</sup> about how the rule should be applied. On the other hand, certain kinds of interpretive rules, such as those in which an agency has determined that a statutory term has only one construction (*e.g.*, rules that take the view that certain conduct is categorically required or forbidden), do not lend themselves to such flexible treatment.<sup>21</sup>

### Recommendation

#### *Recommendations Applicable to All Interpretive Rules*

1. An agency should not use an interpretive rule to create a standard independent of the statute or legislative rule it interprets. That is, noncompliance with an interpretive rule should not form an independent basis for action in matters that determine the rights and obligations of any member of the public.

2. An agency should afford members of the public a fair opportunity to argue for modification, rescission, or waiver of an interpretive rule. In determining whether to modify, rescind, or waive an interpretive rule, an agency should give due regard to any reasonable reliance interests.

3. It is sometimes appropriate for an agency, as an internal agency management matter, to direct some of its employees to act in conformity with an interpretive rule. But the agency should ensure that this does not interfere with the fair opportunity called for in Paragraph 2. For example, an interpretive rule could require officials at one level of the agency hierarchy to follow the interpretive rule, with the caveat that officials at a higher level can authorize a modification, rescission, or waiver of that rule. Agency review should be available when officials fail to follow interpretive rules they are properly directed to follow.

4. An agency should prominently state, in the text of an interpretive rule or elsewhere, that the rule expresses the agency's current interpretation of the law but that a member of the public will, upon proper request, be accorded a fair opportunity to seek modification, rescission, or waiver of the rule.

5. An interpretive rule should not include mandatory language unless the agency is using that language to describe an existing

statutory or regulatory requirement, or the language is addressed to agency employees and will not interfere with the fair opportunity called for in Paragraph 2.

6. An agency should make clear to members of the public which agency officials are required to follow an interpretive rule and where to go within the agency to seek modification, rescission, or waiver from the agency.

7. An agency should instruct all employees engaged in an activity to which an interpretive rule pertains that, although the interpretive rule may contain mandatory language, they should refrain from making any statements suggesting that an interpretive rule may not be contested within the agency. Insofar as any employee is directed, as an internal agency management matter, to act in conformity with an interpretive rule, that employee should be instructed as to the expectations set forth in Paragraphs 2 and 3.

8. When an agency is contemplating adopting or modifying an interpretive rule, it should consider whether to solicit public participation, and, if so, what kind, before adopting or modifying the rule. Options for public participation include meetings or webinars with interested persons, advisory committee proceedings, and invitation for written input from the public with or without a response. In deciding how to proceed, the agency should consider:

a. The agency's own procedures for adopting interpretive rules.

b. The likely increase in useful information available to the agency from broadening participation, keeping in mind that non-regulated persons (regulatory beneficiaries and other interested persons) may offer different information than regulated persons and that non-regulated persons will often have no meaningful opportunity to provide input regarding interpretive rules other than at the time of adoption.

c. The likely increase in rule acceptance from broadening participation, keeping in mind that non-regulated persons will often have no opportunity to provide input regarding interpretive rules other than at the time of adoption, and that rule acceptance may be less likely if the agency is not responsive to input from interested persons.

d. Whether the agency is likely to learn more useful information by having a specific agency proposal as a focal point for discussion, or instead having a more free-ranging and less formal discussion.

e. The practicability of broader forms of participation, including invitation for written input from the public, keeping in mind that broader participation may slow the adoption of interpretive rules and may diminish resources for other agency tasks, including issuing interpretive rules on other matters.

9. If an agency does not provide for public participation before adopting or modifying an interpretive rule, it should consider offering an opportunity for public participation after adoption or modification. As with Paragraph 8, options for public participation include meetings or webinars with interested persons, advisory committee proceedings, and invitation for written input from the public with or without a response.

10. An agency may make decisions about the appropriate level of public participation

interpretive rule-by-interpretive rule or by assigning certain procedures for public participation to general categories of interpretive rules. If an agency opts for the latter, it should consider whether resource limitations may cause some interpretive rules, if subject to pre-adoption procedures for public participation, to remain in draft for substantial periods of time. If that is the case, agencies should either (a) make clear to interested persons which draft interpretive rules, if any, should be understood to reflect current agency thinking; or (b) provide in each draft interpretive rule that, at a certain time after publication, the rule will automatically either be adopted or withdrawn.

11. All written interpretive rules affecting the interests of regulated parties, regulatory beneficiaries, or other interested parties should be promptly made available electronically and indexed, in a manner in which they may readily be found. Interpretive rules should also indicate the nature of the reliance that may be placed on them and the opportunities for modification, rescission, or waiver of them.

#### *Recommendations Applicable Only to Those Interpretive Rules Amenable to Alternative Approaches or Analyses*

12. Interpretive rules that lend themselves to alternative approaches or analyses include those that lay out several lawful options for the public but do not purport to be exhaustive. They may also include rules that, in setting forth decisional factors that are relevant to the meaning of a statute or regulation, leave open the possibility that other decisional factors might also be relevant. Typically, such rules speak at a general level, leaving space for informal adjustments and negotiation between the agency and interested persons about how the rule should be applied. Paragraphs 1–11 above apply with equal force to such rules. However, with respect to such rules, agencies should take additional steps to promote flexibility, as discussed below.

13. Agencies should afford members of the public a fair opportunity to argue for lawful approaches or analyses other than those set forth in an interpretive rule, subject to any binding requirements imposed upon agency employees as an internal management matter. The agency should explain that a member of the public may take a lawful approach different from the one set forth in the interpretive rule, request that the agency take such a lawful approach, or request that the agency endorse an alternative or additional analysis of the rule. The interpretive rule should also include the identity and contact information of officials to whom such a request should be made. Additionally, with respect to such rules, agencies should take further measures to promote such flexibility as provided in Paragraph 14.

14. In order to provide a fair opportunity for members of the public to argue for other lawful approaches or analyses, an agency should, subject to considerations of practicability and resource limitations and the priorities described in Paragraph 15, consider additional measures, including the following:

<sup>20</sup> This Recommendation uses “interested person” rather than “stakeholder,” which Recommendation 2017–5, *supra* note 6, uses. The Conference believes that “interested person” is more precise than “stakeholder” and that “stakeholder,” as used in Recommendation 2017–5, should be understood to mean “interested person.”

<sup>21</sup> See Emerson & Levin, *supra* note 10, at 42–44.

a. Promoting the flexible use of interpretive rules in a manner that still takes due account of needs for consistency and predictability. In particular, when the agency accepts a proposal for a lawful approach or analysis other than that set forth in an interpretive rule and the approach or analysis seems likely to be applicable to other situations, the agency should disseminate its decision and the reasons for it to other persons who might make the argument, to other affected interested persons, to officials likely to hear the argument, and to members of the public, subject to existing protections for confidential business or personal information.

b. Assigning the task of considering arguments for approaches or analyses other than those in an interpretive rule to a component of the agency that is likely to engage in open and productive dialogue with persons who make such arguments, such as a program office that is accustomed to dealing cooperatively with regulated parties and regulatory beneficiaries.

c. When officials are authorized to take an approach or endorse an analysis different from that in an interpretive rule but decline to do so, directing appeals of such a refusal to a higher-level official.

d. Investing in training and monitoring of personnel to ensure that they: (i) Treat parties' ideas for lawful approaches or analyses that are different from those in an interpretive rule in an open and welcoming manner; and (ii) understand that approaches or analyses other than those in an interpretive rule, if undertaken according to the proper internal agency procedures for approval and justification, are appropriate and will not have adverse employment consequences for them.

e. Facilitating opportunities for members of the public, including through intermediaries such as ombudspersons or associations, to propose or support approaches or analyses different from those in an interpretive rule and to provide feedback to the agency on whether its officials are giving reasonable consideration to such proposals.

15. Because measures to promote flexibility (including those listed in Paragraph 14) may take up agency resources, it will be necessary to set priorities for which interpretive rules are most in need of such measures. In deciding when to take such measures, the agency should consider the following, bearing in mind that these considerations will not always point in the same direction:

a. An agency should assign a higher priority to an interpretive rule the greater the rule's impact is likely to be on the interests of regulated parties, regulatory beneficiaries, and other interested parties, either because regulated parties have strong incentives to comply with the rule or because the rule practically reduces the stringency of the regulatory scheme compared to the status quo.

b. An agency should assign a lower priority to promoting flexibility in the use of a rule insofar as the rule's value to the agency and interested persons is primarily consistency rather than substantive content.

## Administrative Conference Recommendation 2019–2

### Agency Recruitment and Selection of Administrative Law Judges

Adopted June 13, 2019

The Administrative Procedure Act (APA) requires that hearings conducted under its main adjudication provisions<sup>1</sup> (sometimes known as “formal” hearings) be presided over by the agency itself, by “one or more members of the body which comprises the agency,” or by “one or more administrative law judges [(ALJs)] appointed under” 5 U.S.C. 3105.<sup>2</sup> Section 3105, in turn, authorizes “[e]ach agency” to “appoint as many [ALJs] as are necessary for proceedings required to be conducted in accordance” with those provisions.<sup>3</sup>

The process for appointing ALJs recently changed as a result of Executive Order (E.O.) 13,843.<sup>4</sup> Until that order was issued, agencies could hire a new ALJ only from a certificate of qualified applicants (that is, a list of applicants eligible for hire) prepared by the Office of Personnel Management (OPM).<sup>5</sup> Each certificate generally had, for each opening, three applicants selected from a much larger register of applicants OPM deemed “qualified.” The “list of three,” as it was known, consisted of the three highest-scoring applicants based upon, among other things, an OPM-administered and -developed examination and panel interview process, as well as veterans' status.<sup>6</sup>

Under E.O. 13,843, newly appointed ALJs were removed from the “competitive service,” and were instead placed in what is known as the “excepted service.”<sup>7</sup> As a result, agencies now hire new ALJs directly—that is, without OPM's involvement—generally using whatever selection criteria and procedures they deem appropriate. E.O. 13,843 was premised on two primary bases. The first was the need to “mitigate” the concern that, after the Supreme Court's 2018

<sup>1</sup> 5 U.S.C. 554, 556–57.

<sup>2</sup> *Id.*

<sup>3</sup> *Id.* § 3105.

<sup>4</sup> Exec. Order No. 13,843, 83 FR 32,755 (July 13, 2018) (issued July 10, 2018); *see also* Memorandum from Jeff T.H. Pon, Dir., Office of Pers. Mgmt., to Heads of Exec. Dep'ts and Agencies, Executive Order—Excepting Administrative Law Judges from the Competitive Service (July 10, 2018), <https://chcoc.gov/print/9282> (noting that “OPM's regulations continue to govern some aspects of ALJ employment”).

<sup>5</sup> This was the process for hiring new ALJs. Many agencies hired incumbent ALJs from other agencies under a process known as “interagency transfer.” This process no longer exists, but agencies are still free to hire ALJs from other agencies using their own process.

<sup>6</sup> *See* Admin. Conf. of the U.S., Recommendation 1992–7, *The Federal Administrative Judiciary*, 57 FR 61,759, 61,761 (Dec. 29, 1992). Qualified veterans received extra points that “had an extremely large impact, given the small range in unadjusted scores.” *Id.* As the Administrative Conference noted in 1992, “application of the veterans' preference has almost always been determinative in the ALJ selection system.” *Id.*

<sup>7</sup> “[T]he ‘excepted service’ consists of those civil service positions which are not in the competitive service or the Senior Executive Service.” 5 U.S.C. 2103.

decision in *Lucia v. Securities and Exchange Commission*,<sup>8</sup> the OPM-administered process might unduly circumscribe an agency head's discretionary hiring authority under the Constitution's Appointments Clause.<sup>9</sup> *Lucia* held that the Securities and Exchange Commission's (SEC) ALJs were officers under the Appointments Clause, with the result being that—assuming that the SEC's ALJs are inferior rather than principal officers<sup>10</sup>—they must be appointed directly by the Commission itself as the head of a department rather than, as was being done, by SEC staff.<sup>11</sup> The second basis was the need to give “agencies greater ability and discretion to assess critical qualities in ALJ candidates . . . and [such candidates'] ability to meet the particular needs of the agency.”<sup>12</sup>

E.O. 13,843 requires only that ALJs be licensed attorneys. In addition, it identifies desirable qualities for ALJs, such as appropriate temperament, legal acumen, impartiality, and the ability to communicate their decisions, explicitly leaving it, however, to each agency to determine its own selection criteria. This Recommendation does not address the substantive hiring criteria that agencies should employ in selecting among ALJ candidates, though it does recommend that agencies publish the minimum qualifications and selection criteria for their ALJ positions. The selection criteria that an agency adopts might include, for example, litigation experience, experience as an adjudicator, experience in dispute resolution, experience with the subject-matter that comprises the agency's caseload, specialized technical skills, experience with case management systems, demonstrated legal research and legal writing skills, a dedicated work ethic, and strong leadership and communications skills.<sup>13</sup>

Each agency must decide not only which selection criteria will apply, but also which are mandatory and which are only desirable or preferred. Of course, agencies must also ensure that recruitment and selection comply with generally applicable legal requirements, such as those relating to veterans' preference and equal employment opportunity and government-wide initiatives to promote diversity and inclusion in the federal workforce.<sup>14</sup>

<sup>8</sup> 138 S. Ct. 2044 (2018).

<sup>9</sup> *See* Exec. Order No. 13,843, *supra* note 4, § 1.

<sup>10</sup> The *Lucia* majority expressly refrained from deciding whether the SEC's ALJs are principal or inferior officers, but did note that “[b]oth the Government and *Lucia* view the SEC's ALJs as inferior officers and acknowledge that the Commission, as a head of department, can constitutionally appoint them.” *Lucia*, 138 S. Ct. at 2051 n.3.

<sup>11</sup> *See id.* This Recommendation takes no position on constitutional questions.

<sup>12</sup> Exec. Order No. 13,843, *supra* note 4, § 1.

<sup>13</sup> *See generally* Jack M. Beermann and Jennifer L. Mascott, Federal Agency ALJ Hiring After *Lucia* and Executive Order 13843 (May 29, 2019) (report to the Admin. Conf. of the U.S.), <https://www.acus.gov/report/final-research-report-federal-agency-alj-hiring-after-lucia-and-eo-13843>. This report is based in part upon interviews with officials at a number of agencies, including those employing the vast majority of ALJs.

<sup>14</sup> *See, e.g.,* Exec. Order No. 13,583, 76 FR 52,847 (Aug. 18, 2011). As far as veterans' preference is

Because the E.O. allows each agency to design its own selection procedures, each agency must now decide which of its officials will be involved in the selection process, how the process will be structured, how vacancies will be announced and otherwise communicated to potential applicants, and whether the agency will review writing samples or use some other evaluation method.

This Recommendation is built upon the view that there is no “one-size-fits-all” procedure for appointing ALJs and is designed to assist agencies that are in the initial stages of thinking through new procedures for appointing ALJs under the E.O.<sup>15</sup> Each agency will have to construct a system that is best suited to its particular needs. Doing so will require consideration of, among other things, the nature of its proceedings, the size of the agency’s caseload, and the substance of the relevant statutes and the procedural rules involved in an agency’s proceedings.

### Recommendation

1. To ensure the widest possible awareness of their Administrative Law Judge (ALJ) vacancies and an optimal and broad pool of applicants, agencies should announce their vacancies on the government-wide employment website (currently operated by the Office of Personnel Management as USAJOBS), their own websites, and/or other websites that might reach a diverse range of potential ALJ applicants. Agencies that desire or require subject-matter, adjudicative, or litigation experience should also reach out to lawyers who practice in the field or those with prior experience as an adjudicator. Each agency should keep the application period open for sufficient time to achieve an optimal and broad pool of applicants.

2. Agencies should formulate and publish minimum qualifications and selection criteria for ALJ hiring. Those qualifications and criteria should include the factors specified in Executive Order 13,843 and the qualifications the agency deems important for service as an ALJ in the particular agency. The notice should distinguish between mandatory and desirable criteria.

3. Agencies should develop policies to review and assess ALJ applications. These policies might include the development of screening panels to select which applicants to interview, interview panels to select which applicants to recommend for appointment, or both kinds of panels. If used, such panels could include internal reviewers only or both internal and external reviewers, and could include overlapping members among the two types of panels or could include entirely

concerned. Executive Order 13,843 provides that “each agency shall follow the principle of veteran preference as far as administratively feasible.” Exec. Order No. 13,843, *supra* note 4, § 3.

<sup>15</sup> Some agencies have already publicly disseminated guidance. *See, e.g.*, Secretary’s Order 07–2018, Procedures for Appointments of Administrative Law Judges for the Department of Labor, 83 FR 44,307 (Aug. 30, 2018); U.S. Dep’t of Health & Human Serv.’s, Administrative Law Judge Appointment Process Under the Excepted Service (Nov. 29, 2018), <https://www.hhs.gov/sites/default/files/alj-appointment-process.pdf>.

different members. These policies might include procedures to evaluate applicants’ writing samples. If used, such writing samples could be submitted with the applicants’ initial applications, as part of a second round of submissions for applicants who meet the agencies’ qualifications expectations, or as part of a proctored writing assignment in connection with an interview.

4. The guidelines and procedures for the hiring of ALJs should be designed and administered to ensure the hiring of ALJs who will carry out the functions of the office with impartiality and maintain the appearance of impartiality.

### Administrative Conference Recommendation 2019–3

#### Public Availability of Agency Guidance Documents

*Adopted June 13, 2019*

Among their many activities, government agencies issue guidance documents that help explain their programs and policies or communicate other important information to regulated entities and the public. Members of the public should have ready access to these guidance documents so that they can understand how their government works and how their government relates to them. Agencies should manage their guidance documents consistent with legal requirements and principles of governmental transparency and accountability.

Guidance documents can take many forms.<sup>1</sup> They include what the Administrative Procedure Act (APA) calls “interpretative rules” and “general statements of policy,” which are two types of rules that are not required to undergo the notice-and-comment procedures applicable to legislative rules.<sup>2</sup> They may also include other materials considered to be guidance documents under other, separate definitions adopted by government agencies.<sup>3</sup> When

<sup>1</sup> To allow agencies flexibility to manage their varied and unique types of guidance documents, this Recommendation does not seek to provide an all-encompassing definition of guidance documents. This Recommendation is addressed, at a minimum, to those guidance documents required by law to be published in the **Federal Register** and any other guidance document required by law to be made publicly available. *See infra* notes 4–7 and accompanying text.

<sup>2</sup> Interpretative rules and general statements of policy are “rules” under the APA. *See* 5 U.S.C. 551(4), 553. Although the APA does not define these two terms, the *Attorney General’s Manual on the Administrative Procedure Act* defines “interpretative rules” as “rules or statements issued by an agency to advise the public of the agency’s construction of the statutes and rules which it administers,” and “general statements of policy” as “statements issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power.” *Attorney General’s Manual on the Administrative Procedure Act* 30 n.3 (1947). In accordance with standard parlance, this Recommendation uses the term “interpretive” in place of the APA’s word “interpretative.”

<sup>3</sup> *See* Cary Coglianese, Public Availability of Agency Guidance Documents (May 15, 2019) (report to the Admin. Conf. of the U.S.), <https://www.acus.gov/report/consultant-report-public-availability-agency-guidance-documents>.

managing the public availability of agency information in implementing this Recommendation, agencies should be clear about what constitutes guidance and what does not.

Several laws require agencies to make at least certain guidance documents available to the public. The Federal Records Act requires agencies to identify “records of general interest or use to the public that are appropriate for public disclosure, and . . . post[] such records in a publicly accessible electronic format.”<sup>4</sup> The Freedom of Information Act (FOIA) requires that agencies publish “statements of *general* policy or interpretations of *general* applicability formulated and adopted by the agency” in the **Federal Register**.<sup>5</sup> FOIA also requires that agencies “make available for public inspection in an electronic format . . . [specific] statements of policy and interpretations which have been adopted by the agency and are not published in the **Federal Register**,” as well as “administrative staff manuals and instructions to staff that affect a member of the public.”<sup>6</sup> Finally, Congress has occasionally enacted agency-specific requirements for posting guidance documents online. For example, the Food and Drug Administration is required to “maintain electronically and update and publish periodically in the **Federal Register** a list of guidance documents” and to ensure that “[a]ll such documents [are] made available to the public.”<sup>7</sup>

The Administrative Conference has recommended that various types of guidance documents be made available online. Recommendation 2017–5, *Agency Guidance Through Policy Statements*, provided that “[a]ll written policy statements affecting the interests of regulated parties, regulatory beneficiaries, or other interested parties should be promptly made available electronically and indexed, in a manner in which they may readily be found.”<sup>8</sup>

<sup>4</sup> 44 U.S.C. 3102.

<sup>5</sup> 5 U.S.C. 552(a)(1)(D) (emphasis added). To the extent that the documents an agency considers guidance would fall within any of the nine FOIA exceptions, such as “records or information compiled for law enforcement purposes,” 5 U.S.C. 552(b)(7), agencies would not be required to disclose them.

<sup>6</sup> 5 U.S.C. 552(a)(2). “Agencies often accomplish this electronic availability requirement by posting records on their FOIA websites in a designated area known as a ‘FOIA Library.’” U.S. Dep’t of Justice, Office of Information Policy, Guide to the Freedom of Information Act: Proactive Disclosures 6 (2019 ed.), available at [https://www.justice.gov/oip/foia-guide/proactive\\_disclosures/download](https://www.justice.gov/oip/foia-guide/proactive_disclosures/download); *see also* E-Government Act, Public Law 107–347, 206, 116 Stat. 2899, 2915 (Dec. 17, 2002) (codified at 44 U.S.C. 3501 note) (requiring agencies, to the extent practicable, to publish online documents that FOIA requires be published in the **Federal Register**); Small Business Regulatory Enforcement Fairness Act, Public Law 104–121, 212, 110 Stat. 847, 858 (Mar. 29, 1996) (codified at 5 U.S.C. 601 note) (requiring agencies to produce a “small entity compliance guide” for some legislative rules and post those guides “in an easily identified location on the website of the agency”).

<sup>7</sup> 21 U.S.C. 371(h)(3).

<sup>8</sup> Admin. Conf. of the U.S., Recommendation 2017–5, *Agency Guidance Through Policy*

Recommendation 2019–1 includes identical language directing agencies to do the same for interpretive rules.<sup>9</sup> Similarly, Recommendation 2018–5, *Public Availability of Adjudication Rules*, urged agencies to “provide updated access on their websites to all sources of procedural rules and related guidance documents and explanatory materials that apply to agency adjudications.”<sup>10</sup>

Although many agencies do post guidance documents online, in recent years concerns have emerged about how well organized, up to date, and easily accessible these documents are to the public. At various times, the Office of Management and Budget (OMB) has instructed agencies on their management of guidance documents.<sup>11</sup> The United States Government Accountability Office has conducted an audit that highlights the management challenges associated with agency dissemination of guidance documents online.<sup>12</sup> Several legislative proposals have been introduced (but not enacted) to create standards for public disclosure of guidance documents.<sup>13</sup>

Agencies should be cognizant that the primary goal of online publication is to facilitate access to guidance documents by regulated entities and the public. In deciding how to manage the availability of their guidance documents, agencies must be mindful of how members of the public will find the documents they need. Four principles for agencies to consider when developing and implementing plans to track and disclose their guidance documents to the

*Statements*, ¶ 12, 82 FR 61,728, 61,737 (Dec. 29, 2017).

<sup>9</sup> Admin. Conf. of the U.S., Recommendation 2019–1, *Agency Guidance Through Interpretive Rules*, 84 FR \_\_\_\_.

<sup>10</sup> Admin. Conf. of the U.S., Recommendation 2018–5, *Public Availability of Adjudication Rules*, ¶ 1, 84 FR 2142, 2142 (Feb. 6, 2019).

<sup>11</sup> For example, OMB Bulletin 07–02 directs Executive Branch departments and agencies to provide a current list of significant guidance documents in effect on their websites. Office of Mgmt. & Budget, Final Bulletin for Agency Good Guidance Practices, 72 FR 3432 (Jan. 25, 2007); Office of Mgmt. & Budget, Memorandum No. M–07–07, *Issuance of OMB’s “Final Bulletin for Agency Good Guidance Practices”* (Jan. 18, 2007), <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2007/m07-07.pdf>; see also Office of Mgmt. & Budget, Memorandum No. M–19–14, *Guidance on Compliance with the Congressional Review Act* (Apr. 11, 2019), <https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-14.pdf> (calling upon both executive and independent regulatory agencies to send certain pre-publication guidance materials to the Office of Information and Regulatory Affairs).

<sup>12</sup> U.S. Gov’t Accountability Office, GAO–15–368, *Regulatory Guidance Processes: Selected Departments Could Strengthen Internal Control and Dissemination Practices* (2015).

<sup>13</sup> The most notable of the pending legislation would require agencies to publish guidance documents on their websites and a centralized website selected by OMB. See Guidance Out of Darkness Act, S. 380, 116th Cong. (2019); S. Rep. No. 116–12 (2019); Guidance Out of Darkness Act, H.R. 4809, 115th Cong. (2018); H.R. Rep. No. 115–972 (2018); see also H.R. 2142, 116th Cong. (2019) (requiring the creation of a centralized website for small business compliance guides). For other legislation, see Coglianesse, *supra* note 3, at 6–7.

public include: (a) Comprehensiveness (whether all relevant guidance documents are available), (b) currency (whether guidance documents are up to date), (c) accessibility (whether guidance documents can be easily located by website users), and (d) comprehensibility (whether website users are likely to be able to understand the information they have located).

With these principles in mind, this Recommendation calls on agencies to consider opportunities for improving the public availability of their guidance documents. Each agency must decide which guidance documents to post online and how to present them in a manner that will ensure their availability and usefulness for regulated parties and the public. The Recommendation provides best practices to guide agencies to make their guidance documents more publicly available. These best practices are intended to be adaptable to fit agency-specific circumstances.<sup>14</sup> The Administrative Conference notes that each agency is different, and the practices outlined in this Recommendation may be employed with flexibility as necessary (perhaps based on factors such as an agency’s internal structures, available resources, types and volume of documents, the parties it regulates, and its end users) so that guidance documents are made available to the public in a logical and suitably comprehensive manner.

#### Recommendation

##### *Procedures for Managing Guidance Documents*

1. Agencies should develop written procedures pertaining to their internal management of guidance documents.

a. The procedures should include:

i. A description of relevant categories or types of guidance documents subject to the procedures; and

ii. examples of specific materials not subject to the procedures, as appropriate.

b. The procedures should address measures to be taken for the:

i. Development of guidance documents, including any opportunity for public comment;

ii. publication and dissemination of draft or final guidance documents; and

iii. periodic review of existing guidance documents.

c. Agency procedures should indicate the extent to which any of the measures created or identified in response to Paragraph 1(b) should vary depending on the type of guidance document or its category, as defined by any provisions in agency procedures responsive to Paragraph 1(a).

2. All relevant agency staff should receive training in agencies’ guidance document management procedures.

<sup>14</sup> For example, even the term “agency” as used in the Recommendation can be construed to address either agencies or sub-agencies within larger departments. Jennifer L. Selin & David E. Lewis, Admin. Conf. of the U.S., *Sourcebook of United States Executive Agencies* 11 (2d ed. 2018), available at <https://www.acus.gov/publication/sourcebook-united-states-executive-agencies-second-edition>.

3. Agencies should develop and apply appropriate internal controls to ensure adherence to guidance document management procedures.

4. To facilitate internal tracking of guidance documents, as well as to help members of the public more easily identify relevant guidance documents, agencies should consider assigning unique identification numbers to guidance documents covered by their written guidance procedures. Once a guidance identification number has been assigned to a guidance document, it should appear on that document and be used to refer to the document whenever it is listed or referenced on the agency’s website, in public announcements, or in the **Federal Register** or the *Code of Federal Regulations*.

5. Using appropriate metrics, agencies should periodically review their guidance document management procedures and their implementation in order to assess their performance in making guidance documents available as well as to identify opportunities for improvement.

6. Agencies should provide opportunities for public feedback on their efforts to promote the public availability of their guidance documents.

##### *Guidance Documents on Agency Websites*

7. Agencies should maintain a page on their websites dedicated to informing the public about the availability of guidance documents and facilitating access to those documents. Such guidance document web pages should include:

a. Agencies’ written guidance document management procedures pursuant to Paragraph 1, if developed;

b. Plain language explanations (sometimes known as “explainers”) that define guidance documents, explain their legal effects, or give examples of different types of guidance documents;

c. A method for users to find relevant guidance documents, which might include:

i. Comprehensively listing and indexing agency guidance documents;

ii. Displaying links to pages where guidance documents are located, which could be organized by topic, type of guidance document, agency sub-division, or some other rubric; or

iii. A dedicated search engine; and

d. Contact information or a comment form to facilitate public feedback related to potentially broken links, missing documents, or other errors or issues related to the agency’s procedures for the development, publication, or disclosure of its guidance documents.

8. Agencies should provide the public with access to a comprehensive set of its guidance documents—either on the dedicated guidance document web page or other web pages—in accordance with its written procedures.

a. Agency websites should include, at minimum, (1) all guidance documents required by law to be published in the **Federal Register** and (2) all other guidance documents required by law to otherwise be made publicly available.

b. Guidance documents should generally be made available in downloadable form.

c. Links to downloadable copies of agencies' Small Entity Compliance Guides—issued in accordance with the Small Business Regulatory Enforcement Fairness Act<sup>15</sup>—should be provided.

d. Agency websites should include relevant information for each guidance document, such as its title, any corresponding regulatory or statutory provision that the guidance document relates to or interprets (if applicable), the date of issuance, and any assigned identifying number.

e. Agencies should keep guidance documents on their websites current. To the extent a website contains obsolete or modified guidance documents, it should include notations indicating that such guidance documents have been revised or withdrawn. To the extent feasible, each guidance document should be clearly marked within the document to show whether it is current and identify its effective date, and, if appropriate, its rescission date. If a guidance document has been rescinded, agencies should provide a link to any successor guidance document.

9. Although not every agency website will have the same population of users, agency websites should be designed to ensure that they are as helpful to the end user as possible. In particular, agencies should ensure:

a. Simple words, such as “guidance,” are used in describing web pages that discuss or list guidance documents;

b. Agency guidance document web pages are easy to find from their website's home page, through such techniques as a linked tab or entry in a pull-down menu;

c. The search engine on agency websites works effectively for finding relevant guidance information;

d. Guidance documents, when listed on web pages, are displayed in a manner that helps the public find a particular document, by using such techniques as indexing, tagging, or sortable tables; and

e. Websites displaying guidance documents are kept up to date, with any broken links fixed and any amended or withdrawn documents clearly labeled as such.

10. To make guidance documents accessible to users who are searching for information elsewhere on agency websites, agencies should strive to ensure that clearly labeled links to all guidance documents related to specific rules, issues, or programs are easily found in the corresponding section of the website where users are likely to find that information especially helpful.

#### Public Notice of Guidance Documents

11. Agencies should undertake affirmative measures to alert interested members of the public to new and revised guidance documents. Such measures could include, among other things, establishing public email distribution lists to disseminate alerts about new or revised guidance documents, using social media to disseminate guidance documents and related information, having

agency staff speak about guidance documents at relevant conferences or meetings, or preparing printed pamphlets or other hard-copy documents. Even when not required to do so by law, agencies should consider publishing information about new or revised guidance documents in the **Federal Register**.

12. Agencies should consider providing descriptive references (such as links, if possible) to relevant guidance documents in appropriate sections of the *Code of Federal Regulations*, stating where the public can access the documents.

#### Administrative Conference Recommendation 2019–4

##### Revised Model Rules for Implementation of the Equal Access to Justice Act

Adopted June 13, 2019

[Note from the Office of the Chairman: Recommendation 2019–4 immediately follows; however, the *Revised Model Rules for Implementation of the Equal Access to Justice Act*, which were adopted by the Assembly as an appendix to Recommendation 2019–4, are published elsewhere in this issue of the **Federal Register**. Federal agencies should consider the *Revised Model Rules* when adopting or revising their own rules in order to promote the uniformity of procedure contemplated by the Equal Access to Justice Act, and in discharging their obligation to consult with the Chairman of the Administrative Conference of the United States under 5 U.S.C. 504(c)(1).]

The Equal Access to Justice Act (*EAJA*), first enacted in 1980, authorizes the award of attorney fees and other expenses to certain individuals, small businesses, and other entities that prevail against the federal government in judicial proceedings and certain adversarial agency adjudicative proceedings, when the position of the government is not substantially justified.<sup>1</sup> The stated purpose of *EAJA* is to, among other things, “diminish the deterrent effect of seeking review of, or defending against, governmental action by providing” the award of certain costs and fees against the United States.<sup>2</sup>

In the case of agency adjudications, agencies must establish “uniform procedures for the submission and consideration of applications for an award of fees and other expenses” “[a]fter consultation with the Chairman of the Administrative Conference of the United States.”<sup>3</sup> To carry out this statutory charge, the Conference's Chairman issued model rules in 1981 to help agencies establish uniform procedures for the submission and consideration of *EAJA* applications.<sup>4</sup> Adoption of these model rules was intended to facilitate consultation between agencies and the Chairman of the

Conference as required by 5 U.S.C. 504.<sup>5</sup> In 1986, the Chairman revised the 1981 model rules following the amendment and reauthorization of *EAJA*.<sup>6</sup> Numerous agencies adopted the 1981 and 1986 model rules, including the Federal Trade Commission, the Consumer Financial Protection Bureau, the Securities and Exchange Commission, and the National Labor Relations Board.<sup>7</sup>

In light of the amendments to *EAJA* made since 1986,<sup>8</sup> as well as evolving adjudicative practices since that time, the Conference's Chairman decided to review and, as necessary, revise the 1986 model rules, just as he recently did in the case of the *Model Adjudication Rules*, which govern agency adjudication procedures generally.<sup>9</sup> Rather than simply revise the rules himself, the Chairman decided to put the rules before the membership of the Conference—first through an ad hoc committee of all interested members—for review so as to assure consideration of as broad a range of views as possible. The Conference considered, among other things, *EAJA* rules that agencies have issued since the promulgation of the 1986 model rules. Where appropriate, the Conference updated the model rules to reflect evolving practice and the latest *EAJA* amendments and made additional revisions to promote greater consistency and clarity. The Conference's revised model rules appear in the appendix to this Recommendation.

Substantial changes have been made to the 1986 model rules. They include, most notably, the elimination of most of what was Subpart A. Subpart A of the 1986 model rules consisted of general provisions addressing, among other things, when *EAJA* applies, eligibility of applicants, proceedings covered, standards for awards, allowable fees and expenses, rulemaking on maximum rates for attorney fees, awards against other agencies,

<sup>5</sup> Admin. Conf. of the U.S., Implementation of the Equal Access to Justice Act: Requests for Comments on Draft Model Rules, 46 FR 15,895 (Mar. 10, 1981).

<sup>6</sup> Admin. Conf. of the U.S., Model Rules for Implementation of the Equal Access to Justice Act: Issuance of Final Revised Model Rules, 51 FR 16,659 (May 6, 1986).

<sup>7</sup> See Equal Access to Justice Act Implementation Rule, 79 FR 7,569 (Consumer Fin. Prot. Bureau Feb. 10, 2014) (codified as amended at 12 CFR pt. 1071); Equal Access to Justice Rules, 54 FR 53,050 (Sec. Exch. Comm'n Dec. 27, 1989) (codified as amended at 17 CFR pt. 200–01); Procedural Rules Implementing Equal Access to Justice Act, 51 FR 36,223 (Nat'l Labor Relations Bd. Oct. 9, 1986) (codified as amended at 29 CFR pt. 102); Procedural Rules Amendments, 51 FR 17,732 (Nat'l Labor Relations Bd. May 15, 1986); Procedural Rules; Miscellaneous Revisions and Corrections, 50 FR 53,302 (Fed. Trade Comm'n Dec. 31, 1985) (codified as amended at 16 CFR pt. 0–5); Equal Access to Justice Rules, 47 FR 609 (Sec. Exch. Comm'n Jan. 6, 1982); Rules Governing Recovery of Awards Under Equal Access to Justice Act, 46 FR 48,910 (Fed. Trade Comm'n Oct. 5, 1981).

<sup>8</sup> Act of Jan. 4, 2011, Public Law 111–350, 5, 124 Stat. 3677, 3841; Small Business Regulatory Enforcement Fairness Act of 1996, 104 Public Law 121, 231, 110 Stat. 847, 862; Religious Freedom Restoration Act of 1993, 103 Public Law 141, 4, 107 Stat. 1488, 1489; Education and Savings Act of 1988, Public Law 100–647, 6239, 102 Stat. 3342, 3746.

<sup>9</sup> Admin. Conf. of the U.S., Model Adjudication Rules, 83 FR 49,530 (Oct. 2, 2018).

<sup>1</sup> 5 U.S.C. 504.

<sup>2</sup> Equal Access to Justice Act, Public Law 96–481, 202(b)(1), 94 Stat. 2321, 2325 (1980) (codified as amended at 5 U.S.C. 504 and 28 U.S.C. 2412).

<sup>3</sup> 5 U.S.C. 504(c)(1).

<sup>4</sup> Admin. Conf. of the U.S., Equal Access to Justice Act: Agency Implementation, 46 FR 32,900 (June 25, 1981).

<sup>15</sup> Public Law 104–121, 212, 110 Stat. 847, 858 (Mar. 29, 1996) (codified at 5 U.S.C. 601 note).

and delegations of authority. The Conference recommends the elimination of these provisions because they address the substantive standard for EAJA awards and other such matters beyond the Conference's statutory charge identified above. Other changes to the rules, including the addition of a definitions section, have also been made to improve their clarity and comprehensibility.

#### Recommendation

The 1986 model rules should be replaced with the revised model rules for the implementation of the Equal Access to Justice Act that appear in the attached appendix. [Note from the Office of the Chairman: The appendix to Recommendation 2019-4 is published elsewhere in this issue of the **Federal Register**.]

[FR Doc. 2019-16946 Filed 8-7-19; 8:45 am]

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## ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

### Revised Model Rules for Implementation of the Equal Access to Justice Act

**AGENCY:** Administrative Conference of the United States.

**ACTION:** Notice of availability; Revised Model Rules for Implementation of the Equal Access to Justice Act.

**SUMMARY:** The Office of the Chairman of the Administrative Conference of the United States is issuing these *Revised Model Rules for Implementation of the Equal Access to Justice Act*. These *Revised Model Rules* update the uniform procedures for the submission and consideration of applications for attorney fees under the Equal Access to Justice Act that were last issued in 1986. These *Revised Model Rules* reflect, among other things, amendments to the Act made by the Small Business Regulatory Enforcement Fairness Act and evolving adjudicative practices. They are designed to assist Federal agencies in adopting or modifying their own regulations for implementation of the Act.

**FOR FURTHER INFORMATION CONTACT:** Alexandria Tindall Webb, Attorney Advisor, Administrative Conference of the United States, Suite 706 South, 1120 20th Street NW, Washington, DC 20036; Telephone 202-480-2080.

**SUPPLEMENTARY INFORMATION:** The Administrative Conference Act, 5 U.S.C. 591-596, established the Administrative Conference of the United States. The Conference studies the efficiency, adequacy, and fairness of the administrative procedures used by Federal agencies and makes recommendations to agencies, the

President, Congress, and the Judicial Conference of the United States for procedural improvements (5 U.S.C. 594(1)). For further information about the Conference and its activities, see [www.acus.gov](http://www.acus.gov).

The Equal Access to Justice Act (EAJA), first enacted in 1980, authorizes the award of attorney fees and other expenses to eligible parties who prevail against the Federal government in judicial proceedings and certain adversarial agency adjudicative proceedings, where the position of the government is not substantially justified.<sup>1</sup> In the case of certain adversarial agency adjudications, “[a]fter consultation with the Chairman of the Administrative Conference of the United States, each agency shall by rule establish uniform procedures for the submission and consideration of applications for an award of fees and other expenses.”<sup>2</sup> In furtherance of this statutory obligation, the Conference Chairman in 1981 issued a set of *Model Rules* for agencies to use when adopting rules for the consideration of applications for EAJA awards in agency adjudications.<sup>3</sup> The Conference Chairman issued a revised set of *Model Rules* in 1986.<sup>4</sup> Many agencies have since promulgated EAJA rules that are substantially based upon these *Model Rules*.<sup>5</sup>

The Office of the Chairman is issuing these *Revised Model Rules* to replace the 1981 and 1986 *Model Rules*. They include revisions made to reflect changes in law and in practice during the intervening thirty years and to promote greater accuracy and clarity. These rules were set forth in an appendix to Conference Recommendation 2019-4, *Revised Model Rules for Implementation of the Equal Access to Justice Act*. Recommendation 2019-4 is published elsewhere in this issue of the **Federal Register**.

<sup>1</sup> 5 U.S.C. 504; 28 U.S.C. 2412.

<sup>2</sup> 5 U.S.C. 504(c)(1).

<sup>3</sup> Admin. Conf. of the U.S., Equal Access to Justice Act: Agency Implementation, 46 FR 32,900 (June 25, 1981).

<sup>4</sup> Admin. Conf. of the U.S., Model Rules for Implementation of the Equal Access to Justice Act, 51 FR 16,659 (May 6, 1986) (previously codified at 1 C.F.R. pt. 315).

<sup>5</sup> See, e.g., Equal Access to Justice Act Implementation Rule, 79 FR 7,569 (Consumer Fin. Prot. Bureau Feb. 10, 2014) (codified as amended at 12 CFR pt. 1071); Equal Access to Justice Rules, 54 FR 53,050 (Sec. Exch. Comm'n Dec. 27, 1989) (codified as amended at 17 CFR pt. 200-01); Procedural Rules Implementing Equal Access to Justice Act, 51 FR 36,223 (Nat'l Labor Relations Bd. Oct. 9, 1986) (codified as amended at 29 CFR pt. 102); Procedural Rules; Miscellaneous Revisions and Corrections, 50 FR 53,302 (Fed. Trade Comm'n Dec. 31, 1985) (codified as amended at 16 CFR pt. 0-5).

Unlike the 1981 and 1986 versions, these *Revised Model Rules* will not be published in the Code of Federal Regulations (CFR). The **Federal Register** Act requires codification of agency documents of general applicability and legal effect in the CFR.<sup>6</sup> However, these model rules are publishing in the Notices section of this issue of the **Federal Register** with the same intended effect of encouraging agencies to set out and implement these model rules as part of their own EAJA rules. Because these model rules are publishing in the Notices section, they will use a different numbering scheme than in past years. Agencies may use a different numbering system than what appears in the *Revised Model Rules*.

The most significant revision to the 1986 *Model Rules* is the elimination of much of the former Subpart A. This change was implemented because its provisions largely addressed substantive matters beyond the Conference's statutory charge. Some provisions of former Subpart A remain and were moved to other parts of the *Revised Model Rules* for the purpose of improved clarity. A new definitions section comprises Part 2 in the current revision. Additional changes were made to comport with the requirements of the Small Business Regulatory Enforcement Fairness Act, which was enacted in 1996.

The *Revised Model Rules* adopted by the Conference's Assembly as an Appendix to Recommendation 2019-4, and now issued by the Office of the Chairman, were initially drafted by a special ad hoc committee that held public meetings to address revision of the *Model Rules*. The materials related to the meetings, including the agendas, the 1981 and 1986 *Model Rules*, and draft versions of the *Revised Model Rules*, can be accessed via a dedicated web page on the Conference's website at <https://www.acus.gov/research-projects/revised-model-rules-implementation-equal-access-justice-act>.

Agencies are encouraged to use these *Revised Model Rules* when drafting or revising their EAJA rules pertaining to adjudications in order to promote the uniformity of procedure contemplated by EAJA. The Office of the Chairman's expectations of how agencies can fulfill the statutory requirement of consultation with the ACUS Chairman are as follows. Agencies that publish proposed rules for comment should notify the Office of the Chairman of their publication by email to [ACUS@info.gov](mailto:ACUS@info.gov), using “Model EAJA Rules Consultation” in the subject line. The

<sup>6</sup> 44 U.S.C. 1510

Office of the Chairman will then provide any suggestions by reply email. Agencies that intend to publish final rules without a public comment period should send a draft to the Office of the Chairman for review and comment before publication if their rules depart significantly from these *Revised Model Rules*; the Office of the Chairman will expedite this review to the extent possible.

Dated: August 1, 2019.

**Shawne C. McGibbon,**  
General Counsel.

## Appendix to Conference Recommendation 2019–4,

*Revised Model Rules for Implementation of the Equal Access to Justice Act*

### Part 1—Scope of These Rules

§ 1.01 Scope of these rules.

### Part 2—Definitions

§ 2.01 Definitions.

### Part 3—EAJA Applications

§ 3.01 Application requirements.

§ 3.02 Net worth exhibit.

§ 3.03 Documentation of fees and expenses.

### Part 4—Procedures for Considering Applications

§ 4.01 Filing and service of documents.

§ 4.02 Answer to application.

§ 4.03 Reply.

§ 4.04 Settlement.

§ 4.05 Further proceedings.

§ 4.06 Decision.

§ 4.07 Agency review.

§ 4.08 Judicial review.

§ 4.09 Stay of decision concerning award.

§ 4.10 Payment of award.

### Part 1—Scope of These Rules

§ 1.01 *Scope of These Rules*

The Equal Access to Justice Act, 5 U.S.C. 504 (called “EAJA” in this part), provides for the award of attorney fees and other expenses to eligible individuals and entities that are parties to certain administrative proceedings (called “adversary adjudications”) before this agency. An eligible party may receive an award when it prevails over an agency, unless the agency’s position was substantially justified or special circumstances make an award unjust. Alternatively, an eligible party, even if not a prevailing party, may receive an award under 5 U.S.C. 504(a)(4) when it successfully defends against an excessive demand made by an agency.

### Part 2—Definitions

§ 2.01 *Definitions*

For the purposes of these rules:

(a) *Adjudicative officer* means the official, whether the official is designated as an administrative law judge or otherwise, that presided over the hearing at the adversary adjudication or the official that presides over an EAJA proceeding.

(b) *Adversary adjudication* means (i) an adjudication under 5 U.S.C. 554 in which the position of the United States is represented by counsel or otherwise, but excludes an adjudication for the purpose of establishing or fixing a rate or for the purpose of granting or renewing a license, (ii) any appeal of a decision made pursuant to 41 U.S.C. 7103 before an agency board of contract appeals as provided in 41 U.S.C. 7105, (iii) any hearing conducted under 31 U.S.C. 3801 *et seq.*, and (iv) the Religious Freedom Restoration Act of 1993.<sup>1</sup>

(c) *Demand* means the express demand of the agency which led to the adversary adjudication, but does not include a recitation by the agency of the maximum statutory penalty (i) in the administrative complaint, or (ii) elsewhere when accompanied by an express demand for a lesser amount.

(d) *Excessive demand* means a demand by an agency, in an adversary adjudication arising from an agency action to enforce a party’s compliance with a statutory requirement, that is substantially in excess of the decision of the adjudicative officer and is unreasonable when compared with such decision, under the facts and circumstances of the case.

(e) *Final disposition* means the date on which a decision or order disposing of the merits of the proceeding or any other complete resolution of the proceeding, such as a settlement or voluntary dismissal, become final and unappealable, both within the agency and to the courts.

(f) *Party* means a party, as defined in 5 U.S.C. 551(3), that is (i) an individual whose net worth did not exceed \$2,000,000 at the time the adversary adjudication was initiated, or (ii) any owner of an unincorporated business, or any partnership, corporation, association, unit of local government, or organization, the net worth of which did not exceed \$7,000,000 at the time the adversary adjudication was initiated, and which had not more than 500 employees at the time the adversary adjudication was initiated; except that an organization described in section

501(c)(3) of the Internal Revenue Code of 1986 exempt from taxation under section 501(a) of such Code, or a cooperative association as defined in section 15(a) of the Agricultural Marketing Act, may be a party regardless of the net worth of such organization or cooperative association. For purposes of 5 U.S.C. 504(a)(4), “party” also includes a small entity as defined in 5 U.S.C. 601.

(g) *Position of the agency* means, in addition to the position taken by the agency in the adversary adjudication, the action or failure to act by the agency upon which the adversary adjudication is based, except that fees and other expenses may not be awarded to a party for any portion of the adversary adjudication in which the party has unreasonably protracted the proceedings.

### Part 3—EAJA Applications

§ 3.01 *Application Requirements*

(a) A party seeking an award under EAJA shall file an application with the agency that conducted the adversarial adjudication within 30 days after the agency’s final disposition of the adversary adjudication.

(b) The application shall identify the applicant and the proceeding for which an award is sought. The application shall show that the applicant has prevailed and identify the position of the agency or agencies that the applicant alleges was not substantially justified; or, if the applicant has not prevailed, shall show that the agency’s demand was substantially in excess of the decision of the adjudicative officer and was unreasonable when compared with that decision under the facts and circumstances of that case. The application shall also identify the agency position(s) in the proceeding that the applicant alleges was (were) not substantially justified or the agency’s demand that is alleged to be excessive and unreasonable. Unless the applicant is an individual, the application shall also state the number of employees of the applicant and describe briefly the type and purpose of its organization or business.

(c) The application shall also show that the applicant meets the definition of “party” in 5 U.S.C. 504(b)(1)(B), including adequate documentation of its net worth, as set forth in section 315.302.

(d) The application shall state the amount of fees and expenses for which an award is sought, subject to the requirements and limitations as set forth in 5 U.S.C. 504(b)(1)(A), with adequate

<sup>1</sup> The language that appears under subsection 315.201(b)(iv) was drawn directly from the Equal Access to Justice Act, 5 U.S.C. 504. The statute does not identify what adjudications involving the Religious Freedom Restoration Act of 1993 are covered.

documentation as set forth in section 315.303.

(e) The application shall be signed by the applicant or an authorized officer or attorney of the applicant. It shall also contain or be accompanied by a written verification under penalty of perjury that the information provided in the application is true and correct.

#### § 3.02 Net Worth Exhibit

(a) Each applicant except a qualified tax-exempt organization, cooperative association, or, in the case of an application for an award related to an allegedly excessive demand by the agency, a small entity as that term is defined by 5 U.S.C. 601, shall provide with its application a detailed exhibit showing the net worth of the applicant as represented in the statement required by section 315.301(c) when the proceeding was initiated. The exhibit may be in any form convenient to the applicant that provides full disclosure of the applicant's assets and liabilities and is sufficient to determine whether the applicant qualifies under the standards provided in section 315.201(e). An adjudicative officer presiding over an EAJA proceeding may require an applicant to file additional information to determine its eligibility for an award.

(b) Ordinarily, the net worth exhibit will be included in the public record of the proceeding. However, an applicant that objects to public disclosure of information in any portion of the exhibit and believes there are legal grounds for withholding it from disclosure may request that the documents be filed under seal or otherwise be treated as confidential, pursuant to [insert cross-reference to appropriate agency rules governing such requests].

#### § 3.03 Documentation of Fees and Expenses

The application shall be accompanied by adequate documentation of the fees and other expenses incurred after initiation of the adversary adjudication, including, but not limited to, the reasonable cost of any study, analysis, engineering report, test, or project. With respect to a claim for fees and expenses involving an excessive demand by the agency, the application shall be accompanied by adequate documentation of such fees and expenses incurred after initiation of the adversary adjudication for which an award is sought attributable to the portion of the demand alleged to be excessive and unreasonable. A separate itemized statement shall be submitted for each professional firm or individual whose services are covered by the

application, showing the hours spent in connection with the proceeding by each individual, a description of the specific services performed, the rate at which each fee has been computed, any expenses for which reimbursement is sought, the total amount claimed, and the total amount paid or payable by the applicant or by any other person or entity for the services provided. An adjudicative officer presiding over an EAJA proceeding may require the applicant to provide vouchers, receipts, or other substantiation for any expenses claimed.

### Part 4—Procedures for Considering Applications

#### § 4.01 Filing and Service of Documents

Any application for an award, or any accompanying documentation related to an application, shall be filed and served on all parties to the proceeding in the same manner as other pleadings in the proceeding, except, as provided in section 315.302(b), for confidential financial information.

#### § 4.02 Answer to Application

(a) Within 30 days after service of an application, counsel representing the agency against which an award is sought may file an answer to the application. Unless agency counsel requests an extension of time for filing or files a statement of intent to negotiate under paragraph (b) of this section, failure to file an answer within the 30-day period may be treated as a consent to the award requested.

(b) If agency counsel and the applicant believe that the issues in the fee application can be settled, they may jointly file a statement of their intent to negotiate a settlement. The filing of this statement shall extend the time for filing an answer for an additional 30 days, and further extensions may be granted by the adjudicative officer presiding over an EAJA proceeding upon request by agency counsel and the applicant.

(c) The answer shall explain in detail any objections to the award requested and identify the facts relied upon in support of agency counsel's position. If the answer is based on any alleged facts not already in the record of the proceeding, agency counsel shall include with the answer either supporting affidavits or a request for further proceedings under section 315.405.

#### § 4.03 Reply

Within 15 days after service of an answer, the applicant may file a reply. If the reply is based on any alleged facts not already in the record of the

proceeding, the applicant shall include with the reply either supporting affidavits or a request for further proceedings under section 315.405.

#### § 4.04 Settlement

The applicant and agency counsel may agree on a proposed settlement of the award before final action on the application, either in connection with a settlement of the underlying adversary adjudication, or after the adversary adjudication has been concluded, in accordance with the agency's standard settlement procedure. If a prevailing party and agency counsel agree on a proposed settlement of an award before an application has been filed, the application shall be filed with the proposed settlement. If a proposed settlement of an underlying proceeding provides that each side shall bear its own expenses and the settlement is accepted, no application may be filed.

#### § 4.05 Further Proceedings

(a) Ordinarily, the determination of an award will be made on the basis of the written record. However, on request of either the applicant or agency counsel, or on his or her own initiative, the adjudicative officer presiding over an EAJA proceeding may, if necessary for a full and fair decision on the application, order the filing of additional written submissions; hold oral argument; or allow for discovery or hold an evidentiary hearing, but only as to issues other than whether the agency's position was substantially justified (such as those involving the applicant's eligibility or substantiation of fees and expenses). Any written submissions shall be made, oral argument held, discovery conducted, and evidentiary hearing held as promptly as possible so as not to delay a decision on the application for fees. Whether or not the position of the agency was substantially justified shall be determined on the basis of the administrative record, as a whole, which is made in the adversary adjudication for which fees and other expenses are sought.

(b) A request for further proceedings under this section shall specifically identify the information sought or the disputed issues and shall explain why the additional proceedings are necessary to resolve the issues.

#### § 4.06 Decision

The adjudicative officer presiding over an EAJA proceeding shall issue an [initial or recommended]<sup>2</sup> decision on

<sup>2</sup> Brackets such as these indicate that an agency is to use its discretion to determine what language or time frame is most appropriate.

the application within [60 days] after the time for filing a reply, or when further proceedings are held, within [60 days] after completion of such proceedings.

(a) *For an application involving a prevailing party.* The decision on the application shall include written findings and conclusions on the applicant's eligibility and status as a prevailing party and an explanation of the reasons for any difference between the amount requested and the amount awarded. The decision shall also include, if applicable, findings on whether the agency's position was substantially justified, whether the applicant unduly protracted the proceedings, or whether special circumstances make an award unjust.

(b) *For an application involving an allegedly excessive agency demand.* The decision on the application shall include written findings and conclusions on the applicant's eligibility and an explanation of the reasons why the agency's demand was or was not determined to be substantially in excess of the underlying decision of the adjudicative officer and was or was not unreasonable when compared with that decision. That determination shall be based upon all the facts and circumstances of the case. The decision on the application shall also include, if at issue, findings on whether the applicant has committed a willful violation of law or otherwise acted in bad faith, or whether special circumstances make an award unjust.

(c) *Awards.* An adjudicative officer presiding over an EAJA proceeding may reduce the amount to be awarded, or deny any award, to the extent that the party during the course of the proceedings engaged in conduct which unduly and unreasonably protracted the final resolution of the matter in controversy.

#### § 4.07 Agency Review

Either the applicant or agency counsel may seek review of the decision of the adjudicative officer on the fee application, or the agency may decide to review the decision on its own initiative, in accordance with [insert cross-reference to agency's regular review procedures].

#### § 4.08 Judicial Review

Judicial review of final agency decisions on awards may be sought as provided in 5 U.S.C. 504(c)(2).

#### § 4.09 Stay of Decision Concerning Award

Any proceedings on an application for fees under these rules shall be

automatically stayed until the agency's final disposition of the decision on which the application is based and either the time period for seeking judicial review expires, or if review has been sought, until final disposition is made by a court and no further judicial review is available.

#### § 4.10 Payment of Award

An applicant seeking payment of an award shall submit to the [comptroller or other disbursing official] of the paying agency a copy of the agency's final decision granting the award, accompanied by a certification that the applicant will not seek review of the decision in the United States courts. [Include here address for submissions at specific agency.] The agency will pay the amount awarded to the applicant within [60 days].

[FR Doc. 2019-16768 Filed 8-7-19; 8:45 am]

BILLING CODE 6110-01-P

## DEPARTMENT OF AGRICULTURE

### Food and Nutrition Service

#### Agency Information Collection Activities: Proposed Collection; Comment Request—Reasons for Underredemption of the WIC Cash-Value Benefit

**AGENCY:** Food and Nutrition Service, U.S. Department of Agriculture.

**ACTION:** Notice.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection for Reasons for Underredemption of the WIC Cash-Value Benefit. This collection is a NEW information collection.

This study informs the U.S. Department of Agriculture's Food and Nutrition Service (FNS) about the reasons behind underredemption of the cash-value benefit (CVB) issued to participants in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). FNS is particularly interested in how CVB redemption rates are affected by State agency policies and practices.

**DATES:** Written comments must be received on or before October 7, 2019.

**ADDRESSES:** Comments may be sent to Ruth Morgan, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 1014, Alexandria, VA 22302. Comments may also be submitted via fax to the attention of Ruth Morgan at 703-305-2576 or via email at [ruth.morgan@usda.gov](mailto:ruth.morgan@usda.gov).

Comments will also be accepted through the Federal eRulemaking Portal. Follow the online instructions at <http://www.regulations.gov> for submitting comments electronically.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

#### FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of this information collection should be directed to Ruth Morgan at 703-457-7759.

**SUPPLEMENTARY INFORMATION:** Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*Title:* Reasons for Underredemption of the WIC Cash-Value Benefit.

*Form Number:* N/A.

*OMB Number:* Not Yet Assigned.

*Expiration Date:* Not Yet Determined.

*Type of Request:* New Collection.

*Abstract:* The Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) provides nutritious supplemental foods, healthcare referrals, breastfeeding support, and nutrition education to low-income pregnant, breastfeeding, and postpartum women, infants and children up to age 5 who are at nutritional risk. A Final Rule was published in the **Federal Register** on March 4, 2014 (79 FR 12273) that revised the WIC food packages to add a monthly cash-value benefit (CVB) for the purchase of fruits and vegetables. This rule also detailed specific provisions for the value of the CVB, the types of fruits and vegetables authorized, and other State options for providing this benefit. Recent studies have estimated that redemption rates for CVBs range from 73 percent to 77 percent;<sup>1 2</sup> however, the reasons for

<sup>1</sup> Phillips, D., Bell, L., Morgan, R., & Pooler, J. (2014). *Transition to EBT in WIC: Review of impact and examination of participant redemption*

underredemption of this benefit have not been fully explored. FNS has funded this study to determine the barriers to CVB redemption and the effects of State agency policies, practices, and other factors on CVB redemption rates.

There are a variety of WIC State agency policies and practices that may contribute to CVB underredemption, including but not limited to: vendor authorization and selection policies, the forms of fruits and vegetables allowed, vendor minimum stocking requirements, and participant tools and training available. Other State and household factors may also affect redemption rates, such as geographic access to WIC vendors or household preferences for certain types of fruits and vegetables.

In order to identify the factors associated with CVB redemption and examine the effects of State agency policies and practices on CVB redemption rates, FNS is conducting a study in 12 States, with more in-depth data collection occurring in 4 of these States. The study will gather data from WIC State plans and policy documents, administrative records, and WIC participants. State plan and policy document data will be collected from 12 States and used to identify variations in State agency policies and practices that may affect CVB redemption rates. Administrative record collection will be limited to electronic benefit transfer (EBT) data previously collected from 12 State agencies for the WIC Food Cost Containment Practices study (OMB Number 0584-0627, Expiration Date 09/30/2020). EBT data will be used to calculate rates in each of the 12 study State agencies and, in conjunction with the policy data, will be used to assess the ways in which redemption rates vary with differences in policies and practices. Participant and State agency staff interviews in 4 of the 12 States will be used to understand the factors that are most salient to participants in

making decisions about purchasing fruits and vegetables with their CVB and barriers to redemption. FNS will select two States with low CVB redemption rates, one State with an intermediate redemption rate, and one State with a high redemption rate for participant and State agency staff interviews.

*Affected Public:* (1) State, local, and tribal governments; (2) nonprofits; and (3) individuals. Identified respondent groups include the following:

1. *State, local, and tribal governments:* State agency staff in four States, local agency staff at six local agencies, and clinic staff at six clinics.

2. *Nonprofits:* Staff at two local agencies and two WIC clinics.<sup>3</sup>

3. *Individuals:* WIC participants in four study States.

*Estimated Number of Respondents:* The total estimated number of respondents is 317 (20 State and local government staff, 4 nonprofit staff, and 293 individuals). Of the 317 respondents to be contacted, 257 are expected to be responsive, and 60 are expected to be nonresponsive. The breakout follows:

1. *20 State and local government staff:* Of 8 State agency staff to be contacted across 4 States, 8 are expected to be responsive; of 6 local agency staff contacted across 6 local agencies, 6 are expected to be responsive; of 6 clinic staff contacted across 6 clinics, 6 are expected to be responsive.

2. *4 nonprofit staff:* Of 2 local agency staff contacted across 2 local agencies, 2 are expected to be responsive; of 2 clinic staff to be contacted across 2 clinics, 2 are expected to be responsive.

3. *293 individuals:* 9 individuals are expected to participate in a pretest. Of 284 individuals to be contacted for the main study, 144 are expected to be responsive.

*Estimated Number of Responses per Respondent:* 4.5, based on the estimated 1,417 total annual responses (1,277 responsive and 140 nonresponsive) to be made by the 317 respondents. See table 1 for the estimated number of responses per respondent for each type of respondent. The breakout follows:

<sup>3</sup> Local agencies and clinics may be either government or nonprofit organizations. It is assumed that no contacted local agencies or clinics will refuse to participate.

1. *WIC State agency staff:* The estimated number of responses per State agency staff is three. Four State agency staff will receive and respond to advance materials and scheduling; the same four State agency staff will take part in a recruitment call. Up to eight State agency staff will participate in a semistructured interview.

2. *WIC local agency staff (including state, local, and tribal governments and non-profits):* The estimated number of responses per local agency staff is four. Eight local agency staff will receive and respond to advance materials and scheduling; the same eight local agency staff will take part in a recruitment call.

3. *WIC clinic staff (including state, local, and tribal governments and non-profits):* The estimated number of responses per local clinic staff is four. Eight clinic staff will receive and respond to advance materials and scheduling; the same 8 clinic staff will take part in a recruitment call.

4. *Individuals (WIC participants):* The estimated number of responses per individual is 5.10. In total, nine individuals will participate in a pretest. 284 individuals will receive a study brochure. Of the 164 who are eligible to participate, 112 will fill out the signup sheet for in-person interviews, and 52 will fill out the signup sheet for phone interviews. Of the 164 who fill out signup sheets, 20 will not respond.

*Estimated Total Annual Responses:* 1,417 (1,277 annual responses for responsive participants and 140 annual responses for nonresponsive participants).

*Estimated Time per Response:* The estimated average response time is 0.12 hours for all respondents (0.12 hours for responsive participants and 0.05 hours for nonresponsive participants). The estimated time of response varies from 30 seconds (0.0083 hours) to 1 hour depending on respondent group and activity, as shown in table 1.

*Estimated Total Annual Burden on Respondents:* 163.38 hours (156.38 hours for responsive participants, and 7.0 hours for nonresponsive participants). See table 1 for estimated total annual burden for each type of respondent.

**BILLING CODE 3410-30-P**

patterns: Final report. Retrieved from [https://altarum.org/sites/default/files/uploaded-publication-files/Altarum\\_Transition%20to%20WIC%20EBT\\_Final%20Report\\_071614.pdf](https://altarum.org/sites/default/files/uploaded-publication-files/Altarum_Transition%20to%20WIC%20EBT_Final%20Report_071614.pdf).

<sup>2</sup> National Academies of Sciences, Engineering, and Medicine. (2017). *Review of WIC food packages: Improving balance and choice: Final report*. Washington, DC: The National Academies Press. DOI: <https://doi.org/10.17226/23655>.

**Table 1. Total Public Burden Hours and Respondent Costs**

Respondent Category	Type of Respondent	Instruments and Activities	Sample Size	Responsive					Nonresponsive					Grand Total Annual Burden Estimate (Hours)	
				Number of Respondents	Frequency of Response	Total Annual Responses	Hours per Response	Annual Burden (Hours)	Number of Nonrespondents	Frequency of Response	Total Annual Responses	Hours per Response	Annual Burden (Hours)		
<b>State, Local, and Tribal Government</b>															
State, Local, and Tribal Government	WIC State agency staff	Advance communications (letter)	4	4	1	4	0.10	0.40	0	0	0	0.00	0.00	0.40	
	WIC State agency staff	Advance communications (FAQ sheet)	4	4	1	4	0.10	0.40	0	0	0	0.00	0.00	0.40	
	WIC State agency staff	Recruitment call	4	4	1	4	0.75	3.00	0	0	0	0.00	0.00	3.00	
	WIC State agency staff	Reminder email	4	4	1	4	0.05	0.20	0	0	0	0.00	0.00	0.20	
	WIC State agency staff	Telephone interviews with up to two staff per State	8	8	1	8	1.00	8.00	0	0	0	0.00	0.00	8.00	
	WIC State agency staff subtotal			8	8	3	24	0.50	12.00	0	0	0	0.00	0.00	12.00
	WIC local agency staff	Advance communications (letter)	6	6	1	6	0.10	0.60	0	0	0	0.00	0.00	0.60	
	WIC local agency staff	Advance communications (FAQ sheet)	6	6	1	6	0.10	0.60	0	0	0	0.00	0.00	0.60	
	WIC local agency staff	Recruitment call	6	6	1	6	0.75	4.50	0	0	0	0.00	0.00	4.50	
	WIC local agency staff	Reminder email	6	6	1	6	0.05	0.30	0	0	0	0.00	0.00	0.30	
	WIC local agency staff subtotal			6	6	4	24	0.25	6.00	0	0	0	0.00	0.00	6.00
	Clinic staff	Advance communications (letter)	6	6	1	6	0.10	0.60	0	0	0	0.00	0.00	0.60	
	Clinic staff	Advance communications (FAQ sheet)	6	6	1	6	0.10	0.60	0	0	0	0.00	0.00	0.60	
	Clinic staff	Recruitment call	6	6	1	6	0.75	4.50	0	0	0	0.00	0.00	4.50	
	Clinic staff	Reminder email	6	6	1	6	0.05	0.30	0	0	0	0.00	0.00	0.30	
	Clinic staff subtotal			6	6	4	24	0.25	6.00	0	0	0	0.00	0.00	6.00
	<b>State, Local, and Tribal government subtotal</b>			<b>20</b>	<b>20</b>	<b>4</b>	<b>72</b>	<b>0.33</b>	<b>24.00</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0.00</b>	<b>0.00</b>	<b>24.00</b>
<b>Nonprofit</b>															
Nonprofit	WIC local agency staff	Advance communications (letter)	2	2	1	2	0.10	0.20	0	0	0	0.00	0.00	0.20	

	WIC local agency staff	Advance communications (FAQ sheet)	2	2	1	2	0.10	0.20	0	0	0	0.00	0.00	0.20
	WIC local agency staff	Recruitment call	2	2	1	2	0.75	1.50	0	0	0	0.00	0.00	1.50
	WIC local agency staff	Reminder email	2	2	1	2	0.05	0.10	0	0	0	0.00	0.00	0.10
	WIC local agency staff subtotal		2	2	4	8	0.25	2.00	0	0	0	0.00	0.00	2.00
	Clinic staff	Advance communications (letter)	2	2	1	2	0.10	0.20	0	0	0	0.00	0.00	0.20
	Clinic staff	Advance communications (FAQ sheet)	2	2	1	2	0.10	0.20	0	0	0	0.00	0.00	0.20
Nonprofit (continued)	Clinic staff	Recruitment call	2	2	1	2	0.75	1.50	0	0	0	0.00	0.00	1.50
	Clinic staff	Reminder email	2	2	1	2	0.05	0.10	0	0	0	0.00	0.00	0.10
	Clinic staff subtotal		2	2	4	8	0.25	2.00	0	0	0	0.00	0.00	2.00
<b>Nonprofit subtotal</b>			4	4	4	16	0.25	4.00	0	0	0.00	0.00	0.00	4.00
<b>Individuals</b>														
Individuals	WIC participants	Pretest	9	9	1	9	0.75	6.75	0	0	0	0.00	0.00	6.75
	WIC participants	Study brochure	284	224	1	224	0.05	11.20	60	1	60	0.05	3.00	14.20
	WIC participants	Eligibility screener form	224	164	1	164	0.05	8.20	60	1	60	0.05	3.00	11.20
	WIC participants	Interview sign-up for in-person interviews	112	112	1	112	0.05	5.60	0	0	0	0.00	0.00	5.60
	WIC participants	Interview call sheet for telephone interviews	52	52	1	52	0.05	2.60	0	0	0	0.00	0.00	2.60
	WIC participants	Reminder call	52	52	1	52	0.008 <sub>3</sub>	0.43	0	0	0	0.00	0.00	0.43
	WIC participants	Consent form	154	144	1	144	0.03	4.32	20	1	20	0.05	1.00	5.32
	WIC participants	Interview protocol	144	144	1	144	0.50	72.00	0	0	0	0.00	0.00	72.00
	WIC participants	Demographic survey	144	144	1	144	0.07	10.08	0	0	0	0.00	0.00	10.08
	WIC participants	Thank-you note	144	144	1	144	0.05	7.20	0	0	0	0.00	0.00	7.20
Individual subtotal			293	233	5.10	1,189	0.11	128.38	60	3	140	0.05	7.00	135.38
<b>TOTAL</b>			<b>317</b>	<b>257</b>	<b>4.97</b>	<b>1,277</b>	<b>0.12</b>	<b>156.38</b>	<b>60</b>	<b>2.33</b>	<b>140</b>	<b>0.05</b>	<b>7.00</b>	<b>163.38</b>

Dated: July 26, 2019.

**Brandon Lipps,**  
*Administrator, Food and Nutrition Service.*  
 [FR Doc. 2019-17016 Filed 8-7-19; 8:45 am]  
**BILLING CODE 3410-30-C**

**DEPARTMENT OF AGRICULTURE**

**Foreign Agricultural Service**

**Adjustment of Appendices Under the Dairy Tariff-Rate Quota Import Licensing Regulation for the 2019 Tariff-Rate Quota Year**

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the transfer of amounts for certain dairy articles from the historical license category (Appendix 1) to the lottery (nonhistorical) license category (Appendix 2) pursuant to the Dairy Tariff-Rate Quota Import Licensing regulations, 7 CFR part 6, for the 2019 quota year.

**DATES:** August 8, 2019.

**FOR FURTHER INFORMATION CONTACT:** Abdelsalam El-Farra, (202) 720-9439; *abdelsalam.el-farra@fas.usda.gov.*

**SUPPLEMENTARY INFORMATION:** The Foreign Agricultural Service, under a delegation of authority from the Under Secretary for Trade and Foreign Agricultural Affairs, administers the Dairy Tariff-Rate Import Quota Licensing Regulation codified at 7 CFR 6.20-6.36 that provides for the issuance of licenses to import certain dairy articles under tariff-rate quotas (TRQs) as set forth in the Harmonized Tariff Schedule (HTS) of the United States. These dairy articles may only be entered into the United States at the low-tier tariff by or for the account of a person or firm to whom such licenses have been issued and only in accordance with the terms and conditions of the regulation.

Licenses are issued on a calendar year basis, and each license authorizes the license holder to import a specified quantity and type of dairy article from a specified country of origin. The Import Policies and Export Reporting Division, Foreign Agricultural Service, U.S. Department of Agriculture, issues these licenses and, in conjunction with U.S.

Customs and Border Protection, U.S. Department of Homeland Security, monitors their use.

The regulation at 7 CFR 6.34(a) states that whenever a historical license is permanently surrendered, revoked by the Licensing Authority, or not issued to an applicant pursuant to the provisions of 6.23, then the amount of such license will be transferred to Appendix 2. Section 6.34(b) provides that the cumulative annual transfers will be published by notice in the **Federal Register**. Accordingly, this document sets forth the revised Appendices for the 2019 tariff-rate quota year in the table below. Although there are no changes to the quantities for designated licenses (Appendix 3 and Appendix 4) nor to the total amount for each article, those numbers are also included in the table below for completeness.

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

Dated: August 2, 2019.

**Ronald Lord,**  
*Licensing Authority.*

**ARTICLES SUBJECT TO DAIRY IMPORT LICENSES FOR CALENDAR YEAR 2019**  
 [Kilograms]<sup>1</sup>

	Historical licenses (Appendix 1) <sup>2</sup>	Lottery licenses (Appendix 2) <sup>3</sup>	Sum of Appendix 1 & 2 <sup>4</sup>	Designated licenses (Tokyo Round, Appendix 3) <sup>4</sup>	Designated licenses (Uruguay Round, Appendix 4) <sup>4</sup>	Total <sup>4</sup>
Non-cheese articles, notes 6, 7, 8, 12, 14 (appendix 1 reduction)						
Butter (Note 6, Commodity Code G) (-1,773 kg) .....	4,301,461	2,675,539	6,977,000	.....	.....	6,977,000
EU-27 .....	62,599	33,562	96,161	.....	.....	.....
New Zealand .....	76,503	74,090	150,593	.....	.....	.....
Other Countries (-1,773 kg) .....	35,382	38,553	73,935	.....	.....	.....
Any Country .....	4,126,977	2,529,334	6,656,311	.....	.....	.....
Dried Skim Milk (Note 7, Commodity Code K) .....	0	5,261,000	5,261,000	.....	.....	5,261,000
Australia .....	0	600,076	600,076	.....	.....	.....
Canada .....	0	219,565	219,565	.....	.....	.....
Any Country .....	0	4,441,359	4,441,359	.....	.....	.....
Dried Whole Milk (Note 8, Commodity Code H) .....	0	3,321,300	3,321,300	.....	.....	3,321,300
New Zealand .....	0	3,175	3,175	.....	.....	.....
Any Country .....	0	3,318,125	3,318,125	.....	.....	.....
Dried Buttermilk/Whey (Note 12, Commodity Code M) ....	0	224,981	224,981	.....	.....	224,981
Canada .....	0	161,161	161,161	.....	.....	.....
New Zealand .....	0	63,820	63,820	.....	.....	.....
Butter Substitutes Containing Over 45 Percent of Butterfat and/or Butter Oil (Note 14, Commodity Code SU) .....	0	6,080,500	6,080,500	.....	.....	6,080,500
Any Country .....	0	6,080,500	6,080,500	.....	.....	.....
Total: Non-Cheese Articles (-1,773 kg) .....	4,301,461	17,563,320	21,864,781	.....	.....	21,864,781
Cheese Articles (Notes 16, 17, 18, 19, 20, 21, 22, 23, 25):						
Cheese and Substitutes for Cheese (Note 16, Commodity Code OT) (-2,142 kg) .....	17,613,583	13,856,148	31,469,731	9,661,128	7,496,000	48,626,859
Argentina .....	0	7,690	7,690	92,310	.....	100,000
Australia .....	535,628	5,542	541,170	758,830	1,750,000	3,050,000
Canada .....	950,162	190,838	1,141,000	.....	.....	1,141,000
Costa Rica .....	0	0	0	.....	1,550,000	1,550,000
EU-27 (-2,142 kg) .....	13,932,093	9,335,563	23,267,656	1,132,568	3,446,000	27,846,224
Of which Portugal is: .....	65,838	63,471	129,309	223,691	.....	353,000
EU-27 not including Portugal (-2,142 kg) .....	13,866,255	9,272,092	23,138,347	908,877	3,466,000	27,493,224
Israel .....	79,696	0	79,696	593,304	.....	673,000
Iceland .....	29,054	264,946	294,000	29,000	.....	323,000

ARTICLES SUBJECT TO DAIRY IMPORT LICENSES FOR CALENDAR YEAR 2019—Continued  
[Kilograms]<sup>1</sup>

	Historical licenses (Appendix 1) <sup>2</sup>	Lottery licenses (Appendix 2) <sup>3</sup>	Sum of Appendix 1 & 2 <sup>4</sup>	Designated licenses (Tokyo Round, Appendix 3) <sup>4</sup>	Designated licenses (Uruguay Round, Ap- pendix 4) <sup>4</sup>	Total <sup>4</sup>
New Zealand .....	1,351,000	3,464,472	4,815,472	6,506,528		11,322,000
Norway .....	122,860	27,140	150,000			150,000
Switzerland .....	512,184	159,228	671,412	548,588	500,000	1,720,000
Uruguay .....	0	0	0		250,000	250,000
Other Countries .....	100,906	100,729	201,635			201,635
Any Country .....	0	300,000	300,000			300,000
Blue-Mold Cheese (Note 17, Commodity Code B) .....	1,933,126	547,875	2,481,001		430,000	2,911,001
Argentina .....	2,000	0	2,000			2,000
EU-27 .....	1,931,126	547,874	2,479,000		350,000	2,829,000
Chile .....	0	0	0		80,000	80,000
Other Countries .....	0	1	1			1
Cheddar Cheese (Note 18, Commodity Code C)(-4,676 kg) .....	2,300,995	1,982,861	4,283,856	519,033	7,620,000	12,422,889
Australia (-4,676 kg) .....	886,570	97,929	984,499	215,501	1,250,000	2,450,000
Chile .....	0	0	0		220,000	220,000
EU-27 .....	52,404	210,596	263,000		1,050,000	1,313,000
New Zealand .....	1,265,070	1,531,398	2,796,468	303,532	5,100,000	8,200,000
Other Countries .....	96,951	42,938	139,889			139,889
Any Country .....	0	100,000	100,000			100,000
American-Type Cheese (Note 19, Commodity Code A) (-17,442 kg) .....	1,165,127	2,000,426	3,165,553	357,003	0	3,522,556
Australia (-3,689 kg) .....	758,201	122,797	880,998	119,002		1,000,000
EU-27 .....	136,075	217,925	354,000			354,000
New Zealand (-9,070 kg) .....	167,795	1,594,204	1,761,999	238,001		2,000,000
Other Countries (-4,683 kg) .....	103,056	65,500	168,556			168,556
Edam and Gouda Cheese (Note 20, Commodity Code E) .....	4,286,917	1,319,485	5,606,402	0	1,210,000	6,816,402
Argentina .....	105,418	19,582	125,000		110,000	235,000
EU-27 .....	4,065,691	1,223,309	5,289,000		1,100,000	6,389,000
Norway .....	111,046	55,954	167,000			167,000
Other Countries .....	4,762	20,640	25,402			25,402
Italian-Type Cheeses (Note 21, Commodity Code D)(-2,288 kg) .....	6,104,896	1,415,651	7,520,547	795,517	5,165,000	13,481,064
Argentina .....	3,692,345	433,138	4,125,483	367,517	1,890,000	6,383,000
EU-27 (-2,288 kg) .....	2,412,551	969,449	3,382,000		2,025,000	5,407,000
Romania .....	0	0	0		500,000	500,000
Uruguay .....	0	0	0	428,000	750,000	1,178,000
Other Countries .....	0	13,064	13,064			13,064
Swiss or Emmenthaler Cheese (Note 22, Commodity Code GR) .....	4,238,006	2,413,308	6,651,314	823,519	380,000	7,854,833
EU-27 .....	2,983,722	2,168,272	5,151,994	393,006	380,000	5,925,000
Switzerland .....	1,220,786	198,701	1,419,487	430,513		1,850,000
Other Countries .....	33,498	46,335	79,833			79,833
Lowfat Cheese (Note 23, Commodity Code LF) .....	1,173,766	3,251,142	4,424,908	1,050,000	0	5,474,908
EU-27 .....	1,173,766	3,251,141	4,424,907			4,424,907
Israel .....	0	0	0	50,000		50,000
New Zealand .....	0	0	0	1,000,000		1,000,000
Other Countries .....	0	1	1			1
Swiss or Emmenthaler Cheese With Eye Formation (Note 25, SW) (-13,091 kg) .....	13,091,848	9,205,483	22,297,331	9,557,945	2,620,000	34,475,276
Argentina .....	0	9,115	9,115	70,885		80,000
Australia .....	209,698	0	209,698	290,302		500,000
Canada .....	0	0	0	70,000		70,000
EU-27 (-13,091 kg) .....	9,762,199	6,714,629	16,476,828	4,003,172	2,420,000	22,900,000
Iceland .....	0	149,999	149,999	150,001		300,000
Israel .....	27,000	0	27,000			27,000
Norway .....	2,285,329	1,369,981	3,655,310	3,227,690		6,883,000
Switzerland .....	759,369	924,736	1,684,105	1,745,895	200,000	3,630,000
Other Countries .....	48,253	37,023	85,276			85,276
<b>Total: Cheese Articles (-39,639 kg) .....</b>	<b>51,908,264</b>	<b>35,992,379</b>	<b>87,900,643</b>	<b>22,764,145</b>	<b>24,921,000</b>	<b>135,585,788</b>
<b>Total: Cheese &amp; Non-Cheese (-41,412 kg) .....</b>	<b>56,209,725</b>	<b>53,555,699</b>	<b>109,765,424</b>	<b>22,764,145</b>	<b>24,921,000</b>	<b>157,450,569</b>

<sup>1</sup> Source of the total TRQs is the U.S. Harmonized Tariff Schedule, Chapter 4, in the corresponding Additional U.S. Notes.

<sup>2</sup> Reduced from 2018 by total of 107,200 KG.

<sup>3</sup> Increased from 2018 by total of 107,200 KG.

<sup>4</sup> No change.

[FR Doc. 2019-16933 Filed 8-7-19; 8:45 am]

BILLING CODE 3410-10-P

**DEPARTMENT OF AGRICULTURE****Foreign Agricultural Service****Assessment of Fees for Dairy Import Licenses for the 2020 Tariff-Rate Import Quota Year****AGENCY:** Foreign Agricultural Service, USDA.**ACTION:** Notice.

**SUMMARY:** This notice announces a fee of \$300 to be charged for the 2020 tariff-rate quota (TRQ) year for each license issued to a person or firm by the Department of Agriculture authorizing the importation of certain dairy articles, which are subject to tariff-rate quotas set forth in the Harmonized Tariff Schedule (HTS) of the United States.

**DATES:** August 8, 2019.

**FOR FURTHER INFORMATION CONTACT:** Abdelsalam El-Farra, (202) 720-9439; [abdelsalam.el-farra@fas.usda.gov](mailto:abdelsalam.el-farra@fas.usda.gov).

**SUPPLEMENTARY INFORMATION:** The Dairy Tariff-Rate Quota Import Licensing Regulation promulgated by the Department of Agriculture and codified at 7 CFR 6.20-6.36 provides for the issuance of licenses to import certain dairy articles that are subject to TRQs set forth in the HTS. Those dairy articles may only be entered into the United States at the in-quota TRQ tariff-rates by or for the account of a person or firm to whom such licenses have been issued and only in accordance with the terms and conditions of the regulation.

Licenses are issued on a calendar year basis, and each license authorizes the license holder to import a specified quantity and type of dairy article from a specified country of origin. The use of such licenses is monitored by the Dairy Import Licensing Program, Import Policies and Export Reporting Division, Foreign Agricultural Service, U.S. Department of Agriculture, and U.S. Customs and Border Protection, U.S. Department of Homeland Security.

The regulation at 7 CFR 6.33(a) provides that a fee will be charged for each license issued to a person or firm by the Licensing Authority to defray the Department of Agriculture's costs of administering the licensing system under this regulation.

The regulation at 7 CFR 6.33(a) also provides that the Licensing Authority will announce the annual fee for each license and that such fee will be set out in a notice to be published in the **Federal Register**. Accordingly, this

notice sets out the fee for the licenses to be issued for the 2020 calendar year.

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

*Notice:* The total cost to the Department of Agriculture of administering the licensing system for 2020 has been estimated to be \$749,300.00 and the estimated number of licenses expected to be issued is 2,500. Of the total cost, \$479,200.00 represents staff and supervisory costs directly related to administering the licensing system, and \$270,100.00 represents other miscellaneous costs, including travel, publications, forms, and Automatic Data Processing (ADP) system support.

Accordingly, notice is hereby given that the fee for each license issued to a person or firm for the 2020 calendar year, in accordance with 7 CFR 6.33, will be \$300 per license.

Dated: August 2, 2019.

**Ronald Lord,***Licensing Authority.*

[FR Doc. 2019-16932 Filed 8-7-19; 8:45 am]

BILLING CODE 3410-10-P

**DEPARTMENT OF AGRICULTURE****Forest Service****Proposed New Fee Site: Conecuh Shooting Range****AGENCY:** Forest Service, USDA.**ACTION:** Notice of Proposed New Fee Site.

**SUMMARY:** The National Forests in Alabama are proposing to charge a new fee at the Conecuh Shooting Range. Fees are assessed based on the level of amenities and services provided, cost of operation and maintenance, market assessment and public comment. Funds from fees would be used for the continued operation and maintenance of this shooting range including lead abatement, berm maintenance, and removal of shell casings and debris. The proposed new fees to help maintain this site would be: \$5 per person per day and \$50 for an annual permit.

**DATES:** Send any comments about these fee proposals by August 15, 2019, so comments can be compiled, analyzed and shared with a Recreation Resource Advisory Committee. New fees would begin after December 2019.

**ADDRESSES:** Cherie Hamilton, Forest Supervisor, National Forests in Alabama, 2946 Chestnut Street

Montgomery, Alabama 36107; or via facsimile 334-241-8111.

**FOR FURTHER INFORMATION CONTACT:** Odell Sanders, Recreation, Engineering, Lands & Minerals Staff Officer, 334-241-8128. Information about proposed fee changes can also be found on the National Forests of Alabama website: <http://www.fs.usda.gov/alabama>.

**SUPPLEMENTARY INFORMATION:** The Federal Recreation Lands Enhancement Act (Title VII, Pub. L. 108-447) directed the Secretary of Agriculture to publish a six-month advance notice in the **Federal Register** whenever new recreation fee areas are established. Once public involvement is complete, these new fees will be reviewed by a Recreation Resource Advisory Committee prior to a final decision and implementation.

Dated: July 8, 2019.

**Richard A. Cooksey,***Acting Associate Deputy Chief, National Forest System.*

[FR Doc. 2019-17015 Filed 8-7-19; 8:45 am]

BILLING CODE 3411-15-P

**DEPARTMENT OF AGRICULTURE****Forest Service****Request for Applications: The Community Forest and Open Space Conservation Program****AGENCY:** Forest Service, USDA.**ACTION:** Request for applications.

**SUMMARY:** The U.S. Department of Agriculture (USDA), Forest Service, State and Private Forestry, Cooperative Forestry staff, requests applications for the Community Forest and Open Space Conservation Program (Community Forest Program or CFP). This is a competitive grant program whereby local governments, qualified nonprofit organizations, and Indian tribes are eligible to apply for grants to establish community forests through fee simple acquisition of private forest land from a willing seller. The purpose of the program is to establish community forests by protecting forest land from conversion to non-forest uses and provide community benefits such as sustainable forest management, environmental benefits including clean air, water, and wildlife habitat; benefits from forest-based educational programs; benefits from serving as models of effective forest stewardship; and recreational benefits secured with public access.

Eligible lands for grants funded under this program are private forest that is at least five acres in size, suitable to

sustain natural vegetation, and at least 75 percent forested. The lands must also be threatened by conversion to non-forest uses, must not be held in trust by the United States on behalf of any Indian Tribe, must not be Tribal allotment lands, must be offered for sale by a willing seller, and if acquired by an eligible entity, must provide defined community benefits under CFP and allow public access.

**DATES:** Interested local government and nonprofit applicants must submit applications to the State Forester. Tribal applicants must submit applications to the appropriate Tribal government officials. All applications, either hardcopy or electronic, must be received by State Foresters or Tribal governments by January 6th, 2020. State Foresters or Tribal government officials must forward applications to the appropriate Forest Service Regional office or International Institute of Tropical Forestry by February 6th, 2020.

**ADDRESSES:** All local government and qualified nonprofit organization applications must be submitted to the State Forester of the State where the property is located. All Tribal applications must be submitted to the equivalent Tribal government official. Applicants are encouraged to contact and work with the Forest Service Region or International Institute of Tropical Forestry, and State Forester or equivalent Tribal government official when developing their proposal. Applicants must consult with the State Forester and equivalent Tribal government official prior to requesting technical assistance for a project. The State Forester's member roster may be found on <https://www.stateforesters.org/who-we-are/our-membership/>. All applicants must also send an email to [communityforest@fs.fed.us](mailto:communityforest@fs.fed.us) to confirm an application has been submitted for funding consideration.

State Foresters and Tribal government officials shall submit applications, either electronic or hardcopy, to the appropriate Forest Service Region/Institute contact noted below.

#### Northern and Intermountain Regions

##### Regions 1 and 4

(ID, MT, ND, NV, UT)

Janet Valle, U.S. Forest Service, 324 25th St., Ogden, UT 84401, 801-625-5258 (phone), 801-625-5716 (fax), [janet.valle@usda.gov](mailto:janet.valle@usda.gov).

#### Rocky Mountain Region

##### Region 2

(CO, KS, NE, SD, WY)

Claire Harper, U.S. Forest Service, 740 Simms Street, Golden, CO 80401, 303-895-6157 (phone), 303-275-5754 (fax), [claire.harper@usda.gov](mailto:claire.harper@usda.gov).

#### Southwestern Region

##### Region 3

(AZ, NM)

Alicia San Gil, U.S. Forest Service, 333 Broadway SE, Albuquerque, NM 87102, 505-842-3289 (phone), 505-842-3165 (fax), [alicia.sangil@usda.gov](mailto:alicia.sangil@usda.gov).

#### Pacific Southwest Region

##### Region 5

(CA)

Miranda Hutten, U.S. Forest Service, 1323 Club Drive, Vallejo, CA 94592, 707-562-9025 (phone), 707-562-9054 (fax), [miranda.l.hutten@usda.gov](mailto:miranda.l.hutten@usda.gov).

(Hawaii, Guam, American, Samoa, Federated States of Micronesia and other Pacific Islands)

Katie Friday, U.S. Forest Service, 60 Nowelo St., Hilo, HI 96720, 808-854-2620 (phone), 503-808-2469 (fax), [kathleen.friday@usda.gov](mailto:kathleen.friday@usda.gov).

#### Pacific Northwest, and Alaska Regions

##### Regions 6 and 10

(AK, OR, WA)

Brad Siemens, U.S. Forest Service, 120 Southwest 3rd Ave., Portland, OR 97204, 503-808-2353 (phone), 503-808-2469 (fax), [bradley.siemens@usda.gov](mailto:bradley.siemens@usda.gov).

#### Southern Region

##### Region 8

(AL, AR, FL, GA, KY, LA, MS, NC, OK, SC, TN, TX, VA)

Mike Murphy, U.S. Forest Service, 1720 Peachtree Rd. NW, Suite 700B 850S North, Atlanta, GA 30309, 404-347-5214 (phone), 404-347-2776 (fax), [michael.w.murphy@usda.gov](mailto:michael.w.murphy@usda.gov).

#### International Institute of Tropical Forestry

(PR, VI)

Magaly Figueroa, U.S. Forest Service, Jardin Botanico Sur, 1201 Calle Ceiba, San Juan, PR 00926-1119, 787-764-7718 (phone), 787-766-6263 (fax) [magaly.figueroa@usda.gov](mailto:magaly.figueroa@usda.gov).

#### Eastern Region

##### Region 9

(CT, DC, DE, IA, IL, IN, MA, MD, ME, MI, MN, MO, NH, NJ, NY, OH, PA, RI, VT, WI, WV)

Neal Bungard, U.S. Forest Service, 271 Mast Road, Durham, NH 03824-4600, 603-868-7719 (phone), 603-868-7604 (fax), [neal.bungard@usda.gov](mailto:neal.bungard@usda.gov).

**FOR FURTHER INFORMATION CONTACT:** For questions regarding the grant application or administrative regulations, contact Scott Stewart, Program Coordinator, 202-205-1618, [scott.stewart@usda.gov](mailto:scott.stewart@usda.gov). Additional information about the Community Forest and Open Space Program may be obtained at <https://www.fs.fed.us/managing-land/private-land/community-forest>.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Relay Service (FRS) at 1-800-877-8339 twenty-four hours a day, every day of the year, including holidays.

**SUPPLEMENTARY INFORMATION:** CFDA number 10.689: To address the goals of Section 7A of the Cooperative Forestry Assistance Act of 1978 (16 U.S.C. 2103d) as amended, the Forest Service is requesting proposals for community forest projects that protect forest land that has been identified as a national, regional, or local priority for protection and to assist communities in acquiring forestland that will provide public recreation, environmental and economic benefits, and forest-based educational programs.

Detailed information regarding what to include in the application, definitions of terms, eligibility, and necessary prerequisites for consideration can be found in the final program rule, published October 20, 2011 (76 FR 65121-65133), which is available at <https://www.fs.fed.us/managing-land/private-land/community-forest/program>.

#### Grant Application Requirements

##### 1. Eligibility Information

a. *Eligible Applicants.* A local governmental entity, Indian Tribe (including Alaska Native Corporations), or a qualified nonprofit organization that is qualified to acquire and manage land (see § 230.2 of the final rule at <https://www.fs.fed.us/managing-land/private-land/community-forest/program>). Individuals are not eligible to receive funds through this program.

b. *Cost Sharing (Matching Requirement).* All applicants must demonstrate a 50 percent match of the

total project cost. The match can include cash, in-kind services, or donations, which shall be from a non-Federal source. For additional information, please see § 230.6 of the final rule.

c. *DUNS Number.* All applicants shall include a Data Universal Numbering System (DUNS) number in their application. For this requirement, the applicant is the entity that meets the eligibility criteria and has the legal authority to apply for and receive the grant. For assistance in obtaining a DUNS number at no cost, call the DUNS number request line 1-866-705-5711 or register on-line at <http://fedgov.dnb.com/webform>.

d. *System for Award Management.* All prospective awardees shall be registered in the System for Award Management prior to award, during performance, and through final payment of any grant resulting from this solicitation. Further information can be found at [www.sam.gov](http://www.sam.gov). For assistance, contact Federal Service Desk 1-866-606-8220.

## 2. Award Information

Funds have not yet been appropriated for CFP in FY 2020. Individual grant applications may not exceed \$600,000, which does not include technical assistance requests. The Federal Government's obligation under this program is contingent upon the availability of appropriated funds.

No legal liability on the part of the Government shall be incurred until funds are committed by the grant officer for this program to the applicant in writing. The initial grant period shall be for two years, and acquisition of lands should occur within that timeframe. Lands acquired prior to the grant award are not eligible for CFP funding. The grant may be reasonably extended by the Forest Service when necessary to accommodate unforeseen circumstances in the land acquisition process. Written annual financial performance reports and semi-annual project performance reports shall be required and submitted to the appropriate grant officer.

Technical assistance funds, totaling not more than 10 percent of all funds, may be allocated to State Foresters and equivalent officials of the Indian tribe. Technical assistance, if provided, will be awarded at the time of the grant. Applicants shall work with State Foresters and equivalent officials of the Indian Tribe to determine technical assistance needs and include the technical assistance request in the project budget.

As funding allows, applications submitted through this request may be funded in future years, subject to the

availability of funds and the continued feasibility and viability of the project.

## 3. Application Information

*Application submission.* All local governments and qualified nonprofit organizations' applications must be submitted to the State Forester where the property is located by January 6th, 2020. All Tribal applications must be submitted to the equivalent Tribal officials by January 6th, 2020. Applications may be submitted either electronically or hardcopy to the appropriate official. The State Forester's contact information may be found at: <https://www.fs.fed.us/managing-land/private-land/community-forest/program>.

All applicants must also send an email to [communityforest@fs.fed.us](mailto:communityforest@fs.fed.us) to confirm an application has been submitted to the State Forester or equivalent Tribal official for funding consideration.

All State Foresters and Tribal government officials must forward applications to the Forest Service by February 6th, 2020.

## 4. Application Requirements

The following section outlines grant application requirements:

a. The application can be no more than eight pages long, plus no more than two maps (eight and half inches by eleven inches in size), the grant forms specified in (b), and the draft community forest plan specified in (e).

b. The following grant forms and supporting materials must be included in the application:

(1) An Application for Federal Assistance (Standard Form 424);  
(2) Budget information (Standard Form SF 424c—Construction Programs); and

(3) Assurances of compliance with all applicable Federal laws, regulations, and policies (Standard Form 424d—Construction Programs).

c. Documentation verifying that the applicant is an eligible entity and that the land proposed for acquisition is eligible (see § 230.2 of the final rule).

d. Applications must include the following, regarding the property proposed for acquisition:

(1) A description of the property, including acreage and county location;

(2) A description of current land uses, including improvements;

(3) A description of forest type and vegetative cover;

(4) A map of sufficient scale to show the location of the property in relation to roads and other improvements as well as parks, refuges, or other protected lands in the vicinity;

(5) A description of applicable zoning and other land use regulations affecting the property;

(6) A description of the type of community being served and the extent of community benefits, including to underserved communities (see selection criteria);

(7) A description of relationship of the property within and its contributions to a landscape conservation initiative, as well as any environmental justice initiatives, if applicable; and

(8) A description of any threats of conversion to non-forest uses, including any encumbrances on the property that prevent conversion to non-forest uses.

e. Information regarding the proposed establishment of a community forest, including:

(1) A description of the benefiting community, including demographics, availability of and access to green spaces and other inequalities faced by the community;

(2) A description of the associated benefits provided by the proposed land acquisition;

(3) A description of community involvement, including marginalized communities, to-date in the planning of the community forest acquisition, and of community participation anticipated in long-term management;

(4) An identification of persons and organizations that support the project and their specific role in establishing and managing the community forest; and

(5) A draft community forest plan. The eligible entity is encouraged to work with the State Forester or equivalent Tribal government official for technical assistance when developing or updating the Community Forest Plan. In addition, the eligible entity is encouraged to work with technical specialists, such as professional foresters, recreation specialists, wildlife biologists, or outdoor education specialists, when developing the Community Forest Plan.

f. Information regarding the proposed land acquisition, including:

(1) A proposed project budget not exceeding \$600,000 and technical assistance needs as coordinated with the State Forester or equivalent Tribal government official (section § 230.6 of the final program rule);

(2) The status of due diligence, including signed option or purchase and sale agreement, title search, minerals determination, and appraisal;

(3) Description and status of cost share (secure, pending, commitment letter, etc.) (section § 230.6 of the final rule);

(4) The status of negotiations with participating landowner(s) including purchase options, contracts, and other terms and conditions of sale;

(5) The proposed timeline for completing the acquisition and establishing the community forest; and;

(6) Long term management costs and funding source(s).

g. Applications must comply with the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards also referred to as the Omni Circular (2 CFR 200).

h. Applications must also include the forms required to process a Federal grant. Section 6 *Grant Requirements* references the grant forms that must be included in the application and the specific administrative requirements that apply to the type of Federal grant used for this program.

A sample grant outline and scoring guidance can be found on the CFP website at <https://www.fs.fed.us/managing-land/private-land/community-forest/program>.

#### 5. Forest Service's Project Selection Criteria

a. Using the criteria described below, to the extent practicable, the Forest Service will give priority to applications that maximize the delivery of community benefits, as defined in the final rule (see section § 230.2 of the final rule); and

b. The Forest Service will evaluate all applications received by the State Foresters or equivalent Tribal government officials and award grants based on the following criteria:

(1) Type and extent of community benefits provided, including to underserved communities. Community benefits are defined in the final program rule as:

(i) Economic benefits, such as timber and non-timber products resulting from sustainable forest management, recreation and tourism;

(ii) Environmental benefits, including clean air and water, stormwater management, and wildlife habitat;

(iii) Benefits from forest-based experiential learning, including K–12 conservation education programs; vocational education programs in disciplines such as forestry and environmental biology; and environmental education through individual study or voluntary participation in programs offered by organizations such as 4–H, Boy or Girl Scouts, Master Gardeners, etc.;

(iv) Benefits from serving as replicable models of effective forest stewardship for private landowners; and

(v) Recreational benefits such as hiking, hunting, and fishing secured through public access.

(2) Extent and nature of community engagement, including participation by marginalized communities, in the establishment and long-term management of the community forest;

(3) Amount of cost share leveraged;

(4) Extent to which the community forest contributes to a landscape conservation initiative, as well as any applicable environmental justice initiatives;

(5) Extent of due diligence completed on the project, including cost share committed and status of appraisal;

(6) Likelihood that, unprotected, the property would be converted to non-forest uses; and

(7) Costs to the Federal Government.

#### 6. Grant Requirements

a. Once an application is selected, funding will be obligated to the grant recipient through a grant adhering to the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards also referred to as the Omni Circular (2 CFR 200).

b. Forest Service must approve any amendments to a proposal or request to reallocate funding within a grant proposal. If negotiations on a selected project fail, the applicant cannot substitute an alternative site.

c. The grant recipient must comply with the requirements in section § 230.8 in the final rule before funds will be released.

d. After the project has closed, as a requirement of the grant, grant recipients will be required to provide the Forest Service with a Geographic Information System (GIS) shapefile: A digital, vector-based storage format for storing geometric location and associated attribute information, of CFP project tracts and cost share tracts, if applicable.

e. Any funds not expended within the grant period must be de-obligated and revert to the Forest Service.

f. All media, press, signage, and other documents discussing the creation of the community forest must reference the partnership and financial assistance by the Forest Service through the CFP.

Additional information may be found in section § 230.9 of the final rule.

Dated: July 3, 2019.

**Patricia Hiramí,**

*Acting Deputy Chief, State and Private Forestry.*

[FR Doc. 2019–17014 Filed 8–7–19; 8:45 am]

**BILLING CODE 3411–15–P**

## COMMISSION ON CIVIL RIGHTS

### Agenda and Notice of Public Meeting of the South Dakota Advisory Committee

**AGENCY:** Commission on Civil Rights.

**ACTION:** Announcement of meeting.

**SUMMARY:** Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a meeting of the South Dakota Advisory Committee to the Commission will convene at 12:00 p.m. (CDT) on Monday, August 19, 2019, in the Breakwater Room of the Arrowhead Resort at Cedar Lodge, 1500 Shoreline Drive, Oacoma, SD 57365. The purpose of the meeting is orientation and planning.

**DATES:** Monday, August 19, 2019. Time: 12:00 p.m. (CDT).

**ADDRESSES:** Extension Room of the Brule County Clerk of Courts, 300 S. Courtland Street, Chamberlain, SD 57325.

**FOR FURTHER INFORMATION CONTACT:**

Evelyn Bohor at [ebohor@usccr.gov](mailto:ebohor@usccr.gov), or 303–866–1040.

**SUPPLEMENTARY INFORMATION:** If other persons who plan to attend the meeting require other accommodations, please contact Evelyn Bohor at [ebohor@usccr.gov](mailto:ebohor@usccr.gov) at the Rocky Mountain Regional Office at least ten (10) working days before the scheduled date of the meeting.

Persons interested in the issue are also invited to submit written comments; the comments must be received in the regional office by Thursday, September 19, 2019. Written comments may be mailed to the Rocky Mountain Regional Office, U.S. Commission on Civil Rights, 1961 Stout Street, 13–201, Denver, CO 80294, faxed to (303) 866–1050, or emailed to Evelyn Bohor at [ebohor@usccr.gov](mailto:ebohor@usccr.gov). Persons who desire additional information may contact the Rocky Mountain Regional Office at (303) 866–1040.

Records and documents discussed during the meeting will be available for public viewing as become available at <https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzm5AAA>, and clicking on the “Meeting Details” and “Documents” links. Records generated from this meeting may also be inspected and reproduced at the Rocky Mountain Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised

to go to the Commission’s website, [www.usccr.gov](http://www.usccr.gov), or to contact the Rocky Mountain Regional Office at the above phone number, email or street address.

**Agenda**

Monday, August 19, 2019; 12:00 p.m. (CDT)

- I. Welcome and Roll Call
- II. Orientation
- III. Planning
- IV. Other Business
- V. Open Comment
- VI. Adjournment

*Exceptional Circumstance:* Pursuant to 41 CFR 102–3.150, the notice for this meeting is given less than 15 calendar days prior to the meeting because of the

exceptional circumstances of the federal government shutdown.

Dated: August 2, 2019.  
**David Mussatt**,  
*Supervisory Chief, Regional Programs Unit.*  
 [FR Doc. 2019–16948 Filed 8–7–19; 8:45 am]  
**BILLING CODE P**

**DEPARTMENT OF COMMERCE**

**Economic Development Administration**

**Notice of Petitions by Firms for Determination of Eligibility To Apply for Trade Adjustment Assistance**

**AGENCY:** Economic Development Administration, U.S. Department of Commerce.

**ACTION:** Notice and opportunity for public comment.

**SUMMARY:** The Economic Development Administration (EDA) has received petitions for certification of eligibility to apply for Trade Adjustment Assistance from the firms listed below. Accordingly, EDA has initiated investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each of the firms contributed importantly to the total or partial separation of the firms’ workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

**SUPPLEMENTARY INFORMATION:**

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION OF ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE  
 [7/19/2019 through 8/1/2019]

Firm name	Firm address	Date accepted for investigation	Product(s)
Harlan Cabinets, Inc .....	12707 Spencerville Road, Harlan, IN 46743.	7/23/2019	The firm manufactures wooden cabinetry and furniture.
York Precision Machining & Hydraulics, LLC.	706 Willow Springs Lane, York, PA 17406.	7/23/2019	The firm manufactures metal parts for hydraulic machines and equipment.

Any party having a substantial interest in these proceedings may request a public hearing on the matter. A written request for a hearing must be submitted to the Trade Adjustment Assistance Division, Room 71030, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than ten (10) calendar days following publication of this notice. These petitions are received pursuant to section 251 of the Trade Act of 1974, as amended.

Please follow the requirements set forth in EDA’s regulations at 13 CFR 315.9 for procedures to request a public hearing. The Catalog of Federal Domestic Assistance official number and title for the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance for Firms.

**Irette Patterson**,  
*Program Analyst.*  
 [FR Doc. 2019–16991 Filed 8–7–19; 8:45 am]  
**BILLING CODE 3510–WH–P**

**DEPARTMENT OF COMMERCE**

**National Telecommunications and Information Administration**

**First Responder Network Authority**

**First Responder Network Authority Finance Committee and Board Meeting**

**AGENCY:** First Responder Network Authority (“FirstNet Authority”), National Telecommunications and Information Administration, U.S. Department of Commerce.

**ACTION:** Notice of open public meetings.

**SUMMARY:** The Board of the First Responder Network Authority (“FirstNet Authority Board”) will convene a meeting of the FirstNet Authority Board and the Finance Committee of the FirstNet Authority Board (“Finance Committee”) that will be open to the public via teleconference and WebEx on August 15, 2019.

**DATES:** A combined meeting of the FirstNet Authority Board and the Finance Committee will be held on August 15, 2019, between 11:00 a.m. and 1:00 p.m., Eastern Daylight Time (EDT). The meeting of the FirstNet Authority Board and the Finance Committee will be open to the public

via teleconference and WebEx only from 11:00 a.m. to 1:00 p.m. EDT.

**ADDRESSES:** The combined meeting of the FirstNet Authority Board and the Finance Committee will be conducted via teleconference and WebEx only. Members of the public may listen to the meeting by dialing toll free 1–888–324–6860 and using passcode 2951211. To view the slide presentation, the public may visit the URL: <https://www.mymeetings.com/nc/join/> and enter Conference Number: PWXW9353101 and Audience Passcode: 2951211. Alternatively, members of the public may view the slide presentation by directly visiting the URL: <https://www.mymeetings.com/nc/join.php?i=PWXW9353101&p=2951211&t=c>.

**FOR FURTHER INFORMATION CONTACT:** Karen Miller-Kuwana, Board Secretary, FirstNet Authority, 12201 Sunrise Valley Drive, M/S 243, Reston, VA 20192; telephone: (571) 665–6177; email: [Karen.Miller-Kuwana@firstnet.gov](mailto:Karen.Miller-Kuwana@firstnet.gov). Please direct media inquiries to Ryan Oremland at (571) 665–6186.

**SUPPLEMENTARY INFORMATION:** This notice informs the public that the FirstNet Authority Board and the Finance Committee will convene a combined meeting open to the public

via teleconference and WebEx only on August 15, 2019.

**Background:** The Middle Class Tax Relief and Job Creation Act of 2012 (47 U.S.C. 1401 *et seq.*) (“the Act”) established the FirstNet Authority as an independent authority within the National Telecommunications and Information Administration that is headed by a Board. The Act directs the FirstNet Authority to ensure the building, deployment, and operation of a nationwide, interoperable public safety broadband network. The FirstNet Authority Board is responsible for making strategic decisions regarding the FirstNet Authority’s operations. The FirstNet Authority Board held its first public meeting on September 25, 2012.

**Matters To Be Considered:** The FirstNet Authority will post a detailed agenda for the combined meeting of the FirstNet Authority Board and Finance Committee on its website, <http://www.firstnet.gov>, prior to the meetings. The agenda topics are subject to change. Please note that the subjects that will be discussed by the FirstNet Authority Board and the Finance Committee may involve commercial or financial information that is privileged or confidential or other legal matters affecting the FirstNet Authority. As such, the FirstNet Authority Board Chair and the Finance Committee Chair may call for a vote to close the meetings only for the time necessary to preserve the confidentiality of such information, pursuant to 47 U.S.C. 1424(e)(2).

**Times and Dates of Meeting:** A combined meeting of the FirstNet Authority Board and the Finance Committee will be held on August 15, 2019, between 11:00 a.m. and 1:00 p.m., Eastern Daylight Time (EDT). The meeting of the FirstNet Authority Board and the Finance Committee will be open to the public via teleconference and WebEx from 11:00 a.m. to 1:00 p.m. EDT. The times listed above are subject to change. Please refer to the FirstNet Authority’s website at [www.firstnet.gov](http://www.firstnet.gov) for the most up-to-date information.

**Place:** The combined meeting of the FirstNet Authority Board and the Finance Committee will be conducted via teleconference and WebEx.

**Other Information:** The combined meeting of the FirstNet Authority Board and the Finance Committee is open to the public via teleconference and WebEx only. On the date and time of the meeting, members of the public may listen to the meeting by dialing toll free 1-888-324-6860 and using passcode 2951211. To view the slide presentation, the public may visit the URL: <https://www.mymeetings.com/nc/join/> and enter Conference Number:

PWXW9353101 and Audience Passcode: 2951211. Alternatively, members of the public may view the slide presentation by directly visiting the URL: <https://www.mymeetings.com/nc/join.php?i=PWXW9353101&p=2951211&t=c>.

If you experience technical difficulty, please contact the Conferencing Center customer service at 1-866-900-1011. Public access will be limited to listen-only. Due to the limited number of ports, attendance via teleconference will be on a first-come, first-served basis. The FirstNet Authority Board and the Finance Committee Meeting is accessible to people with disabilities. Individuals requiring accommodations are asked to notify Ms. Miller-Kuwana by telephone (571) 665-6177 or email at [Karen.Miller-Kuwana@firstnet.gov](mailto:Karen.Miller-Kuwana@firstnet.gov) at least five (5) business days before the applicable meeting.

**Records:** The FirstNet Authority maintains records of all FirstNet Authority Board proceedings. Minutes of the FirstNet Authority Board and the Finance Committee Meeting will be available at [www.firstnet.gov](http://www.firstnet.gov).

Dated: August 5, 2019.

**Karen Miller-Kuwana,**

*Board Secretary, First Responder Network Authority.*

[FR Doc. 2019-16997 Filed 8-7-19; 8:45 am]

**BILLING CODE 3510-TL-P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

[A-821-809]

#### **Certain Hot-Rolled Flat-Rolled Carbon-Quality Steel Products From the Russian Federation: Final Results and Rescission of Antidumping Duty Administrative Review; 2016-2017**

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** The Department of Commerce (Commerce) determines that Novolipetsk Steel (NLMK) did not make a *bona fide* sale during the period of review (POR) December 1, 2016 through November 30, 2017. Therefore, we are rescinding this administrative review.

**DATES:** Applicable August 8, 2019.

**FOR FURTHER INFORMATION CONTACT:** John McGowan or Joshua DeMoss, 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) 482-3019 or (202) 482-3362, respectively.

**SUPPLEMENTARY INFORMATION:**

## Background

On February 19, 2019, Commerce published the *Preliminary Results* of this review in the **Federal Register**<sup>1</sup> and invited parties to comment on the *Preliminary Results*. On March 25, 2019, we received case briefs from NLMK and the Ministry of Economic Development of the Russian Federation. On April 1, 2019, we received a rebuttal brief from a petitioner (*i.e.*, Nucor Corporation). Further, on June 27, 2019, we held a public hearing regarding issues raised in case and rebuttal briefs.

## Scope of the Order

The product covered by this administrative review is certain hot-rolled flat-rolled carbon-quality steel products (hot-rolled steel) from Russia. For the full text of the scope of the order, see the Issues and Decision Memorandum.<sup>2</sup>

## Analysis of the Comments Received

All issues raised in the case and rebuttal briefs submitted in this review are addressed in the Issues and Decision Memorandum. A list of the issues raised is attached as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance’s Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <http://access.trade.gov> and it is available to all parties in the Central Records Unit, Room B8024 of the main Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <http://enforcement.trade.gov/frn/index.html>. The signed Issues and Decision Memorandum and the electronic versions of the Issues and Decision Memorandum are identical in content.

<sup>1</sup> See *Certain Hot-Rolled Flat-Rolled Carbon-Quality Steel Products from the Russian Federation: Preliminary Results of Antidumping Duty Administrative Review*, 84 FR 4776 (February 19, 2019) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum; see also *Certain Hot-Rolled Flat-Rolled Carbon-Quality Steel Products from the Russian Federation: Correction to the Preliminary Results of the 2016-2017 Administrative Review*, 84 FR 16643 (April 22, 2019).

<sup>2</sup> See Memorandum, “Issues and Decision Memorandum for the Final Results of the Administrative Review and Final Rescission of the Antidumping Duty Order on Certain Hot-Rolled Flat-Rolled Carbon-Quality Steel Products from the Russian Federation; 2016-2017,” dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

### Bona Fides Analysis

For the *Preliminary Results*, Commerce analyzed the *bona fide* nature of NLMK's single sale and preliminarily found it was not a *bona fide* sale.<sup>3</sup> Based on Commerce's complete analysis of all the information and comments on the record of this review, Commerce continues to find that NLMK's sale is not a *bona fide* sale. Commerce reached this conclusion based on its consideration of the totality of circumstances, including: (a) The atypical nature of both the price and quantity of the sale; (b) reason to question the arm's-length nature of the transaction; and (c) the circumstances of the sale/customer correspondence. In addition to the above factors, which Commerce determined are a sufficient basis to find NLMK's sale to be non-*bona fide*, it determined that additional factors—*i.e.*, the timing of the sale, late payment by the customer, the sales agent agreement, affiliation concerns, and the fact that NLMK only made one sale during the POR—constituted additional support for its non-*bona fide* finding.

Because we have determined that NLMK had no *bona fide* sales during the POR, we are rescinding this administrative review.

### Assessment

Because Commerce is rescinding this administrative review, we have not calculated a company-specific dumping margin for NLMK. NLMK's entries will be liquidated at the all-others rate applicable to Russian exporters who do not have their own company-specific rate. The all-others rate is 184.56 percent.<sup>4</sup>

### Cash Deposit Requirements

Because we did not calculate a dumping margin for NLMK, NLMK continues to be subject to the all-others rate at which its merchandise entered, 184.56 percent.<sup>5</sup> These cash deposit requirements shall remain in effect until further notice.

### Administrative Protective Order

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, which continues to govern business proprietary information in these segments of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

### Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

### Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(h) and 351.221(b)(5).

Dated: August 2, 2019.

**Jeffrey I. Kessler,**

*Assistant Secretary for Enforcement and Compliance.*

### Appendix

#### List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. Discussion of the Issues

Comment 1: Whether "*Bona Fides*" Testing is Applicable Only to New Shipper Reviews, and Not Administrative Reviews

Comment 2: Whether Record Evidence Confirms that NLMK's Sale Was Not a *Bona Fide* Sale

Comment 3: Whether Rescinding this Administrative Review is Appropriate

#### V. Recommendation

[FR Doc. 2019-17006 Filed 8-7-19; 8:45 am]

**BILLING CODE 3510-DS-P**

### DEPARTMENT OF EDUCATION

[Docket No.: ED-2019-ICCD-0069]

#### Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Federal Perkins Loan Program Regulations

**AGENCY:** Federal Student Aid (FSA), Department of Education (ED).

**ACTION:** Notice.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

**DATES:** Interested persons are invited to submit comments on or before September 9, 2019.

**ADDRESSES:** To access and review all the documents related to the information collection listed in this notice, please use <http://www.regulations.gov> by searching the Docket ID number ED-2019-ICCD-0069. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the [regulations.gov](http://www.regulations.gov) site is not available to the public for any reason, ED will temporarily accept comments at [ICDocketMgr@ed.gov](mailto:ICDocketMgr@ed.gov). Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 550 12th Street SW, PCP, Room 9086, Washington, DC 20202-0023.

**FOR FURTHER INFORMATION CONTACT:** For specific questions related to collection activities, please contact Beth Grebeldinger, 202-377-4018.

**SUPPLEMENTARY INFORMATION:** The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the

<sup>3</sup> See Memorandum, "2016-2017 Antidumping Duty Administrative Review of Certain Hot-Rolled Flat-Rolled Carbon-Quality Steel Products from the Russian Federation: Preliminary *Bona Fides* Sales Analysis for Novolipetsk Steel," dated February 11, 2019.

<sup>4</sup> See *Termination of the Suspension Agreement on Hot-Rolled Flat-Rolled Carbon-Quality Steel Products from the Russian Federation, Rescission of 2013-2014 Administrative Review, and Issuance of Antidumping Duty Order*, 79 FR 77455 (December 24, 2014).

<sup>5</sup> *Id.*, 79 FR at 77456.

Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

*Title of Collection:* Federal Perkins Loan Program Regulations.

*OMB Control Number:* 1845-0023.

*Type of Review:* An extension of an existing information collection.

*Respondents/Affected Public:* Individuals or Households; State, Local, and Tribal Governments; Private Sector.

*Total Estimated Number of Annual Responses:* 8,217,172.

*Total Estimated Number of Annual Burden Hours:* 149,369.

*Abstract:* Institutions of higher education made Federal Perkins loans. This information is necessary to monitor a school's due diligence in its contact with the borrower regarding repayment, billing and collections, reimbursement to its Perkins loan revolving fund, rehabilitation of defaulted loans as well as institutions use of third party collections. There has been no change to the regulations this is a request for an extension of the currently approved reporting and record-keeping requirements contained in the regulations related to the administrative requirements of the Perkins Loan Program.

Dated: August 5, 2019.

**Kate Mullan,**

*PRA Coordinator, Information Collection Clearance Program, Information Management Branch, Office of the Chief Information Officer.*

[FR Doc. 2019-17012 Filed 8-7-19; 8:45 am]

**BILLING CODE 4000-01-P**

## DEPARTMENT OF EDUCATION

### Applications for New Awards; Technical Assistance and Dissemination To Improve Services and Results for Children With Disabilities—National Technical Assistance Center for Systemic Improvement

**AGENCY:** Office of Special Education and Rehabilitative Services, Department of Education.

**ACTION:** Notice.

**SUMMARY:** The mission of the Office of Special Education and Rehabilitative Services (OSERS) is to improve early childhood, educational, and employment outcomes and raise expectations for all people with disabilities, their families, their communities, and the Nation. As such, the Department of Education (Department) is issuing a notice inviting applications for new awards for fiscal year (FY) 2019 for a National Technical Assistance Center for Systemic Improvement, Catalog of Federal Domestic Assistance (CFDA) number 84.326R. This Center will provide differentiated support to States to help them best use their general supervision and professional development (PD) systems to establish and meet high expectations for each child with a disability. This notice relates to the approved information collection under OMB control number 1820-0028.

#### **DATES:**

*Applications Available:* August 8, 2019.

*Deadline for Transmittal of Applications:* September 9, 2019.

*Pre-Application Webinar Information:* No later than August 13, 2019, OSERS will post pre-recorded informational webinars designed to provide technical assistance (TA) to interested applicants. The webinars may be found at [www2.ed.gov/fund/grant/apply/osep/new-osep-grants.html](http://www2.ed.gov/fund/grant/apply/osep/new-osep-grants.html).

*Pre-Application Q & A Blog:* No later than August 13, 2019, OSERS will open a blog where interested applicants may post questions about the application requirements for this competition and where OSERS will post answers to the questions received. OSERS will not respond to questions unrelated to the application requirements for this competition. The blog may be found at [www2.ed.gov/fund/grant/apply/osep/new-osep-grants.html](http://www2.ed.gov/fund/grant/apply/osep/new-osep-grants.html) and will remain open until August 27, 2019. After the blog closes, applicants should direct questions to the person listed under **FOR FURTHER INFORMATION CONTACT.**

**ADDRESSES:** For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768), and available at [www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf](http://www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf).

**FOR FURTHER INFORMATION CONTACT:** Perry Williams, U.S. Department of Education, 400 Maryland Avenue SW, Room 5131, Potomac Center Plaza, Washington, DC 20202-5076. Telephone: (202) 245-7575. Email: [Perry.Williams@ed.gov](mailto:Perry.Williams@ed.gov).

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1-800-877-8339.

#### **SUPPLEMENTARY INFORMATION:**

##### **Full Text of Announcement**

##### **I. Funding Opportunity Description**

*Purpose of Program:* The purpose of the Technical Assistance and Dissemination to Improve Services and Results for Children with Disabilities program is to promote academic achievement and to improve results for children with disabilities by providing TA, supporting model demonstration projects, disseminating useful information, and implementing activities that are supported by scientifically based research.

*Priority:* This competition includes one absolute priority.

In accordance with 34 CFR 75.105(b)(2)(v), this priority is from allowable activities specified in the statute (see sections 663 and 681(d) of the Individuals with Disabilities Education Act (IDEA); 20 U.S.C. 1463 and 1481(d)).

*Absolute Priority:* For FY 2019 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3), we consider only applications that meet this priority.

This priority is:

*National Technical Assistance and Dissemination Center for Systemic Improvement (Center).*

*Background:*

The Department has worked extensively with States to ensure meaningful access to special education and related services for children with disabilities (CWD) and has noted significant improvements in compliance with the IDEA requirements over the last decade. However, educational outcomes in reading and math, as well

as graduation rates, for CWD continue to lag those of children without disabilities. Results of the 2017 National Assessment of Educational Progress (NAEP) in reading and mathematics show the performance of students with disabilities, excluding those with a 504 plan, to be significantly lower than the performance of students without disabilities. In fact, since 2009, performance of students with disabilities, excluding those with a 504 plan, has decreased in 4th and 8th grade mathematics and 4th grade reading. Even where performance improved on the 8th grade reading assessment, the gap between students with disabilities, excluding those with a 504 plan, and those without disabilities increased from 2009 to 2017. Recent data from 2016 to 2017 show that high school graduation rates for all children was 85 percent while the graduation rate for CWD was 66 percent (National Center for Education Statistics, 2019).

States have an important role to play in increasing equal opportunity and improving educational outcomes for CWD, and in reducing the persistent gaps in performance between children with and without disabilities (Tomasello & Brand, 2018). The Elementary and Secondary Education Act of 1965 (ESEA), as amended by the Every Student Succeeds Act of 2015 (ESSA), and the IDEA, reauthorized in 2004, provide States the opportunity to align State plans, priorities, support to local educational agencies (LEAs), and multiple existing efforts across general and special education programs to help close achievement gaps and improve educational outcomes for all children, including CWD.

ESSA contains several key provisions that align with IDEA. States can align ESSA and IDEA implementation efforts to ensure that they—

- (1) Effectively support children with the most significant cognitive disabilities to increase access to the general education curriculum;
- (2) Maintain inclusion of all CWD in accountability systems;
- (3) Promote the use of evidence-based<sup>1</sup> practices (EBPs) to provide intervention and support to LEAs in need of improvement; and
- (4) Include meaningful and authentic stakeholder engagement in all aspects of the planning and implementation

<sup>1</sup> For the purposes of this priority, “evidence-based” means, at a minimum, evidence that demonstrates a rationale (as defined in 34 CFR 77.1), where a key project component included in the project’s logic model is informed by research or evaluation findings that suggest the project component is likely to improve relevant outcomes.

process (National Council on Disability, 2018).

Additionally, ESSA and IDEA underscore the importance of a shared, integrated, and systemic approach to supporting LEAs and schools, and they provide States with a framework to design their accountability systems to improve outcomes for all children. In 2012, OSEP shifted its accountability framework from a predominant focus on compliance with Federal regulations toward an approach of monitoring and supporting States’ implementation of both the results and compliance provisions of IDEA, termed Results-Driven Accountability (RDA).<sup>2</sup>

RDA has provided States with an increased opportunity to rethink, reshape, and refocus the components of their general supervision system<sup>3</sup> by incorporating and using child-level results data to inform decisions related to monitoring, local determinations, and other accountability efforts. One of the major components of RDA within the State Performance Plan (SPP)/Annual Performance Report (APR) that has garnered support and interest from States is the State Systemic Improvement Plan (SSIP). Each State was required to submit an SSIP as part of its SPP/APR beginning in Federal Fiscal Year 2013. Each State identified a State Identified Measurable Result (SIMR) under Part B of IDEA. The SSIP contains three phases: (1) Analysis of data and other information to provide a foundation for the SSIP; (2) development of the plan to improve results; and (3) implementation and evaluation of the plan. States are using the SSIP, a comprehensive, multiyear plan that is focused on improving a SIMR, to leverage resources and enhance their infrastructure and better implement IDEA with an emphasis on improving outcomes for CWD in State-selected areas such as reading, mathematics, or graduation. Each phase of the SSIP requires stakeholder engagement for decision-making and prioritizing outcomes.

All States have developed their SSIPs and are now heavily engaged in capacity-building efforts to implement

<sup>2</sup> Results-Driven Accountability includes three components: (1) The State Performance Plan (SPP)/Annual Performance Report (APR); (2) annual State determinations; and (3) differentiated monitoring and support.

<sup>3</sup> “General supervision system” refers to a State’s system for ensuring compliance and improving results and includes the SPP; policies, procedures, and effective implementation; integrated monitoring activities; fiscal management; data on processes and results; improvement, correction, incentives, and sanctions; effective dispute resolution; and targeted TA and professional development.

and evaluate improvement efforts and report progress under four main elements of the SSIP Phase III report, which are: (1) Data collection, analysis, and use to inform decision-making; (2) development of infrastructure improvement strategies necessary to support, sustain, and scale-up system improvement efforts; (3) selection and use of EBPs that are implemented with fidelity; and (4) engagement of diverse stakeholders to implement key improvement strategies and inform decision-making within the State system. These elements also align with key capacity-building components of ESSA implementation.

OSEP’s review of States’ submitted SSIPs in 2018 and a National Center for Learning Disabilities (NCLD) report, *Assessing ESSA: Missed Opportunities for Children with Disabilities*, indicate there are still multiple challenges that affect States’ abilities to successfully align and implement their ESSA State plans and establish strong comprehensive accountability systems to support schools that struggle to improve results for CWD (NCLD, 2018).

Specifically, those challenges include tracking implementation of EBPs and determining whether they have been implemented with fidelity, high turnover rates of staff at various levels across the State educational agency (SEA) and in LEAs, effective systems alignment with general education efforts, supporting LEAs in selecting and implementing EBPs to meet the needs of children with increasingly high intensity and complex needs (e.g., exposure to opioids), establishing multi-tiered systems of support (MTSS) to provide differentiated TA to LEAs, evaluation of their SSIPs’ infrastructure improvement strategies, leveraging fiscal systems to achieve desired outcomes, designing and implementing professional development that meets the individual needs of teachers, and revising general supervision systems to include results as an integral component.

The Center will engage in collaborative TA activities with other Department-funded TA centers, and it will broaden, deepen, and facilitate systems alignment within State programs and engagement with existing State TA and PD systems. In addition, the Center will assist SEAs with ensuring stakeholder engagement and support to meet shared goals and identify and remove barriers for improving results for CWD. The Center must be operated in a manner consistent with nondiscrimination requirements contained in the U.S. Constitution and Federal civil rights laws.

Further, we acknowledge that States are in the best position to determine implementation of their programs, and as such, the Center will be required to customize its TA to meet each State's specific identified needs and leverage their resources to meet those needs.

**Priority:**

The purpose of this priority is to fund a cooperative agreement to establish and operate a National Technical Assistance Center for Systemic Improvement (Center). The Center must achieve, at a minimum, the following expected outcomes:

(a) Increased capacity of SEAs to align with broader general education initiatives to ensure ESSA and IDEA implementation best supports the needs of CWD;

(b) Increased capacity of SEAs to effectively implement their general supervision systems that serve to improve results for CWD, while maintaining compliance with the IDEA;

(c) Increased capacity of SEAs to effectively implement, evaluate, and revise (as necessary) their SSIPs and ensure progress toward meeting their SIMR;

(d) Increased effectiveness of SEAs in meaningfully and authentically engaging diverse State (including State-level partnerships)<sup>4</sup> and local stakeholders in ways that will support the effective implementation of ESSA and IDEA;

(e) Increased capacity of SEAs to support LEAs in selecting and implementing EBPs within frameworks (e.g., MTSS such as positive behavioral interventions and supports (PBIS), response to intervention (RTI), and others);

(f) Increased capacity of SEAs to fully engage families, including partnerships with OSEP-funded parent centers and the Office of Elementary and Secondary Education (OESE) Statewide Family Engagement Centers in the implementation of systemic improvement efforts;

(g) Increased capacity of SEAs to deliver effective TA to LEAs using an aligned TA model grounded in implementation and improvement sciences through collaboration with OSEP-funded TA centers; and

(h) Improved access to objective information for families and youth with disabilities on the range of quality educational options<sup>5</sup> and supports.

<sup>4</sup> For the purposes of this priority, "State-level partnerships" refers to State affiliates of nationally recognized professional and family networks that form an infrastructure for policy development, dissemination of information, interaction, and learning.

<sup>5</sup> For the purpose of this priority, "educational options" means the opportunity for a child or

**Note:** The OSEP-funded TA related to young children (ages birth through five) with disabilities, and the IDEA Part C and Part B section 619 programs, will primarily be provided by the centers funded under CFDA numbers 84.325B, 84.326B, 84.326P, and 84.373Z. This Center will focus on providing TA to SEAs to implement Part B of the IDEA, which serves children ages 3 through 21, and will develop products or provide TA to SEAs on issues that impact the entire Part B system, such as general supervision or SSIP implementation. Consequently, this Center generally will respond to a State request for products or TA on issues solely associated with CWD ages birth through 5, such as preschool least restrictive environments, early childhood outcomes, and early childhood transition, by referring the State to one or more other OSEP-funded centers that focus on such issues.

In addition to these programmatic requirements, to be considered for funding under this priority, applicants must meet the application and administrative requirements in this priority, which are:

(a) Demonstrate, in the narrative section of the application under "Significance," how the proposed project will—

(1) Address the current and emerging needs of SEAs to meet ESSA and IDEA requirements by aligning structures and improving processes within and across levels of the system to support the implementation and evaluation of their State plans; appropriately apply coherent improvement strategies, based

student (or a family member on their behalf) to create a high-quality personalized path for learning that is consistent with applicable Federal, State, and local laws; is in an educational setting that best meets the child's or student's needs; and, where possible, incorporates evidence-based activities, strategies, or interventions. Opportunities made available to a child or student through a grant program are those that supplement what is provided by a child's or student's geographically assigned school or the institution in which he or she is currently enrolled and may include one or more of the following options: (1) Public educational programs or courses, including those offered by traditional public schools, public charter schools, public magnet schools, public online education providers, or other public education providers; (2) Private or home-based educational programs or courses, including those offered by private schools, private online providers, private tutoring providers, community or faith-based organizations, or other private education providers; (3) Part-time coursework or career preparation, offered by a public or private provider in person or through the internet or another form of distance learning, that serves as a supplement to full-time enrollment at an educational institution, as a stand-alone program leading to a credential, or as a supplement to education received in a homeschool setting; and (4) Other educational services, including credit-recovery, accelerated learning, or tutoring.

on thorough data analyses, that are aligned to current efforts to improve outcomes for all CWD; provide effective TA on how to implement EBPs with fidelity; meaningfully and authentically engage diverse stakeholders (including State-level partnerships); assist States in evaluating their implementation efforts and their impact; and ensure the effective implementation of their results-based general supervision systems to support effective implementation of the IDEA.

To meet this requirement the applicant must—

(i) Demonstrate knowledge of current educational issues and policy initiatives relating to ongoing challenges with implementing ESSA and IDEA alignment efforts by SEAs to target and support LEA improvement efforts;

(ii) Present information and data about the current capacity of SEAs to support systemic change, and how the Center will address this challenge to enhance SEA capacity to support LEAs to implement, scale-up, and sustain EBPs with fidelity;

(iii) Demonstrate knowledge of current educational issues and policy initiatives and the range of quality educational options that may be available in States to families of CWD and how the Center will provide TA and information dissemination to SEAs that increase opportunities and outcomes for CWD and their families;

(iv) Describe how the Center will engage diverse stakeholders (including State-level partnerships), local stakeholders, and Department-funded parent and statewide family engagement centers in the SEAs' decision-making processes to ensure effective implementation and evaluation of the SSIP and other State initiatives that establish high expectations and improved outcomes for CWD; and

(v) Identify and engage with existing State TA and dissemination systems to assist the Center with supporting statewide systemic improvement efforts.

(2) Improve SEA infrastructure (e.g., governance, fiscal systems, quality standards, PD, data sharing and analysis, TA, and accountability/monitoring) so SEAs can effectively implement the IDEA and their SSIPs. Applicants must indicate the likely magnitude or importance of the improvements.

(3) Collaborate and engage with other Department and OSEP-funded TA Centers (e.g., PBIS Center; Collaboration for Effective Educator Development, Accountability, and Reform (CEEDAR) Center; and the State Implementation and Scaling-up of Evidence-based Practices (SISEP) Center) to incorporate

a problem-solving logic and multi-tiered approach in the TA provided to SEAs to address equity issues and effectively and efficiently support the implementation of SSIPs and improve States' general supervision systems.

(b) Demonstrate, in the narrative section of the application under "Quality of the project services," how the proposed project will—

(1) Ensure equal access and treatment for members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. To meet this requirement, the applicant must describe how it will—

(i) Identify the needs of the intended recipients for TA and information; and

(ii) Ensure that services and products meet the needs of the intended recipients of the grant;

(2) Achieve its goals, objectives, and intended outcomes. To meet this requirement, the applicant must provide—

(i) Measurable intended project outcomes; and

(ii) In Appendix A, the logic model<sup>6</sup> by which the proposed project will achieve its intended outcomes that depicts, at a minimum, the goals, activities, outputs, and intended outcomes of the proposed project;

(3) Use a conceptual framework (and provide a copy in Appendix A) to develop project plans and activities, describing any underlying concepts, assumptions, expectations, beliefs, or theories, as well as the presumed relationships or linkages among these variables, and any empirical support for this framework;

**Note:** The following websites provide more information on logic models and conceptual frameworks:

[www.osepideasthatwork.org/logicModel](http://www.osepideasthatwork.org/logicModel) and [www.osepideasthatwork.org/resources-grantees/program-areas/ta-ta/tad-project-logic-model-and-conceptual-framework](http://www.osepideasthatwork.org/resources-grantees/program-areas/ta-ta/tad-project-logic-model-and-conceptual-framework).

(4) Be based on current research and make use of EBPs. To meet this requirement, the applicant must describe—

(i) The current research on the assessment of infrastructure development that builds capacity in SEAs and LEAs to implement, scale-up, and sustain the use of EBPs;

(ii) The current research about adult learning principles, as well as

implementation and improvement science, that will inform the proposed TA; and

(iii) How the proposed project will incorporate current research and EBPs in the development and delivery of its products and services;

(5) Develop products and provide services that are of high quality and sufficient intensity and duration to achieve the intended outcomes of the proposed project. To address this requirement, the applicant must describe—

(i) How it proposes to identify or develop the knowledge base on how to implement components of a comprehensive SSIP and effective general supervision and PD systems;

(ii) Its proposed approach to universal, general TA,<sup>7</sup> which must identify the intended recipients, including the type and number of recipients, that will receive the products and services, a description of the products and services that the Center proposes to make available, and the expected impact of those products and services under this approach;

(iii) Its proposed approach to targeted, specialized TA,<sup>8</sup> which must identify—

(A) The intended recipients, including the type and number of recipients, that will receive the products and services, a description of the products and services that the Center proposes to make available, and the expected impact of those products and services under this approach; and

(B) Its proposed approach to measure the readiness of potential TA recipients to work with the project, assessing, at a minimum, their current infrastructure, available resources, and ability to build capacity at the local level; and

<sup>7</sup> "Universal, general TA" means TA and information provided to independent users through their own initiative, resulting in minimal interaction with TA center staff and including one-time, invited or offered conference presentations by TA center staff. This category of TA also includes information or products, such as newsletters, guidebooks, or research syntheses, downloaded from the TA center's website by independent users. Brief communications by TA center staff with recipients, either by telephone or email, are also considered universal, general TA.

<sup>8</sup> "Targeted, specialized TA" means TA services based on needs common to multiple recipients and not extensively individualized. A relationship is established between the TA recipient and one or more TA center staff. This category of TA includes one-time, labor-intensive events, such as facilitating strategic planning or hosting regional or national conferences. It can also include episodic, less labor-intensive events that extend over a period of time, such as facilitating a series of conference calls on single or multiple topics that are designed around the needs of the recipients. Facilitating communities of practice can also be considered targeted, specialized TA.

(iv) Its proposed approach to intensive, sustained TA,<sup>9</sup> which must identify—

(A) The intended recipients, including the type and number of recipients, that will receive the products and services, a description of the products and services that the Center proposes to make available, and the expected impact of those products and services under this approach;

(B) Its proposed approach to measure the readiness of SEAs to work with the project, including their commitment to the initiative, alignment of the initiative to their needs, current infrastructure, available resources, and ability of the SEAs to build capacity at the local level;

(C) Its proposed plan to prioritize TA recipients whose most recent annual determination by the Secretary was that the State needs intervention under section 616(d)(2)(A)(iii) of IDEA or needs substantial intervention under section 616(d)(2)(A)(iv) of IDEA in implementing the requirements of Part B of IDEA.

(C) Its proposed plan for assisting SEAs to build or enhance PD systems based on adult learning principles and that include sustained coaching; and

(D) Its proposed plan for working with appropriate levels of the education system (e.g., SEAs, educational service agencies (ESAs), LEAs, other TA providers, parents and families) to ensure that there is communication between each level and that there are systems in place to support implementation of EBPs;

(6) Develop products and implement services that maximize efficiency. To address this requirement, the applicant must describe—

(i) How the proposed project will use technology to achieve the intended project outcomes;

(ii) With whom the proposed project will collaborate and the intended outcomes of this collaboration, which must include—

(A) How the proposed project will collaborate with other Department and OSEP-funded TA centers working with SEAs to effectively support the implementation of SSIPs and improve States' general supervision; and

(B) How the proposed project will collaborate with OSEP-funded TA centers working in early childhood

<sup>9</sup> "Intensive, sustained TA" means TA services often provided on-site and requiring a stable, ongoing relationship between the TA center staff and the TA recipient. "TA services" are defined as negotiated series of activities designed to reach a valued outcome. This category of TA should result in changes to policy, program, practice, or operations that support increased recipient capacity or improved outcomes at one or more systems levels.

<sup>6</sup> Logic model (as defined in 34 CFR 77.1) (also referred to as a theory of action) means a framework that identifies key project components of the proposed project (i.e., the active "ingredients" that are hypothesized to be critical to achieving the relevant outcomes) and describes the theoretical and operational relationships among the key project components and relevant outcomes.

systems to align TA on infrastructure development and system improvement efforts between early childhood agencies and the SEA; and

(iii) How the proposed project will use non-project resources to achieve the intended project outcomes.

In the narrative section of the application under “Quality of the evaluation plan,” include an evaluation plan for the project as described in the following paragraphs.

The evaluation plan must describe: Measures of progress in implementation, including the criteria for determining the extent to which the project’s products and services have met the goals for reaching its target population; measures of intended outcomes or results of the project’s activities in order to evaluate those activities; and how well the goals or objectives of the proposed project, as described in its logic model, have been met.

The applicant must provide an assurance that, in designing the evaluation plan, it will—

(1) Designate, with the approval of the OSEP project officer, a project liaison staff person with sufficient dedicated time, experience in evaluation, and knowledge of the project to work in collaboration with the Center to Improve Program and Project Performance (CIP3),<sup>10</sup> the project director, and the OSEP project officer on the following tasks:

(i) Revise, as needed, the logic model submitted in the application to provide for a more comprehensive measurement of implementation and outcomes and to reflect any changes or clarifications to the model discussed at the kick-off meeting;

(ii) Refine the evaluation design and instrumentation proposed in the application consistent with the logic model (e.g., prepare evaluation questions about significant program processes and outcomes; develop quantitative or qualitative data collections that permit both the collection of progress data, including fidelity of implementation, as appropriate, and the assessment of

project outcomes; and identify analytic strategies); and

(iii) Revise, as needed, the evaluation plan submitted in the application such that it clearly—

(A) Specifies the measures and associated instruments or sources for data appropriate to the evaluation questions, suggests analytic strategies for those data, provides a timeline for conducting the evaluation, and includes staff assignments for completing the plan;

(B) Delineates the data expected to be available by the end of the second project year for use during the project’s evaluation (3+2 review) for continued funding described under the heading *Fourth and Fifth Years of the Project*; and

(C) Can be used to assist the project director and the OSEP project officer, with the assistance of CIP3, as needed, to specify the performance measures to be addressed in the project’s Annual Performance Report;

(2) Cooperate with CIP3 staff in order to accomplish the tasks described in paragraph (1) of this section; and

(3) Dedicate sufficient funds in each budget year to cover the costs of carrying out the tasks described in paragraphs (1) and (2) of this section and implementing the evaluation plan.

(d) Demonstrate, in the narrative section of the application under “Adequacy of resources and quality of project personnel,” how—

(1) The proposed project will encourage applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability, as appropriate;

(2) The proposed key project personnel, consultants, and subcontractors have the qualifications and experience to carry out the proposed activities and achieve the project’s intended outcomes;

(3) The applicant and any key partners have adequate resources to carry out the proposed activities; and

(4) The proposed costs are reasonable in relation to the anticipated results and benefits.

(e) Demonstrate, in the narrative section of the application under “Quality of the management plan,” how—

(1) The proposed management plan will ensure that the project’s intended outcomes will be achieved on time and within budget. To address this requirement, the applicant must describe—

(i) Clearly defined responsibilities for key project personnel, consultants, and subcontractors, as applicable; and

(ii) Timelines and milestones for accomplishing the project tasks;

(2) Key project personnel and any consultants and subcontractors will be allocated and how these allocations are appropriate and adequate to achieve the project’s intended outcomes;

(3) The proposed management plan will ensure that the products and services provided are of high quality, relevant, and useful to recipients; and

(4) The proposed project will benefit from a diversity of perspectives, including those of families, educators, TA providers, researchers, and policy makers, among others, in its development and operation.

(f) Address the following application requirements. The applicant must—

(1) Include, in Appendix A, personnel-loading charts and timelines, as applicable, to illustrate the management plan described in the narrative;

(2) Include, in the budget, attendance at the following:

(i) A one and one-half day kick-off meeting in Washington, DC, after receipt of the award, and an annual planning meeting, with the OSEP project officer and other relevant staff during each subsequent year of the project period.

**Note:** Within 30 days of receipt of the award, a post-award teleconference must be held between the OSEP project officer and the grantee’s project director or other authorized representative;

(ii) A two and one-half day project directors’ conference in Washington, DC, during each year of the project period;

(iii) Two annual trips to attend Department briefings, Department-sponsored conferences, and other meetings, as requested by OSEP; and

(iv) A one-day intensive 3+2 review meeting during the last half of the second year of the project period;

(3) Include, in the budget, a line item for an annual set-aside of five percent of the grant amount to support emerging needs that are consistent with the proposed project’s intended outcomes, as those needs are identified in consultation with, and approved by, the OSEP project officer. With approval from the OSEP project officer, the project must reallocate any remaining funds from this annual set-aside no later than the end of the third quarter of each budget period;

(4) Maintain a high-quality website, with an easy-to-navigate design, that meets government or industry-recognized standards for accessibility;

<sup>10</sup> The major tasks of CIP3 are to guide, coordinate, and oversee the design of formative evaluations for every large discretionary investment (i.e., those awarded \$500,000 or more per year and required to participate in the 3+2 process) in OSEP’s Technical Assistance and Dissemination; Personnel Development; Parent Training and Information Centers; and Educational Technology, Media, and Materials programs. The efforts of CIP3 are expected to enhance individual project evaluation plans by providing expert and unbiased TA in designing the evaluations with due consideration of the project’s budget. CIP3 does not function as a third-party evaluator.

(5) Ensure that annual progress toward meeting project goals is posted on the project website; and

(6) Include, in Appendix A, an assurance to assist OSEP with the transfer of pertinent resources and products and to maintain the continuity of services to TA recipients during the transition to this new award period and at the end of this award period, as appropriate.

*Fourth and Fifth Years of the Project:*

In deciding whether to continue funding the project for the fourth and fifth years, the Secretary will consider the requirements of 34 CFR 75.253(a), as well as—

(a) The recommendation of a 3+2 review team consisting of experts selected by the Secretary. This review will be conducted during a one-day intensive meeting that will be held during the last half of the second year of the project period;

(b) The timeliness with which, and how well, the requirements of the negotiated cooperative agreement have been or are being met by the project; and

(c) The quality, relevance, and usefulness of the project's products and services and the extent to which the project's products and services are aligned with the project's objectives and likely to result in the project achieving its intended outcomes.

Under 34 CFR 75.253, the Secretary may reduce continuation awards or discontinue awards in any year of the project period for excessive carryover balances or a failure to make substantial progress. The Department intends to closely monitor unobligated balances and substantial progress under this program and may reduce or discontinue funding accordingly.

*References:*

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Department of Education, Institute of Education Sciences, National Center for Education Statistics. (2017). *National Assessment of Educational Progress (NAEP) reading assessments*. Accessed through the NAEP Data Explorer at <http://nces.ed.gov/nationsreportcard/naepdata/>.

*Waiver of Proposed Rulemaking:*

Under the Administrative Procedure Act (APA) (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed priorities. Section 681(d) of IDEA, however, makes the public comment requirements of the APA inapplicable to the priority in this notice.

**Program Authority:** 20 U.S.C. 1463 and 1481.

**Applicable Regulations:** (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474.

**Note:** The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian Tribes.

**Note:** The regulations in 34 CFR part 86 apply to institutions of higher education (IHEs) only.

**II. Award Information**

**Type of Award:** Cooperative agreement.

**Estimated Available Funds:** \$6,250,000.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2020 from the list of unfunded applications from this competition.

**Maximum Award:** We will not make an award exceeding \$31,250,000 for a project period of 60 months.

**Note:** Applicants must describe, in their applications, the amount of

funding being requested for each 12-month budget period.

*Estimated Number of Awards:* 1.

**Note:** The Department is not bound by any estimates in this notice.

*Project Period:* Up to 60 months.

**III. Eligibility Information**

1. **Eligible Applicants:** SEAs; LEAs, including public charter schools that operate as LEAs under State law; IHEs; other public agencies; private nonprofit organizations; freely associated States and outlying areas; Indian Tribes or Tribal organizations; and for-profit organizations.

2. **Cost Sharing or Matching:** This program does not require cost sharing or matching.

3. **Subgrantees:** A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application. Under 34 CFR 75.708(e), a grantee may contract for supplies, equipment, and other services in accordance with 2 CFR part 200.

4. **Other:** (a) Recipients of funding under this competition must make positive efforts to employ and advance in employment qualified individuals with disabilities (see section 606 of IDEA).

(b) Applicants for, and recipients of, funding must, with respect to the aspects of their proposed project relating to the absolute priority, involve individuals with disabilities, or parents of individuals with disabilities ages birth through 26, in planning, implementing, and evaluating the project (see section 682(a)(1)(A) of IDEA).

**IV. Application and Submission Information**

1. **Application Submission Instructions:** Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768), and available at [www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf](http://www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf), which contain requirements and information on how to submit an application.

2. **Intergovernmental Review:** This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. However, under 34 CFR 79.8(a), we waive intergovernmental review in order to make an award by the end of FY 2019.

3. **Funding Restrictions:** We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

4. *Recommended Page Limit:* The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 70 pages and (2) use the following standards:

- A "page" is 8.5" x 11", on one side only, with 1" margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, reference citations, and captions, as well as all text in charts, tables, figures, graphs, and screen shots.
- Use a font that is 12 point or larger.
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the abstract (follow the guidance provided in the application package for completing the abstract), the table of contents, the list of priority requirements, the resumes, the reference list, the letters of support, or the appendices. However, the recommended page limit does apply to all of the application narrative, including all text in charts, tables, figures, graphs, and screen shots.

## V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210 and are as follows:

- (a) *Significance (10 points).*
- (1) The Secretary considers the significance of the proposed project.
- (2) In determining the significance of the proposed project, the Secretary considers the following factors:
- (i) The extent to which specific gaps or weaknesses in services, infrastructure, or opportunities have been identified and will be addressed by the proposed project, including the nature and magnitude of those gaps or weaknesses.
- (ii) The importance or magnitude of the results or outcomes likely to be attained by the proposed project.
- (iii) The extent to which the proposed project is supported by promising evidence (as defined in 34 CFR 77.1(c)).
- (b) *Quality of project services (35 points).*
- (1) The Secretary considers the quality of the services to be provided by the proposed project.
- (2) In determining the quality of the services to be provided by the proposed

project, the Secretary considers the quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(3) In addition, the Secretary considers the following factors:

(i) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable.

(ii) The extent to which there is a conceptual framework underlying the proposed research or demonstration activities and the quality of that framework.

(iii) The extent to which the services to be provided by the proposed project reflect up-to-date knowledge from research and effective practice.

(iv) The extent to which the training or professional development services to be provided by the proposed project are of sufficient quality, intensity, and duration to lead to improvements in practice among the recipients of those services.

(v) The extent to which the TA services to be provided by the proposed project involve the use of efficient strategies, including the use of technology, as appropriate, and the leveraging of non-project resources.

(vi) The adequacy of mechanisms for ensuring high-quality products and services from the proposed project.

(c) *Quality of the project evaluation (15 points).*

(1) The Secretary considers the quality of the evaluation to be conducted of the proposed project.

(2) In determining the quality of the evaluation, the Secretary considers the following factors:

(i) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project.

(ii) The extent to which the methods of evaluation provide for examining the effectiveness of project implementation strategies.

(iii) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes.

(iv) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible.

(d) *Adequacy of resources and quality of project personnel (15 points).*

(1) The Secretary considers the adequacy of resources for the proposed project and the quality of the personnel who will carry out the proposed project.

(2) In determining the quality of project personnel, the Secretary considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(3) In addition, the Secretary considers the following factors:

(i) The qualifications, including relevant training and experience, of the project director or principal investigator.

(ii) The qualifications, including relevant training and experience, of key project personnel.

(iii) The qualifications, including relevant training and experience, of project consultants or subcontractors.

(iv) The qualifications, including relevant training, experience, and independence, of the evaluator.

(v) The adequacy of support, including facilities, equipment, supplies, and other resources, from the applicant organization or the lead applicant organization.

(vi) The relevance and demonstrated commitment of each partner in the proposed project to the implementation and success of the project.

(vii) The extent to which the budget is adequate to support the proposed project.

(viii) The extent to which the costs are reasonable in relation to the objectives, design, and potential significance of the proposed project.

(e) *Quality of the management plan (25 points).*

(1) The Secretary considers the quality of the management plan for the proposed project.

(2) In determining the quality of the management plan for the proposed project, the Secretary considers the following factors:

(i) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks.

(ii) The extent to which the time commitments of the project director and principal investigator and other key project personnel are appropriate and adequate to meet the objectives of the proposed project.

(iii) The adequacy of mechanisms for ensuring high-quality products and services from the proposed project.

(iv) How the applicant will ensure that a diversity of perspectives are brought to bear in the operation of the proposed project, including those of parents, teachers, the business community, a variety of disciplinary and professional fields, recipients or beneficiaries of services, or others, as appropriate.

**2. Review and Selection Process:** We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

**3. Additional Review and Selection Process Factors:** In the past, the Department has had difficulty finding peer reviewers for certain competitions because so many individuals who are eligible to serve as peer reviewers have conflicts of interest. The standing panel requirements under section 682(b) of IDEA also have placed additional constraints on the availability of reviewers. Therefore, the Department has determined that for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected for funding within specific groups. This procedure will make it easier for the Department to find peer reviewers by ensuring that greater numbers of individuals who are eligible to serve as reviewers for any particular group of applicants will not have conflicts of interest. It also will increase the quality, independence, and fairness of the review process, while permitting panel members to review applications under discretionary grant competitions for which they also have submitted applications.

**4. Risk Assessment and Specific Conditions:** Consistent with 2 CFR 200.205, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose specific conditions and, in appropriate

circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

**5. Integrity and Performance System:** If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently \$250,000), under 2 CFR 200.205(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds \$10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed \$10,000,000.

## VI. Award Administration Information

**1. Award Notices:** If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

**2. Administrative and National Policy Requirements:** We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved

application as part of your binding commitments under the grant.

**3. Open Licensing Requirements:** Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

**4. Reporting:** (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to [www.ed.gov/fund/grant/apply/appforms/appforms.html](http://www.ed.gov/fund/grant/apply/appforms/appforms.html).

**5. Performance Measures:** Under the Government Performance and Results Act of 1993, the Department has established a set of performance measures, including long-term measures, that are designed to yield information on various aspects of the effectiveness and quality of the Technical Assistance and Dissemination to Improve Services and Results for Children with Disabilities program. These measures are:

- **Program Performance Measure #1:** The percentage of Technical Assistance and Dissemination products and services deemed to be of high quality by an independent review panel of experts

qualified to review the substantive content of the products and services.

- **Program Performance Measure #2:** The percentage of Special Education Technical Assistance and Dissemination products and services deemed by an independent review panel of qualified experts to be of high relevance to educational and early intervention policy or practice.

- **Program Performance Measure #3:** The percentage of all Special Education Technical Assistance and Dissemination products and services deemed by an independent review panel of qualified experts to be useful in improving educational or early intervention policy or practice.

- **Program Performance Measure #4:** The cost efficiency of the Technical Assistance and Dissemination Program includes the percentage of milestones achieved in the current annual performance report period and the percentage of funds spent during the current fiscal year.

- **Long-term Program Performance Measure:** The percentage of States receiving Special Education Technical Assistance and Dissemination services regarding scientifically or evidence-based practices for infants, toddlers, children, and youth with disabilities that successfully promote the implementation of those practices in school districts and service agencies.

The measures apply to projects funded under this competition, and grantees are required to submit data on these measures as directed by OSEP.

Grantees will be required to report information on their project's performance in annual and final performance reports to the Department (34 CFR 75.590).

The Department will also closely monitor the extent to which the products and services provided by the Center meet needs identified by stakeholders and may require the Center to report on such alignment in their annual and final performance reports.

6. **Continuation Awards:** In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved

application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

## VII. Other Information

**Accessible Format:** Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (e.g., braille, large print, audiotope, or compact disc) by contacting the Management Support Services Team, U.S. Department of Education, 400 Maryland Avenue SW, Room 5081A, Potomac Center Plaza, Washington, DC 20202-5076. Telephone: (202) 245-7363. If you use a TDD or a TTY, call the FRS, toll free, at 1-800-877-8339.

**Electronic Access to This Document:** The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at [www.govinfo.gov](http://www.govinfo.gov). At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at [www.federalregister.gov](http://www.federalregister.gov). Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: August 6, 2019.

**Laurie VanderPloeg,**

*Director, Office of Special Education Programs.*

[FR Doc. 2019-17059 Filed 8-6-19; 4:15 pm]

**BILLING CODE 4000-01-P**

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## DEPARTMENT OF ENERGY

### Fusion Energy Sciences Advisory Committee

**AGENCY:** Office of Science, Department of Energy.

**ACTION:** Notice of renewal.

**SUMMARY:** Pursuant to the Federal Advisory Committee Act, and in accordance with Title 41 of the Code of Federal Regulations, and following consultation with the Committee Management Secretariat, General Services Administration, notice is hereby given that the Fusion Energy

Sciences Advisory Committee has been renewed for a two-year period.

The Committee will provide advice to the Office of Science (DOE), on long-range plans, priorities, and strategies for advancing plasma science, fusion science and fusion technology—the knowledge base needed for an economically and environmentally attractive fusion energy source. The Secretary of Energy has determined that the renewal of the Fusion Energy Sciences Advisory Committee is essential to the conduct of the Department's business and in the public interest in connection with the performance of duties imposed upon the Department of Energy by law. The Committee will continue to operate in accordance with the provisions of the Federal Advisory Committee Act, the Department of Energy Organization Act (Pub. L. 95-91), the General Services Administration Final Rule on Federal Advisory Committee Management, and other directives and instruction issued in the implementation of those Acts.

**FOR FURTHER INFORMATION CONTACT:** Samuel J. Barish at (301) 903-2917 or email: [sam.barish@science.doe.gov](mailto:sam.barish@science.doe.gov).

Signed in Washington, DC on August 2, 2019.

**Rachael J. Beitler,**

*Acting Committee Management Officer.*

[FR Doc. 2019-16990 Filed 8-7-19; 8:45 am]

**BILLING CODE 6450-01-P**

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## DEPARTMENT OF ENERGY

### Notice of Request for Information (RFI) on Planning and Operation Models and Data Analytics for Solar Grid Integration

**AGENCY:** Solar Energy Technologies Office, Office of Energy Efficiency and Renewable Energy, Department of Energy.

**ACTION:** Request for information.

**SUMMARY:** The U.S. Department of Energy Solar Energy Technologies Office (SETO) is issuing this request for information (RFI) to solicit feedback from industry, academia, research laboratories, government agencies, and other stakeholders. This RFI will inform SETO's strategic planning on research related to the integration of distributed solar energy resources. Specifically, this RFI will inform strategies relating to the modeling, monitoring, predicting, and controlling of solar photovoltaic (PV) systems. As the penetration of solar PV on the grid grows, these strategies will become more important as grid operators consider how solar adoption

impacts grid planning and operations technologies.

**DATES:** Responses to the RFI must be received no later than 12 p.m. (ET) on August 30, 2019.

**ADDRESSES:** Interested parties are to submit comments electronically to [SETO.RFI.SI@ee.doe.gov](mailto:SETO.RFI.SI@ee.doe.gov). Responses to this RFI must be submitted electronically and 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 have 12 point font and 1 inch margins. Only electronic responses will be accepted.

Please identify answers by responding to a specific question or topic if applicable. Respondents may answer as many or as few questions as desired at their discretion. The complete RFI document DE-FOA-0002157 is located at <https://eere-exchange.energy.gov/>.

**FOR FURTHER INFORMATION CONTACT:** Questions may be addressed to Mr. Kemal Celik, (510) 316-6513 or [SETO.RFI.SI@ee.doe.gov](mailto:SETO.RFI.SI@ee.doe.gov). Further instructions can be found in the RFI document DE-FOA-0002157 posted on EERE Exchange.

**SUPPLEMENTARY INFORMATION:** SETO is seeking feedback from industry, academia, research laboratories, government agencies, and other stakeholders. The main focus is enabling high penetration of distributed behind-the-meter (BTM) and small-scale solar generation and decrease its curtailment through better data acquisition and its numerical analysis. Responders are welcome to answer all or subsets of the questions. The RFI DE-FOA-0002157 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 August 1, 2019.

**Charles Gay,**

*Director, Solar Energy Technologies Office.*

[FR Doc. 2019-16998 Filed 8-7-19; 8:45 am]

**BILLING CODE 6450-01-P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket Nos. CP19-491-000, PF17-10-000]

#### National Fuel Gas Supply Corporation; Notice of Application

Take notice that on July 18, 2019, National Fuel Gas Supply Corporation (National Fuel), 6363 Main Street, Williamsville, New York 14221, filed an application in Docket No. CP19-491-000 pursuant to Sections 7(b) and 7(c) of the Natural Gas Act and Part 157 of the Commission's Regulations, for a Certificate of Public Convenience and Necessity to construct and operate its FM100 Project. The FM100 Project would modernize a portion of National Fuel's existing pipeline system and create 330,000 dekatherms per day of additional transportation capacity, all as more fully described 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, contact FERC at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or call toll-free, (866) 208-3676 or TTY, (202) 502-8659.

Specifically, National Fuel seeks authorization for the: (1) Construction of about 29.5 miles of new 20-inch-diameter pipeline (Line YM58) in McKean and Potter Counties, Pennsylvania; (2) construction of about 1.4 miles of 24-inch-diameter pipeline loop (Line YM224 Loop) in Potter

County, Pennsylvania; (3) construction of about 0.4 miles of 12-inch-diameter pipeline (Line KL Extension) in McKean County, Pennsylvania; (4) construction of the new Marvindale Compressor Station (up to 15,165 horsepower) in McKean County, Pennsylvania; (5) construction of the new Tamarack Compressor Station (up to 22,220 hp) in Clinton County, Pennsylvania; (6) modification of the existing Leidy M&R Station in Leidy Township, Clinton County, Pennsylvania; (7) abandonment in place of about 44.9 miles of 12-inch-diameter pipeline (Line FM100) and appurtenances in Clearfield, Elk, Cameron and Potter Counties, Pennsylvania; (8) abandonment by removal of the existing Costello Compression Station in Potter County, Pennsylvania; (9) abandonment by removal of the existing Station WHP-MS-4317X in Potter County, Pennsylvania; (10) construction of the Marvindale Interconnect in McKean County, Pennsylvania; (11) construction of the Carpenter Hollow over-pressurization protection station in Potter County, Pennsylvania; and (12) construction of associated facilities, such as mainline valves and other appurtenant facilities. The estimated cost of the Project is \$279 million.

The additional transportation capacity created by the FM100 Project is fully subscribed to Transcontinental Gas Pipeline Company, LLC (Transco) under a proposed capacity lease which would provide gas supply from production areas of Pennsylvania to Transco's Leidy South Project. Transco will be filing a companion application for its Leidy South Project.

Any questions regarding this application should be directed to Jeffrey Same, Attorney for National Fuel, 6363 Main Street, Williamsville, New York 14221, by telephone at (716) 857-7507, by fax at (716) 857-7206, or by emailing [samej@natfuel.com](mailto:samej@natfuel.com); or Meghan Corcoran, Senior Attorney, National Fuel Gas Supply Corporation, 6363 Main Street, Williamsville, New York 14221-5887, by telephone at (716) 857-7064, by fax at (716) 857-7206, or by email at [corcoranm@natfuel.com](mailto:corcoranm@natfuel.com).

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 final

environmental impact statement (FEIS) or 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 FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 3 copies of filings made in the proceeding with the Commission and must provide a copy to the applicant and to every other party. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

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 commentors will be placed on the Commission's environmental mailing list, and will be notified of any meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties.

However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission and will not have the right to seek court review of the Commission's final order.

As of the February 27, 2018 date of the Commission's order in Docket No. CP16-4-001, the Commission will apply its revised practice concerning out-of-time motions to intervene in any new Natural Gas Act section 3 or section 7 proceeding.<sup>1</sup> Persons desiring to become a party to a certificate proceeding are to intervene in a timely manner. If seeking to intervene out-of-time, the movant is required to show good cause why the time limitation should be waived, and should provide justification by reference to factors set forth in Rule 214(d)(1) of the Commission's Rules and Regulations.<sup>2</sup>

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 3 copies of the protest or intervention to the Federal Energy regulatory Commission, 888 First Street NE, Washington, DC 20426.

*Comment Date:* 5:00 p.m. Eastern Time on August 21, 2019.

Dated: July 31, 2019.

**Kimberly D. Bose,**  
Secretary.

[FR Doc. 2019-16993 Filed 8-7-19; 8:45 am]

**BILLING CODE 6717-01-P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Project No. 14795-002]

#### Shell Energy North America (US), L.P.; Notice of Availability of Draft Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380, the Office of Energy Projects has reviewed the application for license for the Hydro Battery Pearl Hill Pumped Storage Project, which would be located on Rufus Woods Lake, near Bridgeport, Douglas County, Washington and has prepared a Draft Environmental Assessment (DEA) for the project. The project would be located on state lands

<sup>1</sup> *Tennessee Gas Pipeline Company, L.L.C.*, 162 FERC ¶ 61,167 at ¶ 50 (2018).

<sup>2</sup> 18 CFR 385.214(d)(1).

except for the lower reservoir and power generation and pumping equipment which would be located on Rufus Woods Lake, a reservoir operated by the U.S. Army Corps of Engineers (Corps). The Corps, a cooperating agency for the preparation of this environmental assessment, is reviewing Shell's project for permits it would issue under Sections 10 and 14 of the Rivers and Harbors act of 1899 and Section 404 of the Clean Water Act.

The DEA contains staff's analysis of the potential environmental impacts of the project and concludes that licensing the project, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

A copy of the DEA is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website at <http://www.ferc.gov> using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov), (866) 208-3676 (toll free), or (202) 502-8659 (TTY).

You may also register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Any comments should be filed within 30 days from the date of this notice.

Comments may be filed electronically via the internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's website (<http://www.ferc.gov/docs-filing/ferconline.asp>) under the eFiling link. The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P-14795-002.

The Commission anticipates issuing the final EA by November 2019.

For further information, contact Ryan Hansen at (202) 502-8074 or at [ryan.hansen@ferc.gov](mailto:ryan.hansen@ferc.gov).

Dated: August 2, 2019..

**Kimberly D. Bose,**  
Secretary.

[FR Doc. 2019-16953 Filed 8-7-19; 8:45 am]

BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. ER19-2495-000]

#### Wessington Springs Wind, 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 Wessington Springs Wind, 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 August 22, 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](mailto:FERCOnlineSupport@ferc.gov). or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: August 2, 2019.

**Kimberly D. Bose,**  
Secretary.

[FR Doc. 2019-16950 Filed 8-7-19; 8:45 am]

BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Project No. 1894-211]

#### South Carolina Electric & Gas Company; Notice of Application Accepted for Filing, Soliciting Motions To Intervene and Protests, Ready for Environmental Analysis, and Soliciting Comments, Recommendations, Terms and Conditions, and Preliminary Fishway Prescriptions

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

- a. *Type of Application:* New Major License.
- b. *Project No.:* P-1894-211.
- c. *Date filed:* June 28, 2018.
- d. *Applicant:* South Carolina Electric & Gas Company (SCE&G).
- e. *Name of Project:* Parr Hydroelectric Project.
- f. *Location:* The existing project is located on the Broad River, in Newberry and Fairfield Counties, South Carolina. The project occupies 162.61 acres of federal land administered by the Forest Service.
- g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791 (a)—825(r).
- h. *Applicant Contact:* Mr. William Argentieri, P.E., Manager of Civil Engineering, South Carolina Electric & Gas Company, 220 Operation Way, Mail Code A221, Cayce, SC 29033-3701; (803) 217-9162; or email at [bargentieri@scana.com](mailto:bargentieri@scana.com).
- i. *FERC Contact:* Monte TerHaar at (202) 502-6035; or at [monte.terhaar@ferc.gov](mailto:monte.terhaar@ferc.gov).
- j. *Deadline for filing motions to intervene and protests, comments,*

*recommendations, terms and conditions, and preliminary prescriptions:* 60 days from the issuance date of this notice; reply comments are due 105 days from the issuance date of this notice.

The Commission strongly encourages electronic filing. Please file motions to intervene, protests, comments, recommendations, terms and conditions, and preliminary fishway prescriptions using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov), (866) 208-3676 (toll free), or (202) 502-8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P-1894-211.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted for filing and is now ready for environmental analysis.

1. *Project Description:* The project consists of two developments; the 14.88-Megawatt (MW) Parr Shoals Development and the 511.2-MW Fairfield Pumped Storage Development.

The Parr Shoals Development consists of: (1) The 15-mile-long, 4,250-acre Parr Reservoir, at full pond elevation 265.3 feet North American Vertical Datum of 1988 (NAVD 88); (2) the 2,690-foot-long Parr Shoals Dam, which includes a non-overflow section, a spillway section with 10 spillway gates, and a powerhouse intake section; (3) a powerhouse integral with the dam, with six generating units; and (4) transmission facilities that consist of three 950-foot-long, 13.8-kilovolt lines that extend from the hydro station to the non-project Parr sub-station.

The Fairfield Pumped Storage Development consists of: (1) The Parr Reservoir which serves as the lower pool; (2) the 6,800-acre Monticello

Reservoir (upper reservoir), at normal maximum elevation 424.3 feet NAVD 88, which is formed by four earthen dams (A, B, C, and D); (3) a 265-foot-long gated intake channel, located between dams B and C; (4) four 800-foot-long surface penstocks, bifurcating into eight penstocks; (5) an underground generating station, which houses eight pumped-turbine units; and (6) transmission facilities that consist of three 7,000-foot-long lines, extending from the Fairfield switch station to the non-project V.C. Summer switchyard.

The Fairfield Pumped Storage Development is operated to generate during peak demand periods. Generation usually occurs during the day, with the upper reservoir replenished by pumping water at night (non-peak period). The Parr Shoals Development serves as the lower reservoir for the pumped storage project. The Parr Shoals Development operates to maintain a normal maximum elevation of 265.3 feet in Parr Reservoir and release minimum flows for the protection of aquatic resources.

m. A copy of the application is available for review at the Commission in the Public Reference Room, or may be viewed on the Commission's website at <http://www.ferc.gov>, using the "eLibrary" link. Enter the docket number, excluding the last three digits in the docket number field, to access the document. For assistance, contact FERC

Online Support. A copy is also available for inspection and reproduction at the address in item h above.

You may register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. Anyone may submit a protest or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, and .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on, or before, the specified comment date for the particular application.

All filings must: (1) Bear in all capital letters the title PROTEST, MOTION TO INTERVENE, COMMENTS, REPLY COMMENTS, RECOMMENDATIONS, TERMS AND CONDITIONS, or PRELIMINARY FISHWAY PRESCRIPTIONS; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or

intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions, or preliminary prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

o. A license applicant must file no later than 60 days following the date of issuance of this notice: (1) A copy of the water quality certification; (2) a copy of the request for certification, including proof of the date on which the certifying agency received the request; or (3) evidence of waiver of water quality certification.

p. *Procedural schedule:* The application will be processed according to the following revised Hydro Licensing Schedule. Further revisions to the schedule will be made as appropriate.

Milestone	Target date
Filing comments, recommendations, terms and conditions, and preliminary fishway prescriptions .....	September 2019.
Commission issues EA .....	February 2020.
Comments on EA due .....	March 2020.

q. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of this notice.

Dated: July 31, 2019.

**Kimberly D. Bose,**  
Secretary.

[FR Doc. 2019-16995 Filed 8-7-19; 8:45 am]

BILLING CODE 6717-01-P

**DEPARTMENT OF ENERGY**

**Federal Energy Regulatory Commission**

[Project No. 2310-230]

**Pacific Gas and Electric Company;  
Notice of Availability of Environmental Assessment**

In accordance with the National Environmental Policy Act of 1969 and

the Federal Energy Regulatory Commission (Commission) regulations, 18 CFR part 380 (Order No. 486, 52 FR 47897), the Office of Energy Projects has reviewed an application submitted by Pacific Gas and Electric Company (licensee) to allow Placer County Water Agency (PCWA), the use of Drum-Spaulding Hydroelectric Project No. 2310 project lands and water within the project boundary on South Canal for the construction of a raw water intake facility (facility). The Drum-Spaulding Hydroelectric Project is located on the Upper Yuba and Bear Rivers in Nevada and Placer counties, California. The project occupies federal lands administered by the U.S. Forest Service, U.S. Bureau of Reclamation, and U.S. Bureau of Land Management.

An Environmental Assessment (EA) has been prepared as part of Commission staff's review of the proposal. In the application, the

licensee proposes to allow PCWA to construct a raw water intake facility on South Canal. Once constructed and operable, PCWA would use the facility as a redundant water withdrawal location to other withdrawal points within the project that it owns and operates, withdrawing up to 62 million gallons of water per day from the project through the proposed facility. Because the proposed facility would be a redundant withdrawal location, water withdrawn from the proposed facility would not represent an increase in water withdrawn from the project than what is already occurring. Following construction of the facility, PCWA would make minor repairs to an existing storm drain on the bank side of South Canal. This EA contains Commission staff's analysis of the probable environmental impacts of the construction and operation of the proposed facility, as well as the minor

storm drain repairs, and concludes that approval of the proposal would not constitute a major federal action significantly affecting the quality of the human environment.

The EA is available for electronic review and reproduction at the Commission's Public Reference Room, located at 888 First Street NE, Room 2A, Washington, DC 20426. The EA may also be viewed on the Commission's website at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number (P-2310) in the docket number field to access the document. For assistance, contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or toll-free at (866) 208-3372 or for TTY, (202) 502-8659.

For further information, contact Joy Kurtz at (202) 502-6760 or by email at [Joy.Kurtz@ferc.gov](mailto:Joy.Kurtz@ferc.gov).

Dated: August 2, 2019.

**Kimberly D. Bose,**  
Secretary.

[FR Doc. 2019-16951 Filed 8-7-19; 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 exempt wholesale generator filings:

*Docket Numbers:* EG19-159-000.  
*Applicants:* Prevailing Wind Park, LLC.

*Description:* Notice of Self-Certification of Exempt Wholesale Generator Status of Prevailing Wind Park, LLC.

*Filed Date:* 8/2/19.

*Accession Number:* 20190802-5100.

*Comments Due:* 5 p.m. ET 8/23/19.

Take notice that the Commission received the following electric rate filings:

*Docket Numbers:* ER19-2520-000.  
*Applicants:* New England Power Pool Participants Committee.

*Description:* § 205(d) Rate Filing: 133rd Agreement to be effective 10/1/2019.

*Filed Date:* 8/1/19.

*Accession Number:* 20190801-5144.

*Comments Due:* 5 p.m. ET 8/22/19.

*Docket Numbers:* ER19-2521-000.

*Applicants:* PJM Interconnection, L.L.C.

*Description:* § 205(d) Rate Filing: Original ISA, SA No. 5450; Queue No. AD2-108 to be effective 7/10/2019.

*Filed Date:* 8/1/19.

*Accession Number:* 20190801-5151.

*Comments Due:* 5 p.m. ET 8/22/19.

*Docket Numbers:* ER19-2522-000.

*Applicants:* Southwest Power Pool, Inc.

*Description:* Compliance filing: Exit Fee Compliance Revisions In Response to Order on Complaint in EL19-11 to be effective 1/1/2020.

*Filed Date:* 8/1/19.

*Accession Number:* 20190801-5155.

*Comments Due:* 5 p.m. ET 8/22/19.

*Docket Numbers:* ER19-2523-000.

*Applicants:* Southwest Power Pool, Inc.

*Description:* § 205(d) Rate Filing: Bylaws and Membership Agreement Revisions to Amend Exit Fee to be effective 1/1/2020.

*Filed Date:* 8/1/19.

*Accession Number:* 20190801-5157.

*Comments Due:* 5 p.m. ET 8/22/19.

*Docket Numbers:* ER19-2524-000.

*Applicants:* Southwest Power Pool, Inc.

*Description:* § 205(d) Rate Filing: Membership Agreement Revisions to Add Load Serving Entity Definition to be effective 10/1/2019.

*Filed Date:* 8/2/19.

*Accession Number:* 20190802-5000.

*Comments Due:* 5 p.m. ET 8/23/19.

*Docket Numbers:* ER19-2525-000.

*Applicants:* Southwest Power Pool, Inc.

*Description:* § 205(d) Rate Filing: 3186 KCP&L and KEPCO Interconnection Agreement Cancellation to be effective 7/11/2019.

*Filed Date:* 8/2/19.

*Accession Number:* 20190802-5002.

*Comments Due:* 5 p.m. ET 8/23/19.

*Docket Numbers:* ER19-2527-000.

*Applicants:* Prevailing Wind Park, LLC.

*Description:* Baseline eTariff Filing: Application for Market-Based Rate Authorization and Request for Waivers, et al. to be effective 10/1/2019.

*Filed Date:* 8/2/19.

*Accession Number:* 20190802-5078.

*Comments Due:* 5 p.m. ET 8/23/19.

*Docket Numbers:* ER19-2528-000.

*Applicants:* ISO New England Inc., New England Power Pool Participants Committee.

*Description:* § 205(d) Rate Filing: ISO-NE and NEPOOL; Revisions to Reactive Capability Audit Provisions to be effective 10/1/2019.

*Filed Date:* 8/2/19.

*Accession Number:* 20190802-5128.

*Comments Due:* 5 p.m. ET 8/23/19.

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: August 2, 2019.

**Kimberly D. Bose,**  
Secretary.

[FR Doc. 2019-16952 Filed 8-7-19; 8:45 am]

BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. EF19-5-000]

#### Bonneville Power Administration; Notice of Filing

Take notice that on July 29, 2019, Bonneville Power Administration submitted tariff filing per: Bonneville Power Administration Proposed FY2020-2021 Wholesale Power and Transmission Rate Adjustment filing to be effective October 1, 2019.

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](mailto: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 August 28, 2019.

Dated: August 2, 2019.

**Kimberly D. Bose,**  
*Secretary.*

[FR Doc. 2019-16949 Filed 8-7-19; 8:45 am]

**BILLING CODE 6717-01-P**

## FEDERAL RESERVE SYSTEM

### Proposed Agency Information Collection Activities; Comment Request

**AGENCY:** Board of Governors of the Federal Reserve System.

**ACTION:** Notice, request for comment.

**SUMMARY:** The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, with revision, the Savings and Loan Holding Company Registration Statement (FR LL-10(b); OMB No. 7100-0337).

**DATES:** Comments must be submitted on or before October 7, 2019.

**ADDRESSES:** You may submit comments, identified by *FR LL-10(b)*, by any of the following methods:

- *Agency website:* <https://www.federalreserve.gov>. Follow the instructions for submitting comments at <https://www.federalreserve.gov/apps/foia/proposedregs.aspx>.

- *Email:* [regs.comments@federalreserve.gov](mailto:regs.comments@federalreserve.gov). Include the OMB number in the subject line of the message.

- *Fax:* (202) 452-3819 or (202) 452-3102.

- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments are available on the Board's website at <https://www.federalreserve.gov/apps/foia/proposedregs.aspx> as submitted, unless modified for technical reasons or to remove personally identifiable

information at the commenter's request. Accordingly, comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper form in Room 146, 1709 New York Avenue NW, Washington, DC 20006, between 9:00 a.m. and 5:00 p.m. on weekdays. For security reasons, the Board requires that visitors make an appointment to inspect comments. You may do so by calling (202) 452-3684. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395-6974.

**FOR FURTHER INFORMATION CONTACT:** A copy of the Paperwork Reduction Act (PRA) OMB submission, including the reporting form and instructions, supporting statement, and other documentation will be placed into OMB's public docket files, if approved. These documents will also be made available on the Board's public website at <https://www.federalreserve.gov/apps/reportforms/review.aspx> or may be requested from the agency clearance officer, whose name appears below. Federal Reserve Board Clearance Officer—Nuha Elmaghribi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452-3829.

**SUPPLEMENTARY INFORMATION:** On June 15, 1984, OMB delegated to the Board authority under the PRA to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

### Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

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

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

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

### Proposal Under OMB Delegated Authority To Extend for Three Years, With Revision, the Following Information Collection

*Report title:* Savings and Loan Holding Company Registration Statement.

*Agency form number:* FR LL-10(b).

*OMB control number:* 7100-0337.

*Frequency:* As needed.

*Respondents:* Savings and loan holding companies (SLHCs).

*Estimated number of respondents:* 8.

*Estimated average hours per response:* Reporting: 8; recordkeeping: 0.25.

*Estimated annual burden hours:*

Reporting: 64; recordkeeping: 2.

*General description of report:* The FR LL-10(b) requests information from registering SLHCs on the financial condition, ownership, operations, management, and intercompany relationships of the SLHC and its subsidiaries. Additionally, respondents must include information concerning the transaction that resulted in the respondent becoming an SLHC, a description of the SLHC's business, and a description of any changes related to the financial condition, ownership, operations, intercompany relationships, and management of the SLHC and its subsidiaries since the registrant's application to become an SLHC was approved. The principal executive or principal financial officer of the registering SLHC must certify that the information contained in the submission has been carefully reviewed and is true, correct, and complete.

*Proposed revisions:* The Board proposes several revisions to make the

FR LL–10(b) consistent with the format of other Board forms and to reflect the Board's regulations. Specifically, the Board is proposing the following revisions:

(1) Adding several items requesting information regarding any subsidiaries of the SLHC. This information will assist the Federal Reserve System in its supervision of the consolidated SLHC structure;

(2) Adding an item requesting the mailing address of the SLHC, if different from its physical address. This item will help Federal Reserve System staff contact the filer.

(3) Adding an item for the printed name of the officer who signed the FR LL–10(b). This item will help Federal Reserve System staff identify the individual that certified the accuracy of the filing;

(4) Adding an item requesting the date of signature of the FR LL–10(b). This item will inform the Federal Reserve System of the date as of which the signatory certified the accuracy of information included in the filing.

In addition, the Board proposes to revise the FR LL–10(b) to account for a requirement in the FR LL–10(b) instructions that respondents retain a signed copy of the form and data submitted. The FR LL–10(b) does not currently account for this recordkeeping requirement.

**Legal authorization and confidentiality:** The FR LL–10(b) is authorized by Section 10(b)(1) of the Home Owners' Loan Act (HOLA), which requires each SLHC to register with the Federal Reserve within 90 days of becoming an SLHC on forms prescribed by the Board that contain such information as the Board may deem necessary or appropriate. The obligation to respond is mandatory.

Individual respondents may request that information submitted to the Board through the FR LL–10(b) be kept confidential. If a respondent requests confidential treatment, the Board will determine whether the information is entitled to confidential treatment on a case-by-case basis. Information collected through the FR LL–10(b) may be kept confidential under exemption 4 for the Freedom of Information Act, which protects privileged or confidential commercial or financial information, or under FOIA exemption 6, which covers personal information, the disclosure of which would constitute an unwarranted invasion of privacy.

Board of Governors of the Federal Reserve System, August 5, 2019.

**Ann Misback,**

*Secretary of the Board.*

[FR Doc. 2019–17007 Filed 8–7–19; 8:45 am]

**BILLING CODE 6210–01–P**

## FEDERAL TRADE COMMISSION

### Request for Contractor Submission of Final Invoices for Expired Contracts

**AGENCY:** Federal Trade Commission.

**ACTION:** Notice; request for final invoices.

**SUMMARY:** The Federal Trade Commission (“FTC” or “Commission”) currently has open files for contracts that have lapsed. The contract periods of performance for services and final delivery dates for goods have expired and the time allowed for contract file closeout is overdue. To clear the backlog of physically completed contracts (FAR 4.804) the FTC will utilize the procedure described below based on FAR 4.804–5 and 42.708 that will enable the Commission to close these files all at one time in an efficient and cost effective manner. No separate contract modifications will be issued.

**DATES:** The files are deemed closed as of the date of publication of this Notice. To facilitate the closeout, the FTC requests that contractors with contracts identified on the list, contained in Appendix A to this document, submit any outstanding invoices to the FTC Acquisition Division no later than September 13, 2019.

**ADDRESSES:** Contractors should submit invoices as attachments to email messages, which should be addressed to [Acquisitions@ftc.gov](mailto:Acquisitions@ftc.gov).

**FOR FURTHER INFORMATION CONTACT:** Leonard Nadybal, Chief Acquisitions Officer, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. Telephone: (202) 326–2298. Email: [lnadybal@ftc.gov](mailto:lnadybal@ftc.gov).

**SUPPLEMENTARY INFORMATION:** The FTC's backlog of files pose a significant burden on the Commission as this contracting office transitions from one contract writing system to another. Using standard file closure procedures on the volume of old existing files would impede efforts to modernize the FTC's procurement operation and hinder deployment of the interface between the contract writing system and the new financial management system. Importantly, not processing these file closeouts as quickly as possible will further delay contractors from receiving income from potential unpaid balances

or leave them unaware that the claims process remains available.

The procedure takes into account that contractors have the right to concur with closure, to issue final invoices and make claims. The procedure is being applied only to contracts deemed to be extremely low risk. For instance, the contracts listed in the Appendix have lapsed periods of performance, have no or only inconsequential amounts of funds obligated to them that need to be deobligated, have no option periods remaining to be exercised, contain no provisions for post-award adjustments of labor rates or incentives, and have not had any invoice or payment activity in Fiscal Year 2019.

The procedure to be applied was developed and used by other agencies to significantly and swiftly reduce the number of expired contracts with unliquidated funds, and will have mutual benefits for the government and contractors by enabling the Commission to expeditiously close these actions and pay final bills.

Notwithstanding the FTC's intention to close out expeditiously the files identified in Appendix A, contractors' rights are protected under 41 U.S.C. chapter 71 Contract Disputes (commonly known as the Contract Disputes Act of 1978), which establishes procedures for filing claims against Federal Government contracts. Normal contract file retention requirements will apply after closeout. (See 48 CFR 4.805).

This notice will also be published to FedBizOpps at <https://www.fbo.gov/>.

**Leonard A. Nadybal,**

*Chief Procurement Officer/Assistant CFO.*

## Appendix A

### List of Aged FTC Contracts To Be Closed Simultaneously

*Note that the fiscal year of award is shown in the contract number as two digits that follow the prefixes “FTC” or “29FTC1”.*

*A suffix “A” indicates a modification to the contract or order.*

*Digits following a “/” (slash mark) indicate the number of a task order issued under the contract or agreement that is numbered to the left of the slash mark.*

*Confidential and classified contracts are grouped under generic company names “Domestic Awardees” and “Foreign Awardees”. The name of the contractor does not appear. If you believe you own one of the confidential or classified contracts and have an outstanding invoice or claim, contact the FTC Chief of Acquisitions through the email address in the document above.*

3M COMPANY

29FTC117P0081

FTC11H1149

FTC13H3010

55 EAST MONROE INVESTORS IV LLC

FTC08H8036

601 NJ AVENUE LLC  
 FTC06H6087  
 FTC07H7120  
 FTC07H7165  
 FTC08H8064  
 FTC09H9098  
 FTC11H1064  
 FTC12H2006  
 FTC13H3001  
 A & T MARKETING, INC  
 FTC11G1173  
 A TECH SYSTEMS, INC.  
 FTC07H7128  
 AA TEMPS, INC  
 FTC07G7128  
 FTC08G8113  
 FTC10H0229  
 AAA COMPLETE BUILDING SERVICES, INC.  
 FTC11G1023  
 AAF MCQUAY, INC.  
 FTC08H8028  
 FTC09H9006  
 FTC10H0011  
 AARON GERSHBOCK  
 E071689001  
 ABERDEEN LLC  
 29FTC117F0169  
 ACACIA CONSULTING, INC.  
 FTC10H0197  
 ACCELERATE SOLUTIONS INC.  
 FTC09G9202  
 29FTC116F0075  
 FTC10H0331  
 ACCELLION, INC  
 FTC10H0292  
 FTC11H1177  
 FTC12H2198  
 FTC13H3127  
 ACCESS INTELLIGENCE LLC  
 FTC09H9022A  
 FTC10H0048  
 FTC11H1081A  
 ACCESSAGILITY LLC  
 29FTC117F0049  
 29FTC117F0061  
 ACCESSDATA CORP.  
 FTC08H8082  
 FTC10H0144  
 ACCESSDATA GROUP, LLC  
 FTC11H1190  
 FTC12H2199  
 ACCUVANT FEDERAL SOLUTIONS INC  
 FTC13G3060  
 FTC13G3065  
 ACE DATA RECOVERY ENGINEERING, INC.  
 FTC08H8213  
 ACOUSTICAL SOLUTIONS, INC.  
 FTC10H0190  
 ACP PEACHTREE CENTER LLC  
 FTC11H1100  
 ACQUISITION SOLUTIONS, INC  
 FTC11H1137  
 ACTIONABLE INTELLIGENCE  
 TECHNOLOGIES, INC.  
 29FTC116F0054  
 29FTC117F0088  
 FTC10H0267  
 FTC11H1125  
 FTC12H2071  
 ADLIB PUBLISHING SYSTEMS INC  
 FTC11H1094  
 ADVANCED COMPUTER CONCEPTS, INC.  
 29FTC116F0083  
 29FTC117F0101  
 ADVANTAGE WEB SOLUTIONS  
 FTC08H8097A  
 AFFIGENT, LLC  
 FTC11G1122  
 FTC11G1179  
 FTC12H2100  
 FTC12H2206  
 AINS, INC  
 FTC08G8069  
 FTC08G8279  
 FTC09G9053  
 FTC10G0065  
 FTC11G1040  
 FTC12G2047  
 FTC13G3039  
 AIR QUALITY SOLUTIONS, INC  
 FTC09H9044  
 AIR ROVER COMPANY, INC.  
 FTC09G9092  
 ALAMO CITY ENGINEERING SERVICES,  
 INC  
 FTC15G5101  
 FTC15G5065  
 ALDERSON REPORTING COMPANY, INC  
 FTC10H0335  
 ALDOORS OF FLORIDA, INC.  
 FTC07H7020  
 ALLIANCE TECHNOLOGY GROUP, LLC  
 29FTC117F0005  
 29FTC117F0104  
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 ALLSEATING CORP.  
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 ALLSTEEL, INC  
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 ALON, INC  
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 ALPHASIX CORP.  
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 ALTUM, INC.  
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 ALVAREZ & ASSOCIATES LLC  
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 AMERICAN AMPLIFIER & TELEVISION INC.  
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 AMERICAN BAR ASSOCIATION  
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 AMERICAN BUILDING CONTROL, INC  
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 AMERICAN LAW INSTITUTE  
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 AMERICAN RED CROSS  
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 AMES, INC.  
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 ANACAPA MICRO PRODUCTS, INC.  
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 ANALYSIS GROUP, INC.  
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 ANATOMY INC.  
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 ANGSTROMUSH, LLC  
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 ANNAPOLIS TECHNOLOGIES, LLC  
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 AOC SOLUTIONS, INC  
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 APPLE COMPUTER INC.  
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 FTC08G8250  
 FTC09G9176  
 APPLICATION SECURITY, INC  
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 APPLIED DISCOVERY, INC.  
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 FTC08H8140  
 FTC08H8175  
 FTC08H8201  
 FTC09H9103  
 FTC09H9217  
 APPLIED DNA SCIENCES, INC.  
 FTC15H5140  
 APPRIO, INC.  
 FTC14H4136  
 APPTIS INC.  
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 FTC08G8192

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 APRICORN  
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 APRISA TECHNOLOGY LLC  
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 ARCHIVE DATA SOLUTIONS, LLC  
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 ARDELLE TECHNICAL, INC.  
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 ARETE GOVERNMENT SOLUTIONS LLC  
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 ARROW ENTERPRISE COMPUTING SOLUTIONS INC.  
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 ARTELYS CORP.  
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 ARYA CORP.  
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 ASAP SOFTWARE EXPRESS INC  
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 ASPEN SYSTEMS CORP.  
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 ASSOCIATION OF GOVERNMENT ACCOUNTANTS  
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 AT COMM CORP.  
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 AT&T CORP.  
 FTC10H0285  
 AT&T MOBILITY LLC  
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 ATLANTIC AIR CORP.  
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 ATLAS VAN LINES, INC.  
 FTC07G7100  
 ATTASK, INC.  
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 AUDIMATION SERVICES INC  
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 AUGUST TENTH SYSTEMS  
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 AUROTECH INC  
 FTC08H8244

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 FTC10G0255  
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 AVANTSTAR INC  
 FTC12H2248  
 AVITECTURE INC  
 FTC10H0143  
 BAHFED CORP  
 BAHFED CORP  
 BAHFED CORP  
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 BAJARI ECONOMIC CONSULTING  
 FTC09H9040  
 BANCORP BANK THE  
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 BARDEH IT CONSULTING  
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 BARKER ADVERTISING SPECIALTY CO., INC.  
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 BASCH SUBSCRIPTIONS  
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 BELLINGER, DAVID  
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 BENJAMIN OFFICE SUPPLY & SERVICES, INC.  
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 BEST MESSENGER INC  
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 FTC08A8002  
 BETTER DIRECT, LLC  
 FTC16G6011  
 BIG BANG LLC  
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 BIJAN SHAL, INC.  
 FTC09H9106  
 BINARY RESEARCH INTERNATIONAL, INC.  
 FTC09H9210  
 FTC10H0305  
 BLACK BOX CORP OF PENNSYLVANIA  
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 BLDS, LLC  
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 BLUE TECH INC.  
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 BNF TECHNOLOGIES INC.  
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 BOOZ ALLEN HAMILTON INC  
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 BOSQUES DE DURAZNOS NO 67-203  
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 BOXTONE INC.  
 FTC09H9045  
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 BRATTLE GROUP, INC., THE  
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 BRENNAN, JENNIFER M  
 FTC10H0304  
 BRIGHTLINE COMPLIANCE, LLC  
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 BROOKS AND ASSOCIATES LLC  
 FTC10G0028  
 BUCK MANAGEMENT SERVICES  
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 C&C COMPLETE FLOORING ENTERPRISES, INC  
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 C.T. CORP. SYSTEM  
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 CACI INC FEDERAL  
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 CADAPULT LTD  
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 CAIRO CORP.  
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 CAMBRIDGE COMPUTER SERVICES INC.  
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 CANON U.S.A., INC.  
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 CAPITAL ANTENNA COMPANY INC.  
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 CAPITOL NEWS COMPANY, LLC  
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 CAPP INC  
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 CARAHSOFT TECHNOLOGY CORP.  
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FTC12G2045	FTC08H8236	FTC11G1156
FTC12G2059	FTC08H8255	FTC11G1167
FTC12G2087	FTC08H8266	FTC11G1172
FTC12G2105	FTC09H9017	FTC11H1003
FTC12G2109	FTC09H9033	FTC11H1030
FTC12G2110	FTC09H9041	FTC11H1040
FTC12G2111	FTC09H9051	FTC11H1048
FTC12G2141	FTC09H9054	FTC11H1116
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FTC13G3042	FTC08G8002	FTC11H1195
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FTC13G3075	FTC08G8110	FTC12G2033
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FTC14G4150A	FTC08G8119	FTC12G2038
FTC15G5031	FTC08G8120	FTC12G2058
FTC15G5074	FTC08G8181	FTC12G2088
<i>CAREER CONCEPTS INC.</i>	FTC08G8184	FTC12G2116
FTC08A8007	FTC08G8204	FTC12H2002
FTC12G2143	FTC08G8259	FTC12H2009
FTC08A8007/1001	FTC08G8270	FTC12H2029
FTC08A8007/1200	FTC08G8276	FTC12H2038
FTC08A8007/8001	FTC08G8278	FTC12H2099
FTC08A8007/8002	FTC08G8305	FTC12H2166
FTC08A8007/9001	FTC08G8306	FTC12H2187
FTC10H0070	FTC08G8307	FTC12H2227
<i>CAROLINA ADVANCED DIGITAL, INC.</i>	FTC08G8308	FTC12H2247
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<i>CARTRIDGE PLUS, INC</i>	FTC09G9082	FTC12H2259
FTC09G9049	FTC09G9100	FTC13G3070
FTC09G9063	FTC09G9134	FTC13G3072
FTC09G9205	FTC09G9158	FTC13G3121
FTC10G0097	FTC09G9163	FTC13G3126
FTC10G0175	FTC09G9179	FTC13G3128
<i>CARTRIDGE TECHNOLOGIES, INC.</i>	FTC09G9186	FTC13G3139
29FTC116F0088	FTC10G0002	FTC13H3012
<i>CASESOFT LIMITED</i>	FTC10G0055	FTC13H3030
FTC08G8104	FTC10G0062	FTC13H3041
FTC08G8224	FTC10G0077	FTC13H3075
FTC08G8256	FTC10G0125	FTC13H3078
<i>CATAPULT CONSULTANTS LLC</i>	FTC10G0133	FTC14H4092
FTC09H9267	29FTC116F0016	FTC15G5091
FTC11A1004/1105	29FTC116F0059	FTC15G5104
FTC11A1004/1205	29FTC116F0093	FTC15G5138
FTC11A1004/1207	29FTC117F0070	FTC07G7273
FTC11A1004/1208	29FTC117F0079	FTC07G7307
FTC11G1185	29FTC117F0083	FTC08G8027
<i>CAVANAUGH HAGAN PIERSON AND</i>	29FTC117F0116	FTC09G9091
<i>MINTZ INC.</i>	29FTC117F0124	FTC09G9182
FTC07H7183	29FTC118F0008	FTC09H9189
<i>CAVANAUGH, HAGAN &amp; PIERSON, INC.</i>	29FTC118F0052	FTC10G0064
FTC08A8006	FTC08G8084	FTC10G0119
<i>CCH INC.</i>	FTC08G8210	FTC10G0140
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FTC09G9009	FTC08H8023	FTC10H0041
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FTC13G3012	FTC10G0077A	FTC10H0129
FTC15G5062	FTC10H0170	FTC10H0130
FTC16G6019	FTC10H0211	FTC10H0131
<i>CD ROM INC</i>	FTC10H0266	FTC10H0135
FTC09G9198	FTC10H0279	FTC11G1125
<i>CDW GOVERNMENT INC</i>	FTC10H0286	FTC12G2097
FTC08H8076	FTC10H0314	FTC16G6003
FTC08H8086	FTC10H0320	<i>CELLEBRITE USA CORP</i>
FTC08H8110	FTC10H0324	FTC12H2235
FTC08H8113	FTC10H0325	<i>CENTER FOR APPLIED LINGUISTICS</i>
FTC08H8133	FTC11G1028	FTC11H1131
FTC08H8136	FTC11G1043	FTC12G2153
FTC08H8184	FTC11G1054	<i>CENTER FOR IMPROVING VALUE IN</i>
FTC08H8206	FTC11G1064	<i>HEALTH CARE</i>

29FTC117P0085  
CENTER FOR SECURITY AND EMERGENCY  
MANAGEMENT, INC.  
FTC10H0283  
CENTER WEST A CAL LTD PARTNERSHIP  
FTC10H0064  
FTC11H1008  
CERAMI & ASSOCIATES, INC  
29FTC117P0019  
CGI FEDERAL INC.  
FTC14G4205  
CHALLENGEPOST, INC.  
FTC12G2120  
CHAMPION INDUSTRIES, INC  
FTC10G0145  
CHICAGO PARTNERS  
FTC07H7093A  
CHRISTOPHER HEMPHILL  
FTC07H7145A  
CINGULAR WIRELESS LLC (5068)  
FTC07G7113  
CIPHENT, INC.  
FTC12G2094  
CIRCLE SYSTEMS INC  
FTC09H9002  
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FTC11H1009  
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CISION US INC.  
FTC09H9269  
CITRIX SYSTEMS INC  
FTC08G8139  
FTC12H2158  
FTC13H3005  
CLASSIC LEATHER INC  
FTC08G8064  
CLASSIFIED DOMESTIC CONTRACTORS  
FTC06H6111  
FTC07H7028  
FTC07H7062  
FTC07H7161  
COAST2COAST SHREDDING LLC  
FTC06G6207A  
COMBYTE U S A  
FTC12G2084  
COMMERCIAL DATA SYSTEMS INC  
FTC09G9252  
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FTC11H1120  
FTC12H2001  
COMMUNICATIONS PROFESSIONAL, IN  
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FTC15G5120A  
COMPASS LEXECON LLC  
FTC10H0337  
COMPETITIVE MEDIA REPORTING LLC  
FTC07H7170  
COMPU DYNAMICS LLC  
FTC06G6274  
FTC11G1087A  
FTC10G0024  
FTC10G0041  
FTC10G0122  
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FTC10G0186  
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FTC11G1102  
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FTC13G3033  
COMPUTECH INTERNATIONAL, INC.  
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COMPUTER PRODUCTS CORP.  
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COMPUTERLINKS NORTH AMERICA INC.  
FTC11G1038  
FTC11G1078  
FTC12G2067  
COMPUWARE CORP.  
FTC08G8060  
COMSCORE, INC.  
FTC08H8151  
FTC10H0116  
FTC11H1228  
COMSTOR CORP.  
FTC08G8117  
FTC09G9132  
CONGRESSIONAL QUARTERLY INC  
FTC09H9008  
FTC08H8005  
CONNECTLIVE COMMUNICATIONS, INC  
FTC06G6219  
CONTIVO INC.  
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CONVERGENCE TECHNOLOGY  
CONSULTING LLC  
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FTC11H1067  
FTC12H2086  
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COOPER NOTIFICATION, INC.  
FTC09G9262  
CORNERSTONE RESEARCH, INC.  
FTC16H6007  
COUNCIL FOR COMMUNITY AND  
ECONOMIC RESEARCH, THE  
FTC10H0263  
COUNCIL OF BETTER BUSINESS  
BUREAUS, INC.  
FTC11H1041  
FTC13H3200  
COUNTERTRADE PRODUCTS INC.  
FTC11G1024  
FTC11G1036  
FTC12G2026  
FTC12G2082  
CQ-ROLL CALL, INC.  
FTC11H1015  
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CRA INTERNATIONAL INC.  
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CREATE WITH CONTEXT, INC.  
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CREATIVE BREAKTHROUGHS, INC.  
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CRIMSON IMAGING SUPPLIES, LLC.  
29FTC116F0028  
29FTC1170021  
29FTC117F0120  
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FTC13A3001/1301  
CRITICAL ELECTRIC SYSTEMS GROUP, LLC  
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CROSS MATCH TECHNOLOGIES INC.  
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CROWN PARTNERS LLC  
FTC10G0171  
FTC11G1144  
FTC12G2136  
CTR MANAGEMENT GROUP LLC  
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CUADRA ASSOCIATES, INC.  
FTC08G8162  
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FTC12H2220  
CXO MEDIA, INC.  
FTC08H8216  
DATA DEVICES INTERNATIONAL, INC.  
FTC09H9226  
DATACOM NETWORK SERVICES INC  
FTC07H7157  
FTC08H8196  
FTC08H8197  
FTC09H9221  
FTC08H8021  
DALALINE LLC  
FTC11G1048  
DATAMATION SYSTEMS INC  
FTC10H0042  
DATASTREAM CONVERSION SERVICES  
LLC  
FTC07G7283  
DATAWATCH SYSTEMS, INC.  
FTC12H2031  
FTC13H3060  
DATUM FILING SYSTEMS INC  
FTC10G0154  
DCML SERVICES CORP.  
FTC13H3214  
DE ARMOND, ELIZABETH  
FTC08H8145  
DEAL, L.L.C., THE  
FTC10H0176  
FTC11H1115  
FTC12H2154  
FTC15H5110  
DEBRA J. RINGOLD, Ph.D., INC.  
FTC12H2007  
DECISION ANALYST, INC.  
FTC10H0261  
DELL FEDERAL SYSTEMS L.P.  
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FTC11G1174  
DELL MARKETING L.P.  
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FTC09G9230  
FTC09G9236  
FTC10G0049  
FTC10G0089

FTC10G0189	FTC12H2077	DORMA-CAROLINA DOOR CONTROLS, INC
FTC10G0221	FTC12H2101	FTC07H7020A
FTC10G0252	FTC12H2109	FTC08H8032
FTC10G0253	FTC12H2194	DR JAMES MCCORMACK
FTC11G1090	FTC12H2224	FTC08H8055
FTC12G2032	FTC13G3004	DSI INDUSTRIES INC
FTC12G2054	FTC13G3026	FTC09G9166
FTC12G2055	FTC13G3046	DUN & BRADSTREET, INC.
FTC12G2064	FTC13G3095	FTC08G8020
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FTC12G2092	FTC15G5015	FTC10G0010A
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FTC12G2131	FTC15G5098	FTC12G2008
FTC12G2132	FTC15G5121	FTC13G3020
FTC12G2134	DOMA TECHNOLOGIES, LLC	DYNAMIC SYSTEMS, INC.
FTC12G2140	FTC09H9258	FTC16H6014
FTC13G3044	FTC11H1112	EAGLE MARKETING GROUP INC
FTC13G3059	DOMAIN TOOLS, LLC	FTC07G7192
FTC16G6014	FTC15H5025	FTC09G9199
FTC11G1052A	DOMESTIC AWARDEES (UNDISCLOSED)	EAST COAST FIRE PROTECTION, INC.
FTC11G1130A	FTC07H7092	FTC10G0164
DEMBO JONES, P.C.	FTC12H2097	EASTERN TECHNICAL, INC
293G0073	FTC12H2175	FTC10H0300
DEMBO, JONES, HEALY, PENNINGTON	FTC12H2207	FTC08H8185
FTC08G8118	FTC12H2213	FTC12H2196
DESIGN SCIENCE INC.	FTC12H2245	EBSCO INDUSTRIES, INC
FTC06H6164	FTC12H2250	FTC08G8019
FTC11H1109	FTC12H2260	FTC08G8134
DIAMOND HOTEL PHILIPPINES	FTC13H3025	FTC09G9003
FTC12H2179	FTC13H3051	FTC09G9069
DIAMOND, SEIDMAN SHARI	FTC13H3058	FTC10G0011
FTC16H6027	FTC13H3111	FTC10G0084
FTC16H6027	FTC13H3128	FTC11G1009
DIGITAL INTELLIGENCE, INC.	FTC13H3131	FTC11G1042
FTC09H9224	FTC13H3211	FTC08G8019A
FTC11G1134	FTC14H4036	FTC12G2007
DLT FEDERAL BUSINESS SYSTEMS CORP.	FTC14H4061	FTC13G3043
FTC16G6026	FTC14H4110	FTC15H5102
DLT SOLUTIONS, INC.	FTC14H4115	EC AMERICA, INC.
FTC08G8108	FTC14H4131	29FTC117F0106
FTC08G8133	FTC15H5008	FTC13G3003
FTC08G8163	FTC15H5018	FTC16G6021
FTC09G9113	FTC15H5126	FTC16G6030
FTC09H9004	FTC15H5134	EC AMERICA/SAP
FTC09H9111	FTC08H8065	FTC10H0222
FTC09H9119	FTC08H8153	EC AMERICAS/BSNESS OBJECTS AMERICAS
FTC10H0010	FTC08H8161	FTC08G8121
DLT SOLUTIONS, LLC	FTC08H8252	FTC09G9026
29FTC116F0036	FTC08H8274	FTC09G9031
29FTC117F0085	FTC09H9050	FTC09G9131
FTC10G0054	FTC09H9110	FTC09G9196
FTC10G0139	FTC09H9118	FTC09G9224
FTC10G0142	FTC09H9122	FTC09G9225
FTC10G0190	FTC10H0029	FTC10G0038
FTC10G0230	FTC10H0047	FTC10G0047
FTC10G0235	FTC10H0086	FTC10G0071
FTC10G0239	FTC10H0094	FTC10G0120
FTC10G0254	FTC10H0104	FTC10G0165
FTC10H0095	FTC10H0114	FTC10G0192
FTC10H0151	FTC10H0159	FTC10G0226
FTC10H0168	FTC10H0186	FTC11G1083
FTC11G1019	FTC10H0192	FTC12G0001
FTC11G1035A	FTC10H0212	FTC12G2003
FTC11G1063	FTC10H0238	ECONOMIC SYSTEMS, INC.
FTC11G1097	FTC10H0241	FTC08G8018
FTC11H1084	FTC10H0252	FTC08G8255
FTC11H1114	FTC11H1036	FTC10G0019
FTC11H1168	FTC11H1080	FTC11G1010
FTC12G2025	FTC11H1097	FTC11G1022
FTC12G2069	FTC11H1113	EDC CONSULTING LLC
FTC12G2104	FTC11H1155	FTC07G7200
FTC12G2108	FTC11H1172	EDITORIAL EXPERTS, INC
FTC12G2126	FTC11H1203	FTC07G7255
FTC12G2135	FTC11H1219	FTC08G8153
FTC12H2046	FTC12H2028	EDWARD BLONZ
FTC12H2056	FTC12H2037	FTC07H7084A

EECO INC.	FTC11G1020	292Z0001707
FTC07H7021	FTC11G1117	292Z0001711
ELECTRICAL WHOLESALE METRO DC, INC.	FTC12A2007/1301	292Z0001712
FTC10H0196	FTC12A2007/1401	FTC08Z8001/0907
FTC10H0328	EXECUTIVE INFORMATION SYSTEMS,	FTC08Z8001/0908
ELECTRONIC LEGAL SOFTWARE	29FTC117F0084	FTC08Z8001/0804
FTC11H1035	FTC08G8145	FTC08Z8001/0805
ELITE PRODUCTIONS SERVICES LLC	FTC08G8318	FTC08Z8001/0807
FTC15H5039	FTC09G9133	FTC09H9170
ELSEVIER B.V.	FTC10G0149	FTC09Z9001/0901
FTC10H0085	FTC11G1082	FTC09Z9001/0903
FTC11H1077	FTC13G3078	FTC09Z9001/0905
FTC12H2152	29FTC116F0018	FTC09Z9001/1001
EMC CORP.	FTC12G2089A	FTC09Z9001/1004
FTC08H8095	EXPERIAN INFORMATION SOLUTIONS, INC	FTC09Z9001/1005
FTC09H9206	FTC09H9261A	FTC09Z9001/1006
FTC10H0262	EXTRACTIVA INC	FTC09Z9001/1007
FTC12H2139	FTC08H8003A	FTC09Z9001/1008
EMERGENT, LLC	FABRICARE DRAPERIES, INC	FTC09Z9001/1100
29FTC116F0058	FTC07G7279	FTC09Z9001/1102
29FTC117F0031	FTC10G0112	FTC09Z9001/1104
FTC10H0321	FTC10G0115	FTC09Z9001/1105
FTC11G1062	FAST SEARCH & TRANSFER INC	FTC09Z9001/1106
FTC15G5140	FTC08H8119	FTC09Z9001/1107
FTC16G6020	FAST, MICROSOFT	FTC09Z9001/1108
EMERSON NETWORK POWER, LIEBERT SERVICES, INC.	FTC09H9015	FTC09Z9001/1109
FTC09H9035	FCN, INC.	FTC09Z9001/1201
FTC10H0158	FTC08G8167	FTC09Z9001/1202
FTC11H1185	29FTC116F0011	FTC09Z9001/1203
FTC12H2208	29FTC116F0030	FTC09Z9001/1204
EMESEC INC.	FEDERAL ACQUISITION STRATEGIES, LLC	FTC09Z9001/1205
FTC07G7294	FTC13H3087	FTC09Z9001/1206
ENDRUN TECHNOLOGIES, LLC	FEDERAL EXPRESS CORP.	FTC09Z9001/1208
FTC11H1105	FTC07A7005	FTC09Z9001/1209
ENGEL, KATHLEEN	FTC08A8004A	FTC09Z9001/1301
FTC08H8127	FEDERAL SECURITY SYSTEMS, INC	FTC09Z9001/1302
ENTERPRISE TECHNOLOGY SOLUTIONS, INC.	29FTC117C0077	FTC09Z9001/1303
29FTC117F0013	FTC07G7271	FTC09Z9001/1304
29FTC117F0023	FTC12G2086	FTC09Z9001/1305
29FTC117F0034	FEDSTORE CORP.	FTC09Z9001/1306
ENVIRONMENTAL SYSTEMS RESEARCH	FTC09G9018	FTC09Z9001/1307
FTC08G8302	FINANCIAL MARKETS INTL	FTC09Z9001/1308
FTC08G8304	V070501005	FTC09Z9001/1401
FTC09G9045	V070501006	FTC09Z9001/1402
FTC10G0021	FIRE X SALES & SERVICE CORP	FTC09Z9001/1403
FTC10G0123	FTC12H2200	FTC09Z9001/1404
FTC11G1120	FLATIRONS SOLUTIONS CORP.	FTC09Z9001/1405
FTC11G1165	FTC07G7319	FTC09Z9001/1406
FTC12G2010	FLEISHMAN-HILLARD INC.	FTC09Z9001/1407
FTC09H9171	FTC08H8248	FTC09Z9001/1408
FTC11H1056	FTC14Z4004/0102	FTC09Z9001/1409
29FTC116F0055	FTC15H5068	FTC09Z9001/1501
EQUIFAX INFORMATION SERVICES LLC	FTC14Z40046001	FTC09Z9001/1502
FTC06G6102	FTC14Z40047002	FTC09Z9001/1503
ESECURITYTOGO, LLC	FTC14Z40047003	FTC09Z9001/1504
FTC11G1123	FTC14Z40047012	FTC09Z9001/1505
ESVA	FTC05G5145	FTC09Z9001/1506
FTC10H0050	FTC08G8149	FTC09Z9001/1509
EUREKAFACTS LLC	FTC10G0265	29FTC117F0056
FTC16G6034	FLUKE NETWORKS, INC.	FTC09H9129
EVALUATE LTD	FTC11H1200	FTC09H9172
FTC12H2172	FTC13H3017	FTC10H0198
EVALUATEPHARMA LTD	FM TALENT SOURCE LLC	FTC10H0334
FTC10H0161	FTC09G9061	FORCE 3 INC.
FTC11H1127	FTC10H0228	FTC10G0158
EVIGILANTCOM INC.	FOND ROZVYTKU KONKURENTSII, GO	FTC11G1139
FTC14G4014	29FTC117P0089	FTC09H9104
FTC14G4156A	FOR THE RECORD, INC.	FTC10H0318
EXECUTIVE FURNITURE OF WASHING	Contract + Task Order # after “/”	FTC11H1046
FTC08G8189	292Z0001701	FTC12H2042
FTC08G8198	292Z0001702	FTC12H2055
FTC09G9079	292Z0001704	FTC13H3043
FTC09G9178	292Z0001705	FORCE 3, LLC
	292Z0001706	29FTC116F0092
		FTC11H1176A
		FOREIGN AWARDEES (UNDISCLOSED)

29FTC118P0064  
 FTC15H5106  
 FORENSIC STORE, INC  
 FTC16H6012  
 FORRESTER RESEARCH, INC.  
 FTC09H9169  
 FOSTERSOFT, INC  
 FTC11G1182  
 FTC11G1183  
 FTC10H0093  
 FTC10H0330  
 FTC10H0333  
 FTC12H2075  
 FOUR LLC  
 29FTC116F0039  
 29FTC117F0131  
 FTC12H2188  
 FOUR POINTS TECHNOLOGY, L.L.C.  
 29FTC116F0068  
 29FTC117F0158  
 FTC11G1103  
 FTC11G1106  
 FTC12G2152  
 FRANK PARSONS, INC.  
 FTC07G7065  
 FTC08G8130  
 FTC09G9024  
 FTC09G9070  
 FTC09G9119  
 FTC09G9123  
 FTC09G9171  
 FTC10G0030  
 FTC10G0050  
 FTC10G0059  
 FTC10G0150  
 FTC10G0179  
 FTC11G1060  
 FRONTRANGE SOLUTIONS USA INC  
 FTC08G8023  
 FTC08H8220  
 FTI CONSULTING INC  
 FTC08H8022B  
 FTC08H8022C  
 FTC08H8022D  
 G.C.MICRO CORP.  
 29FTC117F0097  
 FTC16G6007  
 GALLUP, INC.  
 29FTC116F0067  
 GARTNER INC.  
 FTC08G8014  
 FTC08G8253  
 FTC10G0004  
 FTC10G0069  
 FTC11G1008  
 FTC12G0002  
 FTC13G3002  
 FTC16G6008  
 GENERAL BINDING CORP.  
 FTC08G8237  
 FTC09G9229  
 GENSLER JR M ARTHUR AND ASSOCIATES  
 INC. (3305)  
 FTC06G6125  
 GEORGE W ALLEN CO INC  
 FTC09G9088  
 FTC10G0046  
 GEORGE WASHINGTON UNIVERSITY, THE  
 FTC09H9144  
 GEORGIA HOSPITAL ASSOCIATION, INC.  
 FTC11H1085  
 FTC13H3083  
 GILL GROUP INC.  
 FTC10G0143  
 GLOBAL PAYMENTS EXPERTS LLC  
 FTC14H4010  
 GLOBAL SOFTWARE TECHNOLOGIES  
 FTC07H7040A  
 GLOBAL TECHNOLOGY RESOURCES, INC.  
 29FTC117F0109  
 GLOBALSCAPE, INC.  
 FTC11H1072  
 GMC TEK, LLC  
 29FTC116F0005  
 GORDON SECURITY SOLUTIONS LLC  
 FTC11H1047  
 GOVCONNECTION INC.  
 FTC08G8126  
 FTC09G9093  
 FTC10G0271  
 FTC11G1177  
 FTC12G2076  
 FTC12G2160  
 FTC13G3069  
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 GOVERNMENT TECHNOLOGY SOLUTION  
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 FTC12G2075  
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 FTC09G9107A  
 GOVPLACE  
 29FTC116F0077  
 GOVSMART, INC.  
 29FTC116P0019  
 29FTC117F0113  
 29FTC117F0148  
 29FTC117F0161  
 GRADUATE SCHOOL  
 FTC10H0293  
 FTC12G2146  
 FTC13G3074  
 FTC15G5111  
 FTC08G8218  
 FTC09G9172  
 GREENWAY&GREENWAY  
 FTC09H9227  
 GRILLI, PETER J PA  
 GTSI CORP.  
 FTC09H9100  
 FTC10H0118  
 FTC11H1224  
 FTC07G7224  
 FTC08G8309  
 FTC09G9250  
 GUARDIUM, INC.  
 FTC09H9001  
 FTC10H0002  
 H M S ENTERPRISES INC.  
 FTC07H7160  
 H. CO. COMPUTER PRODUCTS, INC.  
 29FTC118F0036  
 FTC16G6031  
 HARTEK INC  
 FTC09H9128  
 FTC06H6099  
 FTC06H6103  
 HAWORTH, INC  
 FTC07G7169  
 FTC08G8236  
 FTC09G9140  
 FTC09G9248  
 FTC10G0094  
 HEALTHY BUILDINGS INTERNATIONAL  
 (VA), INC.  
 FTC10G0148  
 FTC11G1163  
 FTC12G2130  
 HERMAN MILLER, INC  
 FTC08G8076  
 FTC08G8201  
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 FTC10G0088  
 HEWLETT PACKARD COMPANY  
 FTC07G7223  
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 HEWLETT PACKARD ENTERPRISE  
 COMPANY  
 29FTC117F0032  
 29FTC117F0112  
 29FTC117F0173  
 FTC16G6022  
 HIGHPOINT DIGITAL, INC.  
 29FTC117F0136  
 HMS TECHNOLOGIES, INC.  
 FTC16G6010  
 HOMELAND OFFICE PRODUCTS AND  
 EQUIPMENT INC.  
 FTC07G7261  
 FTC07G7262  
 HON COMPANY LLC, THE  
 FTC15G5047A  
 HOTEL BOROBUDUR JAKARTA  
 FTC13H3068  
 HOTEL RESTAURANT MARIA MONTEZ  
 FTC12H2264  
 HUMANSIZE CORP  
 FTC09G9193  
 FTC10G0095  
 FTC07G7244  
 I2 INC.  
 FTC09G9177  
 FTC10G0072  
 FTC10G0136  
 FTC10G0193  
 FTC11G1065  
 FTC12G2044  
 I3 FEDERAL LLC  
 FTC11G1176  
 ICF INC., L.L.C.  
 FTC10H0152  
 FTC13G3150  
 FTC14G4184A  
 ICF MACRO, INC  
 29FTC116P0029  
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 ICS NETT, INC.  
 FTC12H2125  
 FTC12H2137  
 FTC13H3003  
 FTC13H3076  
 IDEAL SYSTEM SOLUTIONS, INC.  
 29FTC117P0010  
 FTC09H9180  
 IFE GROUP  
 FTC09G9201  
 IHS GLOBAL INC.  
 FTC12H2155  
 FTC13H3054

IKONAS AUDIOVISUAL GROUP  
 FTC12H2171  
 IMAGES EXPRESS AUDIO VISUAL  
 FTC07H7142  
 IMMIXTECHNOLOGY INC  
 29FTC116F0009  
 FTC08G8026  
 FTC08G8063  
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 IMPACT TRAINING SYSTEMS INC  
 29FTC116F0091  
 29FTC117F0165  
 FTC07G7060  
 FTC07G7282  
 FTC08A8005  
 FTC08A8005/1001  
 FTC08A8005/1101  
 FTC08A8005/8002  
 FTC08A8005/8003  
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 FTC08G8057  
 FTC10G0266  
 FTC10H0243  
 FTC12H2151  
 FTC13A3008/0003  
 FTC13A3008/0003A  
 FTC13A30080004  
 FTC13A3008/0007  
 FTC13A3008/0009  
 IMPRES TECHNOLOGY SOLUTIONS, INC.  
 FTC12H2231  
 FTC12H2238  
 IMS GOVERNMENT SOLUTIONS, INC  
 29FTC117C0022  
 FTC08H8245  
 FTC11H1178  
 IN2TITIVE  
 FTC12H2258  
 INDATA CORP.  
 FTC09H9125  
 FTC10H0173  
 FTC11H1107  
 INDEPENDENT STATIONERS INC  
 FTC09G9020  
 FTC09G9203  
 FTC09G9204  
 FTC09G9218  
 FTC11G1041  
 FTC11G1116  
 FTC12G2127  
 INDIGOIT, LLC  
 FTC08H8279  
 INDUSTRIAL INFO RESOURCES, INC.  
 FTC08H8225  
 FTC11H1154  
 INFORMA BUSINESS INFORMATION, INC.  
 FTC16H6036  
 INFORMATION ANALYSIS INC.  
 FTC08H8070  
 INFOUSA INC.  
 FTC08G8203  
 FTC09G9195  
 FTC10G0176  
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 FTC12G2085  
 INSCAPE CORP.  
 FTC10G0152  
 FTC10G0157  
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 FTC09G9129  
 FTC09G9155  
 FTC10G0124  
 INSYS INC  
 FTC07G7314  
 FTC07G7315  
 INTEGRATION TECHNOLOGIES GROUP,  
 INC.  
 29FTC116F0003  
 29FTC116F0014  
 29FTC116F0053  
 29FTC116F0076  
 29FTC116F0086  
 29FTC117F0036  
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 29FTC117F0087  
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 29FTC118P0008  
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 FTC15G5149  
 INTELLIGENT DECISIONS INC.  
 FTC08G8297  
 FTC13G3092  
 FTC16G6043  
 INTELLIGENT ENTERPRISE SOLUTIONS,  
 LLC  
 FTC10G0166  
 FTC11G1058  
 FTC12H2150  
 INTERACTIVE COMMUNICATIONS  
 SOLUTIONS GROUP, INC.  
 FTC07G7237  
 FTC09G9043  
 INTERFACE AMERICAS INC.  
 FTC08G8190  
 INTERIMAGE, INC.  
 FTC07G7001  
 FTC08G8296  
 FTC13G3001  
 FTC07G7001A  
 FTC07G7001B  
 FTC07G7001C  
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 FTC13H3144  
 INTERNATIONAL BUSINESS MACHINES  
 CORP.  
 FTC09G9211  
 FTC10H0277  
 FTC11H1051  
 INTERNATIONAL SYSTEMS MARKETING,  
 INC.  
 FTC10H0251  
 IPSOS REID PUBLIC AFFAIRS INC.  
 FTC13G3112  
 IRIT AND STEVEN TADELIS  
 FTC15H5067  
 IRON BOW TECHNOLOGIES, LLC  
 29FTC117F0102  
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 FTC10G0263A  
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 IRON MOUNTAIN GOVERNMENT  
 SERVICES INC.  
 FTC07G7037  
 FTC07G7220  
 IRON MOUNTAIN INC.  
 FTC08H8270  
 FTC09H9115  
 IRON MOUNTAIN INFORMATION  
 MANAGEMENT LLC  
 FTC15G5023  
 ISAAC FAIR CORP. (aka FAIR ISAAC)  
 FTC08H8144  
 IT FEDERAL SALES LLC  
 FTC16G6039  
 J B CUBED, INC.  
 FTC09G9260  
 JACQUES WARCOIN  
 FTC08H8052  
 JAMF SOFTWARE, LLC  
 FTC12H2045  
 JDG ASSOCIATES, INC.  
 FTC09H9066  
 JDG COMMUNICATIONS, INC.  
 FTC06G6259  
 JOFCO INC.  
 FTC09G9085A  
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 FTC08G8164  
 FTC08G8239  
 FTC09G9216  
 FTC10G0105  
 FTC10G0174  
 JOHN DAY CONSULTING, INC.  
 FTC13H3142  
 JOHNSON CONTROLS, INC.  
 FTC06G6289A  
 FTC06G6282  
 FTC07G7124  
 FTC07G7216  
 JON KROSNICK CONSULTING  
 29FTC116P0039  
 JONES LANG LASALLE INC.  
 FTC11H1096  
 JTF BUSINESS SYSTEMS INC.  
 FTC14G4025  
 FTC14G4026  
 FTC14G4037  
 FTC14G4041  
 JUDITH KORNER  
 FTC12H2051A  
 JUSEM, PEARL  
 FTC08G8202  
 KATHERINE PORTER  
 FTC09H9048A  
 KATZEN, SALLY  
 FTC11H1078  
 KESSELRUN CORPORATE TRAVEL

SOLUTIONS, LLC  
 FTC14G4141  
 KHAN, IKHLAS  
 FTC16H6018  
 KIMBALL INTERNATIONAL, INC.  
 FTC07G7219  
 FTC07G7281  
 FTC08G8211  
 FTC10G0177  
 FTC07G7251  
 KLEIMANN COMMUNICATION GROUP INC.  
 FTC07H7179  
 FTC09H9038  
 FTC10H0227  
 KNOLL INC.  
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 FTC08G8071  
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 FTC08G8150  
 FTC08G8154  
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 FTC11G1034  
 KONICA MINOLTA BUSINESS SOLUTIONS  
 USA INC.  
 FTC12G2123  
 FTC09H9018  
 KONTURA SLOVAKIA  
 FTC12H2170  
 KROLL CYBER SECURITY, INC.  
 FTC15H5003  
 KRUG INC.  
 FTC10G0108  
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 FTC10G0156  
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 FTC09G9120  
 FTC10G0151  
 KYOCERA MITA AMERICA INC.  
 FTC07G7056  
 FTC08G8040  
 L 3 COMMUNICATIONS CORP. (4475)  
 FTC10G0128  
 FTC10G0204  
 FTC08H8062  
 FTC09H9123  
 FTC10H0107  
 LAMPS PLUS, INC.  
 29FTC117C0174  
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 LANGUAGE DOCTORS INC., THE  
 FTC07G7193  
 LAW BUSINESS RESEARCH LTD  
 FTC15H5033  
 LAW OFFICE OF CHRISTINE M COOPER,  
 THE  
 FTC10H0073  
 LEASE GROUP RESOURCES INC.  
 FTC06H6018  
 FTC07H7015  
 LEASING TECHNOLOGIES, INC.  
 FTC12G2060  
 LECC LLC  
 FTC07H7039  
 FTC07H7127  
 LEE AND ASSOCIATES LLC  
 FTC09G9030  
 LEGAL SCIENCE  
 FTC11H1222  
 LEIDOS ASPEN SYSTEMS CORP.  
 292G0021  
 FTC06G6166A  
 FTC06G6166B  
 FTC07G7098A  
 LEOPOLDO ARISMENDY RODRIGUEZ  
 ARDON  
 FTC08H8187  
 LEVITIN, ADAM  
 FTC08H8162  
 LEXIS NEXIS SPECIAL SERVICES INC.  
 FTC11H1213  
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 LIEBERT GLOBAL SERVICES INC.  
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 LINDEN RESOURCES, INC.  
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 LIOCE GROUP INC., THE  
 29FTC117F0092  
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 LOCKHEED MARTIN FEDERAL  
 HEALTHCARE INC.  
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 LOGICUBE, INC.  
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 FTC10H0303  
 LOGISTICS MANAGEMENT INSTITUTE  
 FTC12H2254  
 LOUDOUN EVENTS LLC  
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 LRP PUBLICATIONS, INC.  
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 L-SOFT SWEDEN AB  
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 LUTHRA & LUTHRA  
 FTC06H6020  
 LYME COMPUTER SYSTEMS, INC.  
 FTC13G3105  
 M A FEDERAL, INC.  
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 M. C. DEAN, INC.  
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 MACDONALD MEDIA, LLC  
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 MACRO INTERNATIONAL, INC  
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 MANAGEMENT CONCEPTS, INC.  
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 MANAGEMENT SUPPORT TECHNOLOGY  
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 MARCO MEETINGS, INC  
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 MARIA VILLAFLO  
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 MARK BUDNITZ, ATTORNEY AT LAW  
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 MARSHALL COMMUNICATIONS CORP.  
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 MARTIN FULLER APPRAISALS, LLC  
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 MARZIK INC  
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 MATTHEW BENDER & COMPANY INC  
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 MATWORKS COMPANY, LLC, THE  
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 MCGRAW-HILL COMPANIES INC, THE  
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 MCKENNEY'S, INC.  
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 MCP COMPUTER PRODUCTS INC  
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 MEMORY EXPERTS INTERNATIONAL  
 (USA) INC.  
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 MERCHANTS AUTOMOTIVE GROUP INC.  
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 MERGERMARKET (U.S.) LTD.  
 MERLIN INTERNATIONAL, INC.  
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 MERLIN SOFTWARE CORP  
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 METRO OFFICE SOLUTIONS INC.  
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FTC09G9168	<i>DRUG PROGRAMS, INC.</i>	<i>NORTH AMERICAN PRECIS SYNDICATE INC.</i>
FTC09G9240	29FTC116C0134	FTC08G8288
FTC09G9247	<i>NATIONAL ECONOMIC RESEARCH ASSOCIATES INC.</i>	FTC07G7186
FTC10G0036	FTC07H7088	FTC09H9167
FTC10G0110	FTC07H7117	<i>NPD GROUP INC</i>
FTC10G0114	FTC13H3122	FTC08H8077
FTC10G0153	<i>NATIONAL INSTITUTE FOR TRIAL ADVOCACY</i>	FTC08H8190
FTC10G0159	FTC11H1164	FTC08H8014
FTC12A2005/1401	FTC12H2122	FTC09H9262
<i>METRO OFFICE SYSTEMS INC</i>	FTC12H2160	FTC10H0106
FTC09H9075	FTC12H2215	FTC12H2072
FTC12H2074	FTC13H3064	<i>NPI, INC.</i>
FTC07H7006	FTC08H8192	FTC08H8118
FTC07H7030	FTC10H0103	FTC09H9124
<i>MICROPACT ENGINEERING INC.</i>	FTC10H0258	FTC09H9200
FTC08G8075	FTC10H0332	FTC14A40060002
FTC08G8234	<i>NATIONAL INSTITUTE OF TRANSITION PLANNING INC</i>	FTC18S0208
FTC10G0026	FTC08H8200	<i>NUMERICAL ALGORITHMS GROUP, INC.</i>
FTC11G1018	FTC09H9201	FTC08H8084
FTC13G3023	FTC10H0291	<i>OCE-USA INC</i>
FTC12G2001A	<i>NATIONAL PRESS CLUB OF WASHINGTON, DC, INC. (THE)</i>	FTC07G7039
<i>MICROSOFT CORP.</i>	FTC10H0120	<i>OCTO CONSULTING GROUP, INC.</i>
FTC08H8072	<i>NAVIGANT CONSULTING, INC.</i>	FTC13Z3012/1001
FTC09H9063	FTC11H1033	<i>OECD</i>
FTC11H1079	FTC16H6043	FTC09H9031
FTC12H2106	<i>NEO TECH SOLUTIONS INC.</i>	<i>OFFICE DESIGN GROUP, INC.</i>
<i>MICROTECHNOLOGIES LLC</i>	FTC12G2037	29FTC117C0108
FTC09H9268	FTC12G2048	<i>OFFICE ENVIRONMENTS INTERNATIONAL</i>
<i>MID-ATLANTIC AUTOMATIC DOOR LLC</i>	<i>NET REACTION, LLC</i>	29FTC117F0154
FTC15H5135	FTC14H4045	<i>OFFICEMAX INC.</i>
<i>MID-WEST MOVING &amp; STORAGE, INC.</i>	<i>NETCENTRICS CORP</i>	FTC08G8125
29FTC117C0100	FTC09H9114	FTC08G8241
<i>MINTEL INTERNATIONAL GROUP LIMITED</i>	<i>NETRATINGS INC.</i>	FTC09G9015
FTC10H0265	FTC06H6163	FTC09G9062
<i>MISSOURI SYSTEM UNIVERSITY OF</i>	<i>NETRATINGS, LLC</i>	FTC09G9074
FTC07H7185	FTC10H0113	<i>OFFICEPRO, INC</i>
FTC10H0187	<i>NEVINS LTD, THE</i>	FTC11G1046
<i>MK 55 WEST INVESTOR LLC</i>	FTC07G7254	<i>OFS BRANDS HOLDINGS INC.</i>
FTC12H2115	<i>NEW HOPE EDUCATIONAL INSTITUTE INC</i>	FTC07G7196
<i>MOBILE VIDEO SERVICES LIMITED</i>	FTC10H0214	<i>OHLHAUSEN RESEARCH INC</i>
FTC06G6342	<i>NEW IMAGE MKTG INC</i>	FTC10H0245
FTC09G9046	FTC09H9070	<i>OIL PRICE INFORMATION SERVICE, LLC</i>
<i>MODERN IMAGING SOLUTIONS, INC.</i>	<i>NEW TECH SOLUTIONS INC.</i>	29FTC116P0033
FTC10H0244	FTC16G6013	FTC11H1153
<i>MOI, INC.</i>	29FTC116F0007	FTC12H2216
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FTC12A2004/2000	29FTC117F0050	FTC13H3151
<i>MRF CONSULTING LLC</i>	29FTC117F0060	FTC13H3152
FTC06G6100	29FTC117F0096	FTC15H5175
FTC07G7199	29FTC117F0117	<i>OMNI ELEVATOR, INC</i>
FTC09G9160	29FTC117F0140	FTC11G1099
<i>MS MIAMI INTERNATIONAL SOFTWARE</i>	29FTC117F0167	<i>ONE TO ONE ENGLISH ACADEMY</i>
FTC08H8275	29FTC118F0078	FTC12H2174
<i>MSAB INC.</i>	FTC16G6015	FTC13H3063
FTC12H2228	<i>NEW TECHNOLOGY PARTNERS INC</i>	<i>ONIX NETWORKING CORP.</i>
<i>MYRIAD SOLUTIONS</i>	FTC10H0290	29FTC116F0031
FTC11G1129	<i>NGUYENIE ASSOCIATION</i>	FTC08G8146
FTC12G2137	FTC08H8099	FTC08G8188
FTC07G7233	<i>NIELSEN COMPANY (US), LLC, THE</i>	FTC09G9112
<i>MYTHICS, INC</i>	FTC10H0177	FTC09G9180
FTC12G2013	<i>NIELSEN COMPANY LLC, THE</i>	FTC10G0170
FTC12G2015	FTC09H9244	FTC10G0188
FTC12G2031	<i>NIELSEN MEDIA RESEARCH INC. (0569)</i>	FTC10G0215
FTC12G2035	FTC06H6180	FTC11G1067
<i>NAMTEK CORP.</i>	FTC08H8154	FTC11G1128
FTC11H1216	FTC08H8199	FTC12G2155
FTC12G2142	<i>NIELSEN, A. C. COMPANY (INC)</i>	<i>OPEN TEXT INC</i>
FTC14G4171	FTC08H8181	FTC13H3155
<i>NATIONAL BUSINESS FURNITURE LLC.</i>	<i>NORRIS WARD MCKINNON</i>	FTC09H9183
FTC09H9027	FTC10H0207	FTC10H0253
FTC08H8198	<i>NORSTAN COMMUNICATIONS INC.</i>	FTC11H1175
<i>NATIONAL CAPITOL CONTRACTING, LLC</i>	FTC08H8001	FTC12H2178
FTC14G4209		<i>OPERATIONAL RESEARCH CONSULTANTS</i>
<i>NATIONAL CONSUMER LAW CENTER, INC</i>		FTC06G6322
FTC08H8067		FTC11G1066
<i>NATIONAL COUNCIL FOR PRESCRIPTION</i>		

ORACLE AMERICA, INC.  
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 ORACLE CORP.  
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 ORACLE USA INC  
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 P AND P GENERAL CONTRACTORS INC.  
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 P B I, INC  
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 PAISLEY CONSULTING, INC.  
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 PARAGON SYSTEMS LLC  
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 PARKER TIDE CORP.  
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 PARTNERSHIP FOR PUBLIC SERVICE, INC.  
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 FTC12H2130  
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 FTC14H4089  
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 FTC15A50020004  
 FTC15G5011  
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 PASSWARE, INC.  
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 PATERVA (PTY) LTD  
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 PATRIOT TECHNOLOGIES INC  
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 PAWPRINTZ SOLUTIONS INC.  
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 PC MALL GOV INC  
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 FTC12G2100  
 FTC12G2164  
 PC SPECIALISTS, INC.  
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 FTC13H3013

PCMG, INC.  
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 PEPCO  
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 PEPCO ENERGY SERVICES INC.  
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 PERIDOT SOLUTIONS, LLC  
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 PIFINITY, INC.  
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 PINTO-MARTIN, JENNIFER A  
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 PITNEY BOWES INC  
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 PKWARE, INC.  
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 PLAN B GOVERNMENT SYSTEMS  
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 POLINGER COMPANY  
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 POLITICO, LLC  
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 PORTFOLIO MEDIA, INC.  
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 POWER SWABS CORP.  
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 PR NEWSWIRE ASSOCIATION LLC  
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 PRATKANIS, ANTHONY R  
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 PREMIER, INC.  
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 PRESIDIO NETWORKED SOLUTIONS, INC.  
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 PRICEWATERHOUSECOOPERS LLP  
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 PRIMESCAPE SOLUTIONS INC.  
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 PROMARK TECHNOLOGY INC  
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 PROMOTOUCH INC  
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 PTY SHUTTLE  
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 QUALITY ASSOCIATES INCORPORATE  
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 RADIO COMPUTING SERVICES, INC.  
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 RAND CONSTRUCTION CORP.

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 RDS MANAGEMENT RESEARCH, INC.  
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 READMORE INC  
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 REALNETWORKS INC  
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 RED RIVER COMPUTER COMPANY INC.  
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 REED ELSEVIER INC.  
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 WORLDWIDE, INC.  
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 RENTACRATE LLC  
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 RESEARCH IN MOTION CORP.  
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 FTC13H3042  
 RICH, DEANA CONSULTING  
 FTC13H3103  
 RICHARDS-WILCOX, INC (DEL)  
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 RICOH AMERICAS CORP.  
 FTC07G7055  
 RISK MANAGEMENT CONSULTING  
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 RJG ASSOCIATES  
 FTC09H9137A  
 ROBB EVANS & ASSOCIATES LLC  
 FTC09H9127  
 ROCK CREEK PUBLISHING GROUP INC.  
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 ROCKHURST UNIVERSITY CONTINUING  
 EDUCATION CENTER INC  
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 ROLL CALL, INC.  
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 RUSSELL L VALENTINE JR  
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 SAFE PASSAGE INTERNATIONAL, INC.  
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 SAP PUBLIC SERVICES, INC.  
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SAS INSTITUTE INC. FTC09H9208 FTC12H2135	FTC07G7017A FTC07G7018A FTC07G7019A	SPIRAX SARCO, INC. FTC08G8213 FTC10H0191
SCAN-OPTICS LLC FTC10H0022 FTC13H3015	FTC07G7020A FTC10H0326 FTC15H5045	SPOK INC FTC08G8004
SCB SOLUTIONS, INC. FTC11H1191	FTC12H2005 SIGNET PARTNERS, A CORP. FTC09G9237	SPRINT COMMUNICATIONS COMPANY L.P. FTC08G8166 FTC09G9212
SCHOONER, HEIDI MANDANIS FTC08H8132	SILEO INC FTC10H0154	ST NET INC. FTC07G7213
SCIENCE APPLICATIONS INTERNATIONAL CORP. 5Z50060501	SITEIMPROVE, INC. 29FTC118F0015	STACEY COFIELD FTC07H7151
SECOND TO NONE, INC. FTC07H7184 FTC09H9034 FTC10H0145 FTC12H2073	SKY TELEVISION INC FTC09H9042 FTC10H0030	STANDARD GRAPHICS MID-ATLANTIC, INC FTC14H4081A
SECURE IDEAS, LLC FTC12H2210	SMITHS DETECTION INC. FTC10G0029	STANLEY PRESSER FTC-15-H-5054
SEEDS OF GENIUS CORP. FTC15G5130	SMS DATA PRODUCTS GROUP INC. FTC08G8050 FTC08H8033	STATAACORP LP FTC07H7137 29FTC116F0025 29FTC117F0119 29FTC116F0087
SEISAN CONSULTING LLC FTC08H8114	SOCIAL & SCIENTIFIC SYSTEMS, INC. FTC13H3167	FTC08H8262 FTC09H9235 FTC10G0231 FTC11G1115 FTC11H1012 FTC12G2029 FTC13G3006 FTC13G3117
SENET INTERNATIONAL CORP FTC07G7221 FTC07G7234	SOFT TECH CONSULTING INC FTC07H7148	STAY ONLINE CORP. FTC10H0097 FTC10H0208
SERVICESOURCE INC FTC09H9239	SOFTCHOICE CORP. FTC10G0060 FTC15H5187	STEELCASE INC FTC14G4193A FTC10G0081 FTC10G0130 FTC10G0137 FTC10G0138 FTC10G0183 FTC09G9136 FTC09G9238
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SHARP ELECTRONICS CORP. FTC10G0225	SOFTWARE & MORE FTC08H8080	STOCKING, JACQUELINE C. FTC15H5133
SHAVLIK TECHNOLOGIES LLC FTC10H0181 FTC10H0210 FTC11H1060 FTC11H1126 FTC11H1144	SOFTWARE FORENSICS, INC FTC10H0308 FTC11H1183	STRATEGIC INITIATIVES CONSULTI FTC13G3151
SHAW INDUSTRIES INC. FTC07G7280 FTC10G0191	SOFTWARE INFORMATION RESOURCE CORP. FTC08H8253 FTC10H0049 FTC11H1076	SUMMATION LEGAL TECHNOLOGIES INC. FTC07H7146
SHELTERED OCCUPATIONAL CENTER OF NORTHERN VIRGINIA INC. FTC07H7101	FTC12H2044 FTC12H2104 FTC13H3007 FTC13H3031 FTC13H3040 FTC13H3057 FTC13H3074 FTC13G3037	SUMMIT GROUP LLC FTC11H1121A FTC14H4101
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SHPS HUMAN RESOURCE SOLUTIONS INC FTC12H2123	SOLTANI LLC FTC12H2204	SUNNYMOON PRODUCTIONS FTC11H1174
SHUGOLL RESEARCH, INC. FTC14G4178A FTC10H0260	SONIC SOLUTIONS FTC08H8006 FTC09H9012 FTC10H0012	SUPERIOR INFORMATION SERVICES INC. FTC05H5246
SI INTERNATIONAL INC. FTC07G7288	SPACESAVER STORAGE SYSTEMS INC FTC05G5219	SUPPLYSOURCE DC, LLC 29FTC117F0172
SICO AMERICA INC. FTC07H7140	SPAETH COMMUNICATIONS INC 29FTC117P0080 FTC08G8157	SWISH DATA CORP. FTC12H2095
SIEMENS BUILDING TECHNOLOGIES INC FTC09H9003 FTC09H9102 FTC09H9198 FTC10H0014 FTC11H1038 FTC07H7017 FTC08H8020	SPECTRA LOGIC CORP. FTC-11-G1088 FTC07G7318 FTC08G8082 FTC08G8294 FTC09G9068 FTC10G0169 FTC12H2140	SWORD & SHIELD ENTERPRISE SECURITY, INC.
SIEMENS COMMUNICATIONS INC FTC08G8008 FTC08G8011A	SPECTRUM SYSTEMS, INC. FTC08G8169 FTC10G0045 FTC12G2024	
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SIEMENS INDUSTRY INC FTC06G6004 FTC07G7011A		

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 SYSTEM ENGINEERING INTERNATIONAL  
 INC  
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 SYSTEM TOOLS, LLP  
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 TANDBERG, INC  
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 TECH, INC  
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 TENABLE NETWORK SECURITY, INC.  
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 TESS WALD PRODUCTIONS, INC.  
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 THE BUREAU OF NATIONAL AFFAIRS  
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 THE GUNLOCKE COMPANY  
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 HON COMPANY, THE  
 FTC09G9165  
 MATHWORKS INC., THE  
 29FTC116P0017  
 FTC08H8156  
 FTC08H8261  
 FTC09H9162  
 FTC10H0013  
 FTC10H0224  
 FTC11H1024  
 FTC11H1146  
 FTC12H2004  
 FTC12H2176  
 FTC15H5157A  
 OGILVY GROUP INC., THE  
 FTC07G7310  
 PRESIDIO CORP., THE  
 FTC08G8112  
 FTC09G9039  
 FTC09G9096  
 FTC09G9098  
 FTC09G9099  
 FTC09G9208  
 FTC10G0126  
 FTC11G1049  
 THERM-O-LITE INC  
 FTC09G9156  
 THOMAS W BLACK  
 FTC09H9109  
 THOMSON HEALTHCARE INC.  
 FTC08H8069  
 THOMSON REUTERS (HEALTHCARE) INC.  
 FTC09H9207  
 THREE WIRE SYSTEMS  
 FTC09G9032  
 THUNDERCAT TECHNOLOGY, LLC  
 29FTC116F0080  
 29FTC117F0160  
 FTC12H2223  
 TINA Y MARK  
 FTC07G7336  
 TKC INTEGRATION SERVICES LLC  
 FTC09G9040  
 FTC10G0118  
 T-MOBILE USA INC  
 FTC08G8045  
 FTC08G8172  
 FTC10G0067  
 FTC08G8045A  
 TONER EXPRESS USA INC  
 FTC08G8055  
 FTC08G8258  
 TRACTENBERG, ROCHELLE  
 FTC14H4084  
 TRANSOURCE SERVICES CORP.  
 29FTC117F0006  
 29FTC117F0041  
 TRIAL RUN INC  
 FTC08A8012/8002  
 FTC08A8012/9001  
 FTC08A8012/9002  
 TRIGEO NETWORK SECURITY INC  
 FTC09H9036  
 FTC10H0045  
 FTC10H0315  
 FTC11H1058  
 FTC11H1118  
 FTC07H7155  
 TRINH ANH TUAN  
 FTC08H8100  
 TRINITY FURNITURE INC.  
 FTC10G0106  
 TSRC, INC.  
 FTC12G2036  
 FTC12G2079  
 FTC12G2080  
 FTC13G3029  
 FTC13G3062  
 FTC15G5017  
 UCG INFORMATION SERVICES LLC  
 FTC08H8010  
 UCG INFORMATION SERVICES, LLC  
 FTC08H8183  
 FTC09H9138  
 FTC09H9188  
 FTC10H0220  
 FTC11H1025  
 FTC11H1152  
 UI WIZARDS INC  
 FTC14H4102  
 UNICA CORP.  
 FTC08H8051  
 UNICOM GOVERNMENT, INC.  
 FTC08G8319  
 UNISTAR-SPARCO COMPUTERS, INC.  
 29FTC116F0037  
 29FTC116F0085  
 29FTC116F0089  
 UNISYS CORP.  
 FTC08G8079  
 FTC10G0134  
 FTC11G1101  
 UNITED BUSINESS MACHINES, INC.  
 FTC08H8267  
 UNITED PARCEL SERVICE INC (OH)  
 FTC07A7004  
 UNIVERSITY OF MISSISSIPPI  
 FTC09H9047  
 URLA MENENDEZ  
 V070501007  
 URS FEDERAL SERVICES, INC.  
 FTC12G2128  
 US INVESTIGATIONS SERVICES INC.  
 FTC13G3031  
 V & C BROTHERS  
 FTC07A7002  
 V3GATE, LLC  
 29FTC118F0042  
 VADOR VENTURES INC  
 FTC09H9259  
 FTC11H1061  
 FTC05L5029  
 FTC05L5029A  
 FTC05L5029B  
 VARIDESK, LLC  
 29FTC117C0132  
 FTC15H5074

VARITRONIC SYSTEMS INC. FTC07G7323	FTC11G1153	FTC14A4002/0009
VBRICK SYSTEMS, INC FTC09G9086	WESTPORT63 CONSULTING FTC08H8011	FTC14A4002/0011
FTC10G0232	WHITAKER BROTHERS BUSINESS MACHINES INC FTC10G0117	FTC14A4002/0012
VERISIGN INC. FTC07G7203	WILLIAM S. HEIN & CO., INC. FTC09H9089	FTC14A4002/0015
FTC08H8068	FTC10H0127	FTC14A4002/0017
FTC09H9056	FTC11H1089	FTC14A4002/0018
FTC10H0066	FTC12H2126	FTC15G5081
FTC11H1123	FTC14H4077	FTC16G6045
VERISPAN LLC FTC07H7169	FTC15H5112	[FR Doc. 2019-16954 Filed 8-7-19; 8:45 am]
FTC08H8179	WILMARTH JR, ARTHUR E FTC08H8142	<b>BILLING CODE 6750-01-P</b>
VERITY, INC FTC08G8131	WILSON-EPES PRINTING CO INC FTC09H9087	<b>FEDERAL TRADE COMMISSION</b>
FTC09G9104	WINERMAN, MARC FTC14H4088	<b>Agency Information Collection Activities; Proposed Collection; Comment Request; Extension</b>
VERSAR SECURITY SYSTEMS, LLC FTC07G7149	WIRTHLIN WORLDWIDE, LLC FTC08G8285	<b>AGENCY:</b> Federal Trade Commission.
VERTIV SERVICES, INC. FTC10H0046	WOLFRAM RESEARCH INC. FTC08H8278	<b>ACTION:</b> Notice.
VIAFORENSICS FTC14H4063	FTC09H9126	<b>SUMMARY:</b> The Federal Trade Commission (“FTC” or “Commission”) is seeking public comment on its proposal to extend for an additional three years the current Paperwork Reduction Act (“PRA”) clearance for information collection requirements in its “Used Motor Vehicle Trade Regulation Rule” (“Used Car Rule” or “Rule”), which applies to used vehicle dealers. That clearance expires on December 31, 2019.
VICTORIA A HASTIE FTC09H9264	FTC10H0017	<b>DATES:</b> Comments must be filed by October 7, 2019.
VISION TECHNOLOGIES, INC. FTC15A5003/03	FTC08H8075	<b>ADDRESSES:</b> Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the <b>SUPPLEMENTARY INFORMATION</b> section below. Write “Used Car Rule, PRA Comment, FTC File No. [P137606]” on your comment, and file your comment online at <a href="https://www.regulations.gov">https://www.regulations.gov</a> by following the instructions on the web- based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex J), Washington, DC 20024.
FTC15A5003/2	FTC10H0215	<b>FOR FURTHER INFORMATION CONTACT:</b> Elizabeth Scott, (312) 960-5609, Attorney, Midwest Region, Federal Trade Commission, 230 South Dearborn Street, Suite 3030, Chicago, IL 60604.
FTC15A5003	FTC11H1023	<b>SUPPLEMENTARY INFORMATION:</b> The Used Car Rule promotes informed purchasing decisions by requiring that used car dealers display a form called a “Buyers Guide” on each used car offered for sale that, among other things, discloses information about warranty coverage,
FTC15A5003	FTC11H1132	
VISIONTECH INC FTC10G0207B	FTC16H6021	
VMWARE, INC. FTC08H8195	WORKRITE ERGONOMICS INC FTC15G5054	
FTC10H0213	WORLD WIDE TECHNOLOGY INC FTC08G8101	
FTC12H2153	FTC08G8122	
VVL SYSTEMS & CONSULTING, LLC FTC14H4178	FTC08G8142	
W S I MANUFACTURING INC. FTC09G9102	FTC09G9083	
FTC11G1055	FTC09G9251	
WASHINGTON EXPRESS LLC FTC12G2014	FTC11G1029	
WASHINGTON REFRIGERATION CO., INC. FTC09H9113	FTC11G1033	
WAVE SOFTWARE, LLC FTC12H2041	FTC11G1168	
FTC13H3035	29FTC117F0162	
FTC15H5153	XEROX CORP. FTC06G6300	
WAYSIDE TECHNOLOGY GROUP, INC. FTC08H8063	FTC06G6300A	
WEAVER, CONNIE M FTC10H0327	FTC08G8034A	
WEINSCHENK INSTITUTE, LLC FTC13H3034	FTC13G3015	
FTC13H3069	XL CONSTRUCTION, LLC FTC10H0223	
WERRES CORP. FTC09G9183	YORK TELECOM CORP. Task order number after the “/” 29FTC116F0024	
WEST PUBLISHING CORP FTC08G8006B	29FTC117F0024	
FTC08G8053	29FTC117F0003	
FTC08H8272	29FTC117F0004	
FTC09G9076	29FTC117F0010	
FTC09G9243	29FTC117F0030	
FTC11G1069	29FTC117F0037	
FTC11G1157	29FTC117F0040	
FTC12G2061	29FTC117F0059	
FTC12H2120	29FTC117F0074	
FTC13G3053	29FTC117F0086	
FTC13G3061	29FTC117F0143	
FTC13H3157	29FTC118F0003	
FTC16G6052	29FTC118F0013	
WESTAT, INC FTC08G8065	29FTC118F0043	
FTC06G6261	29FTC118F0044	
WESTCON GROUP NORTH AMERICA, INC. FTC14A4002/0002	29FTC118F0053	
	29FTC118F0065	
	FTC14A4002/0002	
	FTC14A4002/0003	
	FTC14A4002/0004	
	FTC14A4002/0005	
	FTC14A4002/0006	
	FTC14A4002/0007	
	FTC14A4002/0008	

and other information to assist purchasers.

### Burden Statement

Under the PRA, 44 U.S.C. 3501–3521, Federal agencies must obtain OMB approval for each collection of information they conduct or sponsor. “Collection of information” includes agency requests or requirements to submit reports, keep records, or provide information to a third party. 44 U.S.C. 3502(3); 5 CFR 1320.3(c). As required by section 3506(c)(2)(A) of the PRA, the FTC is providing this opportunity for public comment before requesting that OMB extend the existing paperwork clearance for the Used Car Rule, 16 CFR part 455 (OMB Control Number 3084–00108).

The Rule has no recordkeeping or reporting requirements. As detailed further under the Request for Comment, the FTC seeks clearance for the Rule’s disclosure requirements and the estimated PRA burden for them.

*Estimated total annual hours burden:* 2,368,993.

As explained in more detail below, this total is based on estimates of the number of used car dealers (53,779<sup>1</sup>), the number of used cars sold by dealers annually (approximately 29,214,371<sup>2</sup>), and the time needed to fulfill the information collection tasks required by the Rule.<sup>3</sup>

The Rule requires that used car dealers display a one-page, double-sided Buyers Guide on each used car that they offer for sale. The component tasks associated with the Rule’s required display of Buyers Guides include: (1) Ordering and stocking Buyers Guides; (2) entering data on Buyers Guides; (3) displaying the Buyers Guides on vehicles; (4) revising Buyers Guides as necessary; and (5) complying with the Rule’s requirements for sales conducted in Spanish.

1. *Ordering and Stocking Buyers Guides:* Dealers should need no more than an average of two hours per year to obtain Buyers Guides, which are

<sup>1</sup> 37,026 independent dealers. *NIADA Used Car Industry Report* (2014), at 16. 16,753 franchised new car dealers in 2018. *NADA Data 2018: Annual Report*, at 5.

<sup>2</sup> The estimated number of used car sold annually is based on records for calendar year 2017 from the NIADA. *NIADA Used Car Industry Report* (2018), at 22.

<sup>3</sup> Some dealers opt to contract with outside contractors to perform the various tasks associated with complying with the Rule. Staff assumes that outside contractors would require about the same amount of time and incur similar costs as dealers to perform these tasks. Accordingly, the hour and cost burden totals shown, while referring to “dealers,” incorporate the time and cost borne by outside companies in performing the tasks associated with the Rule.

readily available from many commercial printers or can be produced by an office word-processing or desk-top publishing system.<sup>4</sup> Based on an estimated population of 53,779 dealers, the annual hours burden for producing or obtaining and stocking Buyers Guides is 107,558 hours.

2. *Entering Data on Buyers Guides:* The amount of time required to enter applicable data on Buyers Guides may vary substantially, depending on whether a dealer has automated the process. For used cars sold “as is,” copying vehicle-specific data from dealer inventories to Buyers Guides and checking the “No Warranty” box may take two to three minutes per vehicle if done by hand, and only seconds for those dealers who have automated the process or use pre-printed forms. Staff estimates that dealers will require an average of two minutes per Buyers Guide to complete this task. Similarly, for used cars sold under warranty, the time required to check the “Warranty” box and to add warranty information, such as the additional information required in the Percentage of Labor/Parts and the Systems Covered/Duration sections of the Buyers Guide, will depend on whether the dealer uses a manual or automated process or Buyers Guides that are pre-printed with the dealer’s standard warranty terms. Staff estimates that these tasks will take an average of one additional minute, *i.e.*, cumulatively, an average total time of three minutes for each used car sold under warranty.

Staff estimates that dealers sell approximately fifty percent of used cars “as is” and the other half under warranty. Therefore, staff estimates that the overall time required to enter data on Buyers Guides consists of 486,906 hours for used cars sold without a warranty (29,214,371 vehicles × 50% × 2 minutes per vehicle) and 730,359 hours for used cars sold under warranty (29,214,371 vehicles × 50% × 3 minutes per vehicle) for a cumulative estimated total of 1,217,265 hours.

3. *Displaying Buyers Guides on Vehicles:* Although the time required to display the Buyers Guides on each used car may vary, FTC staff estimates that dealers will spend an average of 1.75 minutes per vehicle to match the correct Buyers Guide to the vehicle and to display it on the vehicle. The estimated burden associated with this task is approximately 852,086 hours for the estimated 29,214,371 vehicles sold

annually (29,214,371 vehicles × 1.75 minutes per vehicle).

4. *Revising Buyers Guides as Necessary:* If negotiations between the buyer and seller over warranty coverage produce a sale on terms other than those originally entered on the Buyers Guide, the dealer must revise the Buyers Guide to reflect the actual terms of sale. According to the original rulemaking record, bargaining over warranty coverage rarely occurs. Staff notes that consumers often do not need to negotiate over warranty coverage because they can find vehicles that are offered with the desired warranty coverage online or in other ways before ever contacting a dealer. Accordingly, staff assumes that dealers will revise the Buyers Guide in no more than two percent of sales, with an average time of two minutes per revision. Therefore, staff estimates that dealers annually will spend approximately 19,476 hours revising Buyers Guides (29,214,371 vehicles × 2% × 2 minutes per vehicle).

5. *Spanish Language Sales:* The Rule requires dealers to make contract disclosures in Spanish if the dealer conducts a sale in Spanish.<sup>5</sup> The Rule permits displaying both an English and a Spanish language Buyers Guide to comply with this requirement.<sup>6</sup> Many dealers with large numbers of Spanish-speaking customers likely will post both English and Spanish Buyers Guides to avoid potential compliance violations.

Calculations from United States Census Bureau surveys indicate that approximately 5.4 percent of the United States population speaks Spanish at home, without also speaking fluent English.<sup>7</sup> Staff therefore projects that dealers will conduct approximately 5.4 percent of used car sales in Spanish. Dealers will incur the additional burden of completing and displaying a second Buyers Guide in 5.4 percent of sales assuming that dealers choose to comply with the Rule by posting both English and Spanish Buyers Guides. The annual hours burden associated with completing and displaying Buyers Guides is 2,069,351 hours (1,217,265 hours for entering data on Buyers Guides + 852,086 hours for displaying Buyers Guides). Therefore, staff estimates that the additional burden caused by the Rule’s requirement that

<sup>5</sup> 16 CFR 455.5.

<sup>6</sup> *Id.*

<sup>7</sup> U.S. Census Bureau, TableB16001. *Language Spoken at Home. 2017 American Community Survey 1-Year Estimates*, available at: [https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ACS\\_11\\_1YR\\_B16001&prodType=table](https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ACS_11_1YR_B16001&prodType=table) (last visited June 7, 2019) (5.4% of the United States population 5 years or older who speaks Spanish or Spanish Creole in the home speaks English less than “very well.”).

<sup>4</sup> Buyers Guides are also available online from the FTC’s website, [www.ftc.gov](http://www.ftc.gov), at <http://business.ftc.gov/selected-industries/automobiles>.

dealers display Spanish language Buyers Guides when conducting sales in Spanish is 111,745 hours (2,069,351 hours  $\times$  5.4% of sales). The other components of the annual hours burden, *i.e.*, purchasing Buyers Guides and revising them for changes in warranty coverage, remain unchanged.

6. *Optional Disclosures of Non-Dealer Warranties:* The Rule does not require dealers to disclose information about non-dealer warranties, but provides dealers with the options to disclose such warranties on Buyers Guides. FTC staff has estimated that dealers will make the optional disclosures on 25% of used cars offered for sale. Staff believes that checking the optional boxes to disclose a non-dealer warranty should require dealers no more than 30 seconds per vehicle. Accordingly, based on 29,214,371 used cars sold, staff estimates that making the optional disclosures entails a burden of 60,863 hours (25%  $\times$  29,214,371 vehicles sold  $\times$  1/120 hour per vehicle).

*Estimated annual cost burden:* \$40,083,362 in labor costs and \$8,764,311 in non-labor costs.

1. *Labor costs:* Labor costs are derived by applying appropriate hourly cost figures to the burden hours described above. Staff has determined that all of the tasks associated with ordering forms, entering data on Buyers Guides, posting Buyers Guides on vehicles, and revising them as needed, including the corresponding tasks associated with Spanish Buyers Guides and providing optional disclosures about non-dealer warranties, are typically done by clerical or low-level administrative personnel. Using a clerical cost rate of \$16.92 per hour<sup>8</sup> and an estimated burden of 2,368,993 hours for disclosure requirements, the total labor cost burden is \$40,083,362 (\$16.92 per hour  $\times$  2,368,993 hours).

2. *Capital or other non-labor costs:* Although the cost of Buyers Guides may vary, staff estimates that the average cost of each Buyers Guide is thirty cents based on industry input. Therefore, the estimated cost of Buyers Guides for the 29,214,371 used cars sold by dealers in 2017 is approximately \$8,764,311. In making this estimate, staff assumes that all dealers will purchase pre-printed forms instead of producing them internally, although dealers may produce them at lower expense using their own office automation technology.

Capital and start-up costs associated with the Rule are minimal.

*Request for Comment:* Pursuant to Section 3506(c)(2)(A) of the PRA, the FTC invites comments on: (1) Whether the disclosure, recordkeeping, and reporting requirements are necessary, including whether the resulting information will be practically useful; (2) the accuracy of our burden estimates, including whether the methodology and assumptions used are valid; (3) how to improve the quality, utility, and clarity of the disclosure requirements; and (4) how to minimize the burden of providing the required information to consumers.

You can file a comment online or on paper. For the FTC to consider your comment, we must receive it on or before October 7, 2019. Write “Used Car Rule, PRA Comment, FTC File No. [P137606]” on your comment. Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online, or to send them to the Commission by courier or overnight service. To make sure that the Commission considers your online comment, you must file it through the <https://www.regulations.gov> website by following the instructions on the web-based form provided. Your comment—including your name and your state—will be placed on the public record of this proceeding, including the <https://www.regulations.gov> website. As a matter of discretion, the Commission tries to remove individuals’ home contact information from comments before placing them on the [regulations.gov](https://www.regulations.gov) site.

If you file your comment on paper, write “Used Car Rule, PRA Comment, FTC File No. [P137606]” on your comment and on the envelope, and mail it to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex J), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible website at [www.regulations.gov](https://www.regulations.gov), you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal

information, such as your or anyone else’s Social Security number; date of birth; driver’s license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any “trade secret or any commercial or financial information which . . . is privileged or confidential”—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled “Confidential,” and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted publicly at [www.regulations.gov](https://www.regulations.gov), we cannot redact or remove your comment unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before October 7, 2019. For information on the Commission’s privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>.

**Heather Hipsley,**

*Deputy General Counsel.*

[FR Doc. 2019-16945 Filed 8-7-19; 8:45 am]

**BILLING CODE 6750-01-P**

<sup>8</sup>The hourly rate is based on the Bureau of Labor Statistics estimate of the mean hourly wage for office clerks, general. *Occupational Employment and Wages, May 2018, 43-9061 Office Clerks, General*, available at: <https://www.bls.gov/oes/current/oes439061.htm#nat>.

**DEPARTMENT OF DEFENSE****GENERAL SERVICES  
ADMINISTRATION****NATIONAL AERONAUTICS AND  
SPACE ADMINISTRATION**

[OMB Control No. 9000-0193; Docket No. 2019-0003; Sequence No. 22]

**Submission for OMB Review; FAR Part 9 Responsibility Matters**

**AGENCY:** Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

**ACTION:** Notice.

**SUMMARY:** Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division has submitted to the Office of Management and Budget (OMB) a request to review and approve a revision and renewal of a previously approved information collection requirement regarding the responsibility of prospective contractors.

**DATES:** Submit comments on or before September 9, 2019.

**ADDRESSES:** Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for GSA, Room 10236, NEOB, Washington, DC 20503 or at [Oira\\_submission@omb.eop.gov](mailto:Oira_submission@omb.eop.gov). Additionally submit a copy to GSA by any of the following methods:

- *Federal eRulemaking Portal:* This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments. Go to <http://www.regulations.gov> and follow the instructions on the site.

- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405. ATTN: Lois Mandell/IC 9000-0193, FAR Part 9 Responsibility Matters.

*Instructions:* All items submitted must cite Information Collection 9000-0193, FAR Part 9 Responsibility Matters. Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check [www.regulations.gov](http://www.regulations.gov), approximately two-to-three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

**FOR FURTHER INFORMATION CONTACT:** Ms. Mahruba Uddowla, Procurement Analyst, at telephone 703-605-2868, or [mahruba.uddowla@gsa.gov](mailto:mahruba.uddowla@gsa.gov).

**SUPPLEMENTARY INFORMATION:****A. OMB Control Number, Title, and Any Associated Form(s)**

9000-0193, FAR Part 9 Responsibility Matters.

**B. Needs and Uses**

DoD, GSA, and NASA are in the process of combining OMB Control Nos. for the Federal Acquisition Regulation (FAR) by FAR part. This consolidation is expected to improve industry's ability to easily and efficiently identify all burdens associated with a given FAR part. The review of the information collections by FAR part allows improved oversight to ensure there is no redundant or unaccounted for burden placed on the public. Lastly, combining information collections in a given FAR part is also expected to reduce the administrative burden associated with reviewing, processing, or commenting on multiple information collections.

This justification supports renewal of OMB Control No. 9000-0193 and combines it with the previously approved information collections OMB Control No(s). 9000-0094, with the new title "FAR Part 9 Responsibility Matters". Upon approval of this consolidated information collection, OMB Control No(s). 9000-0094 will be discontinued. The burden requirements previously approved under the discontinued Number(s) will be covered under OMB Control No. 9000-0193.

This clearance covers the information that offerors and contractors must submit to comply with the following FAR requirements:

1. *Prohibition on Contracting With Corporations with Delinquent Taxes or a Felony Conviction (FAR 52.209-11, 52.209-12, and 52.212-3(q)).* FAR provision 52.209-11, Representation by Corporations Regarding Delinquent Tax Liability or a Felony Conviction under any Federal Law, and its equivalent for commercial acquisitions at FAR provision 52.212-3(q), implement sections 744 and 745 of Division E of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235). Sections 744 and 745 prohibit agencies from entering into a contract with any corporation with any delinquent Federal tax liability or a felony conviction, unless the agency has considered suspension or debarment of the corporation and has made a determination that this further action is not necessary to protect the interests of the Government.

FAR provision 52.209-12, Certification Regarding Tax Matters, implements section 523 of the Commerce, Justice, Science, and Related Agencies Appropriations Act, 2015 (Division B) and the same provision in subsequent appropriations acts. Agencies funded by these acts include the Department of Commerce, the Department of Justice, NASA, as well as some smaller agencies. This section prohibits award of any contract in an amount greater than \$5,000,000 by those covered agencies, unless the offeror affirmatively certifies that it has filed all Federal tax returns required during the three years preceding the certification; has not been convicted of a criminal offense under the Internal Revenue Code of 1986; and has not, more than 90 days prior to certification, been notified of any unpaid Federal tax assessment for which the liability remains unsatisfied, unless the assessment is the subject of an installment agreement or offer in compromise that has been approved by the Internal Revenue Service and is not in default, or the assessment is the subject of a non-frivolous administrative or judicial proceeding.

2. *Debarment, Suspension, and other Responsibility Matters (FAR 52.209-5, 52.209-6, and 52.212-3(h)).* The Competition in Contracting Act of 1984 requires that contract awards be made to responsible prospective contractors only. To be determined responsible, a prospective contractor must meet a series of general standards. The standards include having a satisfactory record of integrity and business ethics, and being otherwise qualified and eligible to receive an award under applicable laws and regulations. FAR provision 52.209-5, Certification Regarding Responsibility Matters, and its equivalent for commercial acquisitions at FAR provision 52.212-3(h), require the disclosure of certain critical factors by an offeror to be considered by the contracting officer in making a responsibility determination. These critical factors, e.g., suspended, debarred, criminal offense conviction, etc., determine whether the offeror is eligible for an award. The provision also requires offerors to provide immediate written notice to the contracting officer if, at any time prior to contract award, the offeror learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

FAR clause 52.209-6, Protecting the Government's Interest When Subcontracting with Contractor's Debarred, Suspended, or Proposed for Debarment, similarly ensures that the

Government deals with responsible subcontractors. Paragraph (b) of 52.209-6 prohibits contractors from entering into any subcontract in excess of \$35,000 with a subcontractor that is debarred, suspended, or proposed for debarment by any executive agency unless there is a compelling reason to do so. Paragraph (c) of the clause requires the contractor to require each proposed subcontractor whose subcontract will exceed \$35,000, to disclose to the contractor in writing, whether as of the time of award of the subcontract, the subcontractor, or its principals, is or is not debarred, suspended, or proposed for debarment by the Government. Paragraph (d) of clause requires that before entering into a subcontract with a party that is debarred, suspended, or proposed for debarment, a corporate officer or designee of the contractor must notify the contracting officer, in writing, of the name of the subcontractor; why the subcontractor is debarred, suspended, or ineligible; the compelling reason(s) for doing business with the subcontractor; and how the contractor will protect the Government's interests when dealing with such subcontractor. For any subcontract subject to Government consent, contracting officers shall not consent to such subcontracts, unless the agency head or a designee states in writing the compelling reasons for approving such subcontract.

3. *Information Regarding Responsibility Matters and Updates to that Publicly Available Information (FAR 52.209-7 and 52.209-9)*. Section 872 of the Duncan Hunter National Defense Authorization Act of 2009 (Pub. L. 110-417), enacted on October 14, 2008, required the development and maintenance of an information system that contains specific information on the integrity and performance of covered Federal agency contractors and grantees. The Federal Awardee Performance and Integrity Information System (FAPIIS) was developed to address these requirements. FAPIIS provides users access to integrity and performance information from the FAPIIS reporting module in the Contractor Performance Assessment Reporting System (CPARS), as well as proceedings information and suspension/debarment information from SAM. FAR provision 52.209-7, Information Regarding Responsibility Matters, requires information that is necessary to: (1) Determine the responsibility of prospective contractors; and (2) ensure that contractors maintain for accuracy and completeness, their integrity and performance information upon which

responsibility determinations rely. Paragraph (b) of the provision contains a check box to be completed by the offeror indicating whether or not it has current active Federal contracts and grants with total value greater than \$10,000,000. Paragraph (c) of the provision states that, if the offeror indicated in paragraph (b) that it has current active Federal contracts and grants with total value greater than \$10,000,000, then, by submission of the offer, the offeror represents that the information entered into FAPIIS is current, accurate, and complete as of the date of submission of the offer.

FAR clause 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters, implements the requirement to keep FAPIIS up-to-date and the requirement of section 3010 of the Supplemental Appropriations Act, 2010 (Pub. L. 111-212), to make all information posted in FAPIIS on or after April 15, 2011, except past performance reviews, publicly available. Paragraph (a) of the clause at 52.209-9 requires the contractor to update responsibility information on a semiannual basis, throughout the life of the contract, by posting the information in SAM. Paragraph (c) of the clause lets contractors know of their ability to provide feedback on information posted by the Government in FAPIIS and the procedure to follow in the event information exempt from public disclosure is slated to become publicly available information in FAPIIS.

4. *Prohibition on Contracting with Inverted Domestic Corporations (FAR 52.209-2, 52.209-10, and 52.212-3(n))*. Section 745 of Division D of the Consolidated Appropriations Act, 2008 (Pub. L. 110-161) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions) prohibit, on a Governmentwide basis, the use of appropriated (or otherwise made available) funds for contracts with either an inverted domestic corporation, or a subsidiary of such a corporation.

FAR provision 52.209-2, Prohibition on Contracting with Inverted Domestic Corporations-Representation, and its equivalent for commercial acquisitions at FAR provision 52.212-3(n), requires each offeror to represent whether it is, or is not, an inverted domestic corporation or a subsidiary of an inverted domestic corporation.

FAR clause 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations, requires the contractor to promptly notify the contracting officer in the event the contractor becomes an inverted domestic corporation or a

subsidiary of an inverted domestic corporation during the period of performance of the contract.

### C. Annual Burden

*Respondents/Recordkeepers:* 1,333,801. (1,328,450 respondents + 5,351 recordkeepers).

*Total Annual Responses:* 1,437,826.4.

*Total Burden Hours:* 1,511,005. (975,905 reporting hours + 535,100 recordkeeping hours).

### D. Public Comment

A 60-day notice published in the **Federal Register** at 84 FR 24523 on May 28, 2019. No comments were received.

*Obtaining Copies:* Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405, telephone 202-501-4755. Please cite OMB Control No. 9000-0193, FAR Part 9 Responsibility Matters, in all correspondence.

**Janet Fry,**

*Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.*

[FR Doc. 2019-16976 Filed 8-7-19; 8:45 am]

**BILLING CODE 6820-EP-P**

## DEPARTMENT OF DEFENSE

### GENERAL SERVICES ADMINISTRATION

### NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000-0069; Docket No. 2019-0003; Sequence No. 20]

### Submission for OMB Review; Indirect Cost Rates, Predetermined Indirect Cost Rates, and Bankruptcy Notifications

**AGENCY:** Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

**ACTION:** Notice.

**SUMMARY:** Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division has submitted to the Office of Management and Budget (OMB) a request to review and approve a revision and renewal of a previously approved information collection requirement regarding indirect cost rates, predetermined indirect cost rates, and bankruptcy notifications.

**DATES:** Submit comments on or before September 9, 2019.

**ADDRESSES:** Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for GSA, Room 10236, NEOB, Washington, DC 20503 or at [Oira\\_submission@omb.eop.gov](mailto:Oira_submission@omb.eop.gov). Additionally submit a copy to GSA by any of the following methods:

- **Federal eRulemaking Portal:** This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments. Go to <http://www.regulations.gov> and follow the instructions on the site.

- **Mail:** General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405. ATTN: Lois Mandell/IC 9000–0069, Indirect Cost Rates, Predetermined Indirect Cost Rates, and Bankruptcy Notifications.

**Instructions:** All items submitted must cite Information Collection 9000–0069, Indirect Cost Rates, Predetermined Indirect Cost Rates, and Bankruptcy Notifications. Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check [www.regulations.gov](http://www.regulations.gov), approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

**FOR FURTHER INFORMATION CONTACT:** Zenaida Delgado, Procurement Analyst, at telephone 202–969–7207, or [zenaida.delgado@gsa.gov](mailto:zenaida.delgado@gsa.gov).

**SUPPLEMENTARY INFORMATION:**

**A. OMB Control Number, Title, and Any Associated Form(s)**

9000–0069, Indirect Cost Rates, Predetermined Indirect Cost Rates, and Bankruptcy Notifications.

**B. Needs and Uses**

The Federal Acquisition Regulatory Council is in the process of combining OMB Control Numbers for the Federal Acquisition Regulation (FAR) by FAR part to the maximum practicable extent. This consolidation is expected to improve industry's ability to easily and efficiently identify all burdens associated with a given FAR part. The review of the information collections by FAR part allows improved oversight to ensure there is no redundant or

unaccounted for burden placed on industry. Lastly, combining information collections in a given FAR part is also expected to reduce the administrative burden associated with processing multiple information collections.

This justification supports revision and extension of the expiration date of OMB Control No. 9000–0069 and combines it with the previously approved information collection OMB Control No. 9000–0108, with the new title “Indirect Cost Rates, Predetermined Indirect Cost Rates, and Bankruptcy Notifications”. Upon approval of this consolidated information collection, OMB Control No. 9000–0108 will be discontinued. The burden requirements previously approved under the discontinued Number will be covered under OMB Control No. 9000–0069.

This clearance covers the information that contractors must submit to comply with the following FAR requirements:

1. 52.216–7, Allowable Cost and Payment, paragraph (d), requires that final annual indirect cost rates and the appropriate bases shall be established in accordance with FAR subpart 42.7. These rates are used, in part, in cost reimbursement contracts, time and materials contracts (other than for commercial items and not for labor-hour contracts), and for certain types of fixed price contracts construction contracts. The clause requires the contractor to submit an adequate final indirect cost rate proposal to the contracting officer and the auditor within the 6-month period following the expiration of each of its fiscal years. The proposed rates shall be based on the contractor's actual cost experience for that period. This clause provides a list of the data required to be submitted. The data is customary business financial information that the contractor can access from its automated business systems.

2. 52.216–15, Predetermined Indirect Cost Rates, used in solicitations and contracts for a cost-reimbursement research and development contract with an educational institution and addresses how the allowable indirect costs under the contract shall be obtained by applying predetermined indirect costs to bases agreed by the parties. This clause repeats the requirement in FAR 52.216–7, paragraph (d), for the contractor to submit an adequate final indirect cost rate proposal, however it does not impose any additional reporting requirements.

3. 52.242–4, Certification of Final Indirect Costs, requires the contractor's proposal of final indirect cost rates to be certified to establish or modify the rates used to reimburse the contractor for the

costs of performing under the contract. The supporting cost data are the cost accounting information normally prepared by organizations under sound management and accounting practices. This clause is incorporated into all solicitations and contracts, except for the Department of Energy Management and Operating contracts, that provide for establishment of final indirect cost rates.

4. 52.242–13, Bankruptcy. This clause requires contractors to notify the contracting officer within five days after initiating the proceedings relating to bankruptcy filing.

**C. Annual Burden**

*Respondents:* 6,145.

*Total Annual Responses:* 6,145.

*Total Burden Hours:* 1,578,868.

**D. Public Comment**

A 60-day notice was published in the **Federal Register** at 84 FR 25277, on May 31, 2019. No comments were received.

**Obtaining Copies:** Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405, telephone 202–501–4755.

Please cite OMB Control No. 9000–0069, Indirect Cost Rates, Predetermined Indirect Cost Rates, and Bankruptcy Notifications, in all correspondence.

**Janet Fry,**

*Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.*

[FR Doc. 2019–16975 Filed 8–7–19; 8:45 am]

**BILLING CODE 6820–EP–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Agency for Healthcare Research and Quality**

**Agency Information Collection Activities: Proposed Collection; Comment Request**

**AGENCY:** Agency for Healthcare Research and Quality, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) reapprove the proposed information collection project: “*Medical Expenditure Panel Survey—Insurance Component.*”

**DATES:** Comments on this notice must be received by 60 days after date of publication.

**ADDRESSES:** Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at [doris.lefkowitz@AHRQ.hhs.gov](mailto:doris.lefkowitz@AHRQ.hhs.gov).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

**FOR FURTHER INFORMATION CONTACT:** Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at [doris.lefkowitz@AHRQ.hhs.gov](mailto:doris.lefkowitz@AHRQ.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**Proposed Project**

*Medical Expenditure Panel Survey—Insurance Component*

Employer-sponsored health insurance is the source of coverage for 84.4 million current and former workers, plus many of their family members, and is a cornerstone of the U.S. health care system. The Medical Expenditure Panel Survey—Insurance Component (MEPS-IC) measures the extent, cost, and coverage of employer-sponsored health insurance on an annual basis. These statistics are produced at the National, State, and sub-State (metropolitan area) level for private industry. Statistics are also produced for State and Local governments.

This research has the following goals:

- (1) To provide data for Federal policymakers evaluating the effects of National and State health care reforms.
- (2) to provide descriptive data on the current employer-sponsored health insurance system and data for modeling the differential impacts of proposed health policy initiatives.
- (3) to supply critical State and National estimates of health insurance spending for the National Health Accounts and Gross Domestic Product.

This study is being conducted by AHRQ through the Bureau of the Census, pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to the cost and use of health care services and with respect to health statistics and surveys. 42 U.S.C. 299a(a)(3) and (8); 42 U.S.C. 299b-2.

**Method of Collection**

To achieve the goals of this project the following data collections for both private sector and state and local government employers will be implemented:

(1) Prescreener Questionnaire—The purpose of the Prescreener Questionnaire, which is collected via telephone, varies depending on the insurance status of the establishment contacted (establishment is defined as a single, physical location in the private sector and a governmental unit in state and local governments). For establishments that do not offer health insurance to their employees, the prescreener is used to collect basic information such as number of employees. Collection is completed for these establishments through this telephone call. For establishments that do offer health insurance, contact name and address information is collected that is used for the mailout of the establishment and plan questionnaires. Obtaining this contact information helps ensure that the questionnaires are directed to the person in the establishment best equipped to complete them.

(2) Establishment Questionnaire—The purpose of the mailed Establishment Questionnaire is to obtain general information from employers that provide health insurance to their employees. Information such as total active enrollment in health insurance, other employee benefits, demographic

characteristics of employees, and retiree health insurance is collected through the establishment questionnaire.

(3) Plan Questionnaire—The purpose of the mailed Plan Questionnaire is to collect plan-specific information on each plan (up to four plans) offered by establishments that provide health insurance to their employees. This questionnaire obtains information on total premiums, employer and employee contributions to the premium, and plan enrollment for each type of coverage offered—single, employee-plus-one, and family—within a plan. It also asks for information on deductibles, copays, and other plan characteristics.

The primary objective of the MEPS-IC is to collect information on employer-sponsored health insurance. Such information is needed in order to provide the tools for Federal, State, and academic researchers to evaluate current and proposed health policies and to support the production of important statistical measures for other Federal agencies.

**Estimated Annual Respondent Burden**

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in the MEPS-IC. The Prescreener questionnaire will be completed by 29,931 respondents and takes about 5 minutes to complete. The Establishment questionnaire will be completed by 25,819 respondents and takes about 23 minutes to complete. The Plan questionnaire will be completed by 22,859 respondents and will require an average of 2.2 responses per respondent. Each Plan questionnaire takes about 11 minutes to complete. The total annualized burden hours are estimated to be 21,611 hours.

Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to participate in this data collection. The annualized cost burden is estimated to be \$705,599.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS FOR THE 2020–2021 MEPS-IC

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Prescreener Questionnaire .....	29,931	1	5/60	2,494
Establishment Questionnaire .....	25,819	1	* 23/60	9,897
Plan Questionnaire .....	22,859	2.2	11/60	9,220
Total .....	78,609	na	na	21,611

\* The burden estimate printed on the establishment questionnaire is 45 minutes which includes the burden estimate for completing the establishment questionnaire and two plan questionnaires (on average, each establishment completes 2.2 plan questionnaires), plus the prescreener. The establishment and plan questionnaires are sent to the respondent as a package and are completed by the respondent at the same time.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN FOR THE 2020–2021 MEPS–IC

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Prescreener Questionnaire .....	29,931	2,494	\$32.65	\$81,429
Establishment Questionnaire .....	25,819	9,897	32.65	323,137
Plan Questionnaire .....	22,859	9,220	32.65	301,033
<b>Total .....</b>	<b>78,609</b>	<b>21,611</b>	<b>na</b>	<b>705,599</b>

\*Based upon the mean hourly wage for Compensation, Benefits, and Job Analysis Specialists occupation code 13–1141, at <https://www.bls.gov/oes/current/oes131141.htm> (U.S. Department of Labor, Bureau of Labor Statistics.).

**Request for Comments**

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, comments on AHRQ’s information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ’s estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency’s subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: August 5, 2019.

**Virginia L. Mackay-Smith,**  
Associate Director.

[FR Doc. 2019–17001 Filed 8–7–19; 8:45 am]

**BILLING CODE 4160–90–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60Day–19–1015; Docket No. CDC–2019–0061]

**Proposed Data Collection Submitted for Public Comment and Recommendations**

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled National Electronic Health Records Survey (NEHRS) which will collect data on office-based physicians’ adoption and use of electronic health record (EHR) systems, practice information, patient engagement, controlled substances prescribing practices, use of health information exchange, and documentation and burden associated with medical record systems.

**DATES:** CDC must receive written comments on or before October 7, 2019.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC–2019–0061 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, of the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

*Instructions:* All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

*Please note:* Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–

D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: [omb@cdc.gov](mailto:omb@cdc.gov).

**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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.
5. Assess information collection costs.

**Proposed Project**

National Electronic Health Records Survey (NEHRS) (OMB Control No. 0920–1015, Exp. 7/31/2020)—Revision—National Center for Health

Statistics (NCHS), Centers for Disease Control and Prevention (CDC)

*Background and Brief Description*

NEHRS is a national survey of office-based physicians conducted by the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC). NEHRS is sponsored by the Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (DHHS). The survey is conducted under authority of Section 306 of the Public Health Service Act (41 U.S.C. 242k). NEHRS data collection years are for 2020, 2021 and 2022.

The purpose of this study is to collect information on office-based physicians' adoption and use of electronic health record (EHR) systems, practice

information, patient engagement, controlled substances prescribing practices, use of health information exchange, and documentation and burden associated with medical record systems. The respondents are a sample of office-based physicians. The data collection is done directly through a self-administered web questionnaire, self-administered paper questionnaire or computer-assisted telephone interview. NEHRS collects information on characteristics of U.S. office-based physicians practicing ambulatory medical care, including specific focus on EHR adoption and use. Having data that can identify a physician office's ability to perform specific computerized tasks helps track the adoption and use of new health information technologies across various physician and practice characteristics (e.g., specialty, office

type, and ownership) over time. These annual data, together with trend data, may be used to monitor the effects of change in the health care system, provide new insights into ambulatory medical care, and stimulate further research on the use, organization, and delivery of ambulatory care.

Data from NEHRS has been used by researchers in reports and programs such as *Health, United States and Healthy People 2020*, in addition to various other reports and research across federal, public, and international communities. The results of the data will help provide more information about the use and adoption of EHRs by office-based physicians both nationally and by state. CDC requests approval for 5,151 annual burden hours. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Office-based Physicians or office staff .....	NEHRS .....	10,302	1	30/60	5,151
Total .....	.....	.....	.....	.....	5,151

**Jeffrey M. Zirger,**

*Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.*

[FR Doc. 2019-16964 Filed 8-7-19; 8:45 am]

BILLING CODE 4163-18-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60Day-19-19BLE; Docket No. CDC-2019-0062]

**Proposed Data Collection Submitted for Public Comment and Recommendations**

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995.

This notice invites comment on a proposed information collection project titled 'Templates for Extramural Data Management Plans.' The aim of this collection is to provide Cooperative Agreement applicants and awardees with templates for the creation of Data Management Plans (DMP).

**DATES:** CDC must receive written comments on or before October 7, 2019.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2019-0062 by any of the following methods: Federal eRulemaking Portal: *Regulations.gov*. Follow the instructions for submitting comments.

- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS-D74, Atlanta, Georgia 30329.

*Instructions:* All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

*Please note:* Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and

instruments, contact Jeffrey Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: *omb@cdc.gov*.

**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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.
5. Assess information collection costs.

**Proposed Project**

Templates for Extramural Data Management Plans—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

**Background and Brief Description**

Data management plans (DMPs) are required of entities using CDC funds to collect or generate public health data. DMPs will be submitted to CDC by grant and cooperative agreement awardees for assessment to verify that they are concordant with CDC's data sharing policy. Currently, CDC does not have a standard template for a DMP. DMPs can be a checklist, paragraph, or any other format. Due to this fact, CDC has had to refer extramural applicants and

recipients to external websites for examples on how to construct a DMP. This new ICR is being developed by CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) to create standardized templates for DMPs so that they will be easier to create, easier to review, better ensure compliance with CDC's requirements, and increase the likelihood of first time approval by project officers. DMPs will be submitted as standalone sections of the Notice of Funding Opportunity (NOFO) and annual continuation applications; revisions can also be submitted by the awardees as needed. CDC requests approval for 933 Burden Hours. There are no costs to respondents other than their time.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Applicants and Awards Recipients ...	DMP .....	933	1	60/60	933
	Template .....				
Total .....	.....	.....	.....	.....	933

**Jeffrey M. Zirger,**

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019-16962 Filed 8-7-19; 8:45 am]

BILLING CODE 4163-18-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60Day-19-0987; Docket No. CDC-2019-0064]

**Proposed Data Collection Submitted for Public Comment and Recommendations**

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995.

This notice invites comment on a proposed information collection project titled Qualitative Information Collection on Emerging Diseases among the Foreign-born in the U.S. that enables CDC improve the planning and implementation of disease prevention and control strategies targeting communicable diseases and other emerging health issues among high-risk foreign-born communities in specific and limited geographic areas in the United States where high numbers of those populations live.

**DATES:** CDC must receive written comments on or before October 7, 2019.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2019-0064 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS-D74, Atlanta, Georgia 30329.

*Instructions:* All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

*Please note:* Submit all comments through the Federal eRulemaking portal

(*regulations.gov*) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, of the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: *omb@cdc.gov*.

**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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.
5. Assess information collection costs.

**Proposed Project**

Qualitative Information Collection on Emerging Diseases among the Foreign-born in the U.S. (OMB Control no. 0920-0987, Exp. 12/31/2019)—Extension—Division of Global Migration and Quarantine (DGMQ), National Center for Emerging Zoonotic and Infectious Diseases (NCEZID), Centers

for Disease Control and Prevention (CDC).

**Background and Brief Description**

The Centers for Disease Control and Prevention (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Global Migration and Quarantine (DGMQ), requests approval for an extension of the current generic information collection Qualitative Information Collection on Emerging Diseases among the Foreign-born in the U.S.

This qualitative data collection is needed by DGMQ because foreign-born individuals are considered hard-to-reach populations and are often missed by routine information collection systems in the United States. As a consequence, limited information is available about the health status, knowledge, attitudes, health beliefs and practices related to communicable diseases and other emerging health issues (e.g., tuberculosis, parasitic diseases, lead poisoning, and mental health issues) among foreign-born populations in the United States. Foreign-born populations are very diverse in terms of countries of origin, socio-demographic, cultural and linguistic characteristics and geographic

destinations in the U.S. Data is especially limited at the local level.

The purpose of the extension is to continue efforts to improve the agency's understanding of the health status, risk factors for disease, and other health outcomes among foreign-born individuals in the United States. Numerous types of data will be collected under the auspices of this generic information collection. These include, but are not limited to, knowledge, attitudes, beliefs, behavioral intentions, practices, behaviors, skills, self-efficacy, and health information needs and sources.

Under the terms of this generic, CDC will employ focus groups and key informant interviews to collect information. Depending on the specific purpose, the information collection may be conducted either in-person, by telephone, on paper, or online. For each generic information collection, CDC will submit to OMB the project summary and information collection tools.

CDC requests a total of 450 burden hours annually. The respondents to these information collections are foreign-born individuals in the United States. There is no cost to respondents other than the time required to provide the information requested.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Foreign-born from specific country of birth in the United States.	Screeners for focus groups (assuming 2 screenings for each recruited participant in focus groups) (150 × 2 = 300).	300	1	10/60	50
Foreign-born from specific country of birth in the United States.	Focus Groups (Approximately 15 focus groups/year and 10 participants per focus group).	150	1	2	300
Foreign-born community leaders and staff from organizations serving those communities.	Key informant interviews (Approximately 100 interviews/year).	100	1	1	100
<b>Total</b> .....	.....	.....	.....	.....	<b>450</b>

**Jeffrey M. Zirger,**

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019-16963 Filed 8-7-19; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[30Day-19-0457]**

**Agency Forms Undergoing Paperwork Reduction Act Review**

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled “Aggregate

Reports for Tuberculosis Program Evaluation” to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on April 23, 2019 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project.

The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

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

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

**Proposed Project**

Aggregate Reports for Tuberculosis Program Evaluation (OMB Control No. 0920-0457, Exp. 2/29/2020)—Revision—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

**Background and Brief Description**

To ensure the elimination of tuberculosis in the United States, CDC’s Division of Tuberculosis Elimination (DTBE) provides cooperative agreement funding to tuberculosis (TB) control programs located in state and local health departments. Key program activities include finding tuberculosis infections in recent contacts of cases and in other persons likely to be infected, and providing therapy for latent tuberculosis infection (LTBI).

In 2000, CDC began collecting two aggregate reports from cooperative agreement awardees: The Follow-up and Treatment for Contacts of Tuberculosis Cases Form and the Targeted Testing and Treatment for Latent Tuberculosis Infection Form. These reports contain only de-identified, summary information without client-level identifying information. Awardees submit the reports to CDC on an annual basis, primarily utilizing the National Tuberculosis Indicators Project (NTIP), a secure web-based system. No other federal agency collects this type of national tuberculosis data. CDC uses the information to monitor awardee activities, plan national TB control strategy, and estimate funding needs. CDC also provides ongoing assistance in the preparation and utilization of these

reports at the local and state levels of public health jurisdiction, as well as technical support for the NTIP software.

In this Revision request, CDC proposes minor changes to the report forms, data definitions, and reporting instructions. All tuberculosis control programs will discontinue manual data compilation methods and will completely transition to electronic information submission through the NTIP. In addition, three optional questions will be added to each form as recommended by the Association Council for the Elimination of Tuberculosis. The optional questions on nativity, diagnostic tests, and drug regimens will improve understanding of the epidemiology of tuberculosis, the adoption of new diagnostic tests, and the effectiveness of new short-course drug regimens in increasing the initiation and completion of preventive treatment. These changes will help programs assess high-risk populations served and will also address a shift in the national strategies for TB control and prevention, which emphasize treatment of individuals with LTBI and at high risks of progression to TB disease.

OMB approval is requested for three years. Participation in aggregate reporting for tuberculosis program evaluation is required by the cooperative agreement. The number of funded health departments will decrease from 68 to 67. The revised estimated burden per response for each aggregate form is 2 hours and the total estimated annualized burden hours are 268, an increase of 42 hours.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Health Department Awardee (state, local, city, or other jurisdiction).	Follow-up and Treatment of Contacts to Tuberculosis Cases Form.	67	1	2
	Targeted Testing and Treatment for Latent Tuberculosis Infection.	67	1	2

**Jeffrey M. Zirger,**  
*Lead, Information Collection Review Office,  
 Office of Scientific Integrity, Office of Science,  
 Centers for Disease Control and Prevention.*

[FR Doc. 2019-16961 Filed 8-7-19; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Provision of Child Support Services in IV-D Cases Under the Hague Child Support Convention; Federally Approved Forms (OMB #0970-0488)**

**AGENCY:** Office of Child Support Enforcement, Administration for Children and Families, HHS.

**ACTION:** Request for public comment.

**SUMMARY:** The Office of Child Support Enforcement (OCSE), Administration for Children and Families (ACF) is requesting a three-year extension of the Hague Child Support Forms (OMB #0970-0488, expiration 4/30/2020).

There are no changes requested to the form.

**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:* On January 1, 2017, the 2007 Hague Convention on the International Recovery of Child Support and Other Forms of Family Maintenance entered into force for the United States. This multilateral Convention contains groundbreaking provisions that, on a

worldwide scale, establish uniform, simple, fast, and inexpensive procedures for the processing of international child support cases. Under the Convention, U.S. states process child support cases with other countries that have ratified the Convention under the requirements of the Convention and Article 7 of the Uniform Interstate Family Support Act (UIFSA 2008). In order to comply with the Convention, the U.S. implements the Convention's case processing forms.

State and Federal law require states to use federally approved case processing forms. Section 311(b) of UIFSA 2008, which has been enacted by all 50 states, the District of Columbia, Guam, Puerto Rico, and the Virgin Islands, requires states to use forms mandated by Federal law. 45 CFR 303.7 also requires child support programs to use federally approved forms in intergovernmental IV-D cases unless a country has provided alternative forms as a part of its chapter in a Caseworker's Guide to Processing Cases with Foreign Reciprocating Countries.

*Respondents:* State agencies administering a child support program under title IV-D of the Social Security Act.

**ANNUAL BURDEN ESTIMATES**

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours
Annex I: Transmittal form under Article 12(2) .....	54	45	1	2,430
Annex II: Acknowledgment form under Article 12(3) .....	54	90	.5	2,430
Annex A: Application for Recognition and Enforcement, including restricted information on the applicant .....	54	18	.5	486
Annex A: Abstract of Decision .....	54	4	1	216
Annex A: Statement of Enforceability of Decision .....	54	18	0.17	165
Annex A: Statement of Proper Notice .....	54	4	.5	108
Annex A: Status of Application Report—Article 12 .....	54	36	.33	642
Annex B: Application for Enforcement of a Decision Made or Recognized in the Requested State, including restricted information on the applicant .....	54	18	.5	486
Annex B: Status of Application Report—Article 12 .....	54	36	.33	642
Annex C: Application for Establishment of a Decision, including restricted information on the Applicant .....	54	4	.5	108
Annex C: Status of Application Report—Article 12 .....	54	9	.33	160
Annex D: Application for Modification of a Decision, including Restricted Information on the Applicant .....	54	4	.5	108
Annex D: Status of Application Report—Article 12 .....	54	9	.33	160
Annex E: Financial Circumstances Form .....	54	45	2	4,860

*Estimated Total Annual Burden Hours:* 13,001.

*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. 654(20) and 666(f).

**Mary B. Jones,**  
*ACF/OPRE Certifying Officer.*

[FR Doc. 2019-16968 Filed 8-7-19; 8:45 am]

**BILLING CODE 4184-41-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2012-N-0560]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable**

**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 September 9, 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 [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0582. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRAStaff@fda.hhs.gov](mailto: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.

**Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable**

*OMB Control Number 0910-0582—Extension*

FDA's investigational device regulations are intended to encourage the development of new, useful devices in a manner that is consistent with public health, safety, and compliant with ethical standards. Investigators

should have freedom to pursue the least burdensome means of accomplishing this goal. However, to ensure that the balance is maintained between product development and the protection of public health, safety, and ethical standards, FDA has established human subject protection regulations addressing requirements for informed consent and institutional review board (IRB) review that apply to all FDA-regulated clinical investigations involving human subjects. In particular, informed consent requirements further both safety and ethical considerations by allowing potential subjects to consider both the physical and privacy risks they face if they agree to participate in a trial.

Under FDA regulations, clinical investigations using human specimens conducted in support of premarket submissions to FDA are considered human subject investigations (see 21 CFR 812.3(p)). Many investigational device studies are exempt from most provisions of part 812, Investigational Device Exemptions, under 21 CFR 812.2(c)(3), but FDA's regulations for the protection of human subjects (21 CFR parts 50 and 56) apply to all clinical investigations that are regulated by FDA (see 21 CFR 50.1, 21 CFR 56.101, and 21 U.S.C. 360j(g)(3)(A) and (D)).

FDA regulations do not contain exceptions from the requirements of informed consent on the grounds that the specimens are not identifiable or that they are remnants of human specimens collected for routine clinical care or analysis that would otherwise have been discarded. Nor do FDA regulations allow IRBs to decide whether or not to waive informed consent for research involving leftover or unidentifiable specimens.

In the document entitled "Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable," issued under the Good Practices regulation (21 CFR 10.115), FDA outlines the circumstances in which it intends to exercise enforcement discretion as to the informed consent regulations for clinical investigators, sponsors, and IRBs.

The recommendations of the guidance impose a minimal burden on industry. FDA estimates that 700 studies will be affected annually. Each study will result in one annual record, estimated to take 4 hours to complete. This results in a total recordkeeping burden of 2,800 hours (700 × 4 = 2,800).

In the **Federal Register** of March 5, 2019 (84 FR 7906), FDA published a 60-

day notice requesting public comment on the proposed collection of information. FDA received the following comments:

(Comment 1) Some comments strongly support further harmonization between the updated Common Rule and FDA regulations. Although the comments support FDA's 2006 Guidance and discretionary enforcement, the comments suggested that scientists would welcome expanded efforts to remove investigations using de-identified human tissues from FDA's human subject regulations, consistent with the Common Rule. The comments suggest there is little practical utility in FDA maintaining de-identified specimens as part of human subject investigations. The comments suggest that removing de-identified specimens from these requirements would allow for safety and ethical considerations while reducing administrative burden for investigators, ensuring consistency with the Common Rule and streamlining effectiveness. The comments suggest there is a longstanding tradition of research using de-identified human tissue in a way that demonstrates adherence to the Belmont principles of justice, beneficence, and respect for persons. Further the comments express the belief that requiring consent for tissue routinely archived would render a very large and crucial resource essentially off limits for research because most institutions/hospitals, particularly outside academia, do not include consent for surplus tissue use prior to surgery or tissue biopsy. The comments suggested that asking for consent retrospectively is very cumbersome, costly, and may be perceived as intrusive by patients.

(Response) These comments are not related to the information collection or burden estimate. However, we have forwarded the comment to the appropriate program office for consideration.

(Comment 2) A comment suggested that 4 hours per recordkeeper may be a significant underestimation of the burden of the information collection. The comment referenced Section V of the 2006 Guidance and stated that the two-step process in that section amounts to both a general review of policies and procedures and a study-by-study IRB review to ensure compliance. The comment suggested that requiring reviews at the level of individual FDA investigations will lead to an aggregate of more than 4 hours per year per recordkeeper.

(Response) The comment was considered but FDA does not believe that the 4-hour estimate is a significant

underestimation given that these actions should not be a burdensome process for the recordkeeper.

(Comment 3) The commenter opposed changing the default from “opt-in” to “opt-out” for patients to consent to their tissue being used for research. Although simple malformations, such as warts and tumors, may be useful to labs to fine-tune their tests, and although many (even most) patients might be willing to share this tissue, a significant minority of Americans hold beliefs about the human body that would prevent them from consenting, and all Americans

likely assume that their tissue is destroyed (burned as medical waste) after procedures have been performed. The commenter believes that changing what happens without changing the public understanding of what happens is fundamentally dishonest. The commenter recognizes that obtaining consent is time-consuming, particularly when the patient does not speak English as a first language, or has other comprehension issues; however, the commenter believes no lab has a right to the tissue of an American citizen for its private, profit-making use.

(Response) The subject of the comment deals with sample acquisition, a step that happens in advance of the information communicated in this guidance. Therefore, patient “opt-in” versus “opt-out” is out of scope. This guidance describes the enforcement discretion policy FDA uses when sponsors choose to use de-identified samples for IVD medical device clinical trials.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping regarding leftover human specimens that are not individually identifiable that are used in certain IVD studies .....	700	1	700	4	2,800

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: August 5, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–17026 Filed 8–7–19; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2019–N–0006]

**Advisory Committees; Filing of Closed Meeting Reports**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing that, as required by the Federal Advisory Committee Act, the Agency has filed with the Library of Congress the annual reports of those FDA advisory committees that held closed meetings during fiscal year 2018.

**ADDRESSES:** Copies are available at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500. You also may access the docket at <http://www.regulations.gov> for the annual reports of those FDA advisory committees that held closed meetings

during fiscal year 2018. Insert the docket number found in brackets in the heading of this document at <http://www.regulations.gov> into the “Search” box, clear filter under Document Type (left side of screen), and check “Supporting and Related Material,” then Sort By Best Match (from the drop-down menu; top right side of screen), “ID Number (Z–A)” or Sort By Best Match (from the drop-down menu) “Title (A–Z),” also found in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Russell Fortney, Director, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1068.

**SUPPLEMENTARY INFORMATION:** Under section 10(d) of the Federal Advisory Committee Act (5 U.S.C. app.) and 21 CFR 14.60(d), FDA has filed with the Library of Congress the annual reports for the following FDA advisory committees that held closed meetings during the period October 1, 2017, through September 30, 2018:

*Center for Biologics Evaluation and Research:*

Blood Products Advisory Committee  
Vaccine and Related Biological Products Advisory Committee

*National Center for Toxicological Research:*

Science Board to the National Center for Toxicological Research

*Center for Drug Evaluation and Research:*

Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee

*Office of Commissioner*

Joint Meeting of the Pediatric Advisory Committee and the Endocrinologic and Metabolic Drugs Advisory Committee

Annual Reports are available for public inspections between 9 a.m. and 4 p.m., Monday through Friday, at:

(1) The Library of Congress, Madison Building, Newspaper and Current Periodical Reading Room, 101 Independence Ave. SE, Rm. 133, Washington, DC; 20540; and

(2) Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: August 5, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–16992 Filed 8–7–19; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-N-0414]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Manufactured Food Regulatory Program Standards**

**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 September 9, 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](mailto:oira_submission@omb.eop.gov). All comments should be identified with the

OMB control number 0910-0601. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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.

**Manufactured Food Regulatory Program Standards**

*OMB Control Number 0910-0601—Extension*

In the **Federal Register** of July 20, 2006 (71 FR 41221), FDA announced the availability of a document entitled “Manufactured Food Regulatory Program Standards.” These program standards are the framework that States should use to design and manage their manufactured food programs. There are 43 State programs enrolled, which receive an average of \$230,000 (maximum of \$300,000) each year for a period of 5 years from the year they first enroll, provided there is significant

conformance with and/or maintenance of the 10 standards.

In the first year of implementing the program standards, the State program conducts a baseline self-assessment to determine if it meets the elements of each standard. FDA suggests that the State program use the worksheets and forms contained in the draft program standards; however, it can use alternate forms that are equivalent. The State program maintains the documents and verifies records required for each standard. The information contained in the documents must be current and fit for use. If the State program fails to meet all program elements and documentation requirements of a standard, it develops a strategic plan which includes the following: (1) The individual element of documentation requirement of the standard that was not met, (2) improvements needed to meet the program element or documentation requirement of the standard, and (3) projected completion dates for each task.

In the **Federal Register** of April 17, 2019 (84 FR 16020), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

**TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>**

Respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
State Departments of Agriculture or Health .....	43	1	43	569	24,467

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

**TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>**

Respondent	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per record-keeping	Total hours
State Departments of Agriculture or Health .....	43	10	430	40	17,200

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

One additional State has enrolled in the program since 2016. The total estimated burden of this collection has increased to 41,667 hours among 43 respondents, from a previous total of 15,792 hours among 42 respondents. This increase is due to a change in the self-reported response times provided by the respondents. Because this is a long-term program, we believe this change is the result of more precise documentation by participating agencies

as they have grown more experienced over time.

Dated: August 1, 2019.  
**Lowell J. Schiller,**  
*Principal Associate Commissioner for Policy.*  
 [FR Doc. 2019-16937 Filed 8-7-19; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2019-D-2973]

**Fabry Disease: Developing Drugs for Treatment; Draft Guidance for Industry; 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 entitled “Fabry Disease: Developing Drugs for Treatment.” This draft guidance describes the Agency’s current recommendations regarding eligibility criteria, trial design considerations, and efficacy endpoints to be used in clinical development programs of investigational drugs to treat Fabry disease. Through this draft guidance, the Agency provides clear and specific guidance to foster greater efficiency in drug development in this rare disease with the goal of enhancing clinical trial data quality and supporting the development of treatments for Fabry disease.

**DATES:** Submit either electronic or written comments on the draft guidance by November 6, 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-2973 for “Fabry Disease: Developing Drugs for Treatment.” 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 and 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 Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Jeannie Roule, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5332, Silver Spring, MD 20993-0002, 301-796-3993; 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.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “Fabry Disease: Developing Drugs for Treatment.” This draft guidance describes the Agency’s recommendations regarding the structure of clinical development programs for drugs intended to treat Fabry disease. The draft guidance is intended to facilitate greater consistency in approaches among development programs and to ensure that sponsors receive clear and specific guidance to foster greater efficiency of drug development in this rare disease. The draft guidance describes specific considerations relating to eligibility criteria and trial design and discusses the Agency’s current recommendations for efficacy endpoints that can be used to support approval of drugs for Fabry disease.

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 “Fabry Disease: Developing Drugs for Treatment.” 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 under 21 CFR part 312 (Investigational New Drug Application) have been approved under OMB control number 0910–0014. The collections of information in 21 CFR parts 50 and 56 (Protection of Human Subjects: Informed Consent; Institutional Review Boards) have been approved under OMB control number 0910–0755.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics>, or <https://www.regulations.gov>.

Dated: August 5, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–16994 Filed 8–7–19; 8:45 am]

BILLING CODE 4164–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2019–N–3018]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Healthcare Provider Perception of Boxed Warning Information Survey

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on Healthcare

Provider Perception of Boxed Warning Information Survey.

**DATES:** Submit either electronic or written comments on the collection of information by October 7, 2019.

**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 October 7, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 7, 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–3018 for “Healthcare Provider Perception of Boxed Warning Information Survey.” 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:** Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

### Healthcare Provider Perception of Boxed Warning Information Survey

OMB Control Number 0910—NEW

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

The proposed collection of information will investigate healthcare providers’ (HCPs’) awareness, perceptions and beliefs about the benefits and risks of an FDA-approved product that carries a boxed warning. The prescribing information for an FDA-approved drug or biologic (sometimes referred to as the “PI”, “package insert”, or “prescription drug labeling”) provides a summary of the essential

information needed for the safe and effective use of that medication, described in FDA guidance entitled “Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biologic Products—Content and Format,” published in October 2011 (<https://www.fda.gov/media/71866/download>). In certain situations, a drug’s prescribing information may include a boxed warning in addition to other sections of the labeling to highlight important safety information about specific serious risks of that drug. Boxed warning information may be included as part of prescribing information at the time of FDA approval. Boxed warning information may also be added or modified to the prescribing information of drugs already on the market on the basis of new safety information.

Boxed warnings are an important and frequently used communication tool. A review of literature has suggested that the addition or modification of boxed warning information in the postmarket setting (after a drug has been approved) has had varying effects on HCPs’ practices regarding prescribing, dosing, and patient monitoring (Ref. 1). However, this review and others have identified several gaps in the existing literature, including the limited number of drugs or drug classes studied (Ref. 2). Further, little research has focused under understanding *how* HCPs receive, process, and use boxed warning information to support their treatment decisions and patient counseling.

To address this research gap, we propose conducting a web-based survey of HCPs. The proposed collection of information will strengthen FDA’s understanding of how HCPs may receive, process, and use boxed warning and other safety labeling information. This survey will be conducted as part of a mixed methods research approach to explore HCPs’ beliefs (or “mental models”) about the benefits and risks of a drug that carries a boxed warning and how the drug’s boxed warning information may influence their communication with patients, their treatment decisions and related decisions such as prescreening for risk factors or monitoring for adverse events (Ref. 3). This survey research will build upon preliminary qualitative research FDA has conducted, under OMB control number 0910–0695, with HCPs in this target population, through indepth individual interviews.

The general research questions in this data collection are as follows:

1. What awareness, knowledge, and beliefs do HCPs have regarding boxed

warning information for a prescription drug or class of drugs?

2. When making prescribing decisions, how do HCPs consider boxed warning information about a potential treatment? How does boxed warning information factor into their assessments of a drug’s potential benefits and risks to their patients?

3. How do HCPs communicate with their patients about boxed warning information?

4. What factors (*e.g.*, experience treating a condition) are associated with HCPs’ awareness, knowledge, and beliefs about boxed warning information?

In order to explore a range of potential perceptions and uses of boxed warning information that may exist under different contexts, this survey research will evaluate two medical product scenarios involving an FDA-approved medication or class of medications that include boxed warning information. The scenarios will include pertinent prescribing information from the FDA-approved labeling for these medications. We plan to conduct one pretest survey with 25 voluntary participants and one main survey with 1,156 voluntary participants. The survey will be conducted online. Survey response is estimated to take no longer than 20 minutes.

Participants in the pretest survey and main survey will be recruited online through a web-based HCP survey research panel. Participants will be HCPs with prescribing authority who prescribe medications to treat one of medical conditions in the medical product scenarios. Participants will include primary care providers (including internal medicine, family medicine, and general medicine, as well as nurse practitioners, and physician assistants) and relevant medical specialists. Participants will be screened for their current amount of time spent in direct patient care, prescribing volume, and experience treating the relevant medical condition. Demographic soft quotas will be used to help ensure that the survey population is generally reflective of the demographic composition of physicians in the United States, according to the American Medical Association.

The pretest and main studies will have the same design and will follow the same procedure. In advance of the pretest survey, we will conduct cognitive testing of the survey questionnaire to refine the survey instruments. The main survey will be refined as necessary following the pretest survey.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretest Screener .....	42	1	42	0.05 (3 minutes) .....	2
Pretest Informed Consent .....	25	1	25	0.05 (3 minutes) .....	1
Pretest Survey Completes .....	25	1	25	0.28 (17 minutes) .....	7
Main Survey Screener .....	1,927	1	1,927	0.05 (3 minutes) .....	96
Main Survey Informed Consent .....	1,156	1	1,156	0.05 (3 minutes) .....	58
Main Survey Completes .....	1,156	1	1,156	0.28 (17 minutes) .....	324
<b>Total</b> .....			<b>4,331</b>		<b>488</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

**References**

The following references are on display with 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; they are not available electronically at <https://www.regulations.gov> as these references are copyright protected. 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.

- Dusetzina, S.B., et al., “Impact of FDA Drug Risk Communications on Health Care Utilization and Health Behaviors: A Systematic Review.” *Medical Care*, 50(6):466–478, 2012.
- Briesacher, B.A., et al., “A Critical Review of Methods to Evaluate the Impact of FDA Regulatory Actions.” *Pharmacoepidemiology Drug and Safety*. 22(9):986–994, 2013.
- Morgan, M.G. et al., *Risk Communication: A Mental Models Approach*. Cambridge University Press, 2002.

Dated: August 1, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–16935 Filed 8–7–19; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Scholarships for Disadvantaged Students Program OMB No. 0915–0149—Revision**

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR should be received no later than October 7, 2019.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the ICR title for reference.

**Information Collection Request Title: Scholarships for Disadvantaged Students Program**

*OMB No. 0915–0149—Revision*

*Abstract:* HRSA seeks to update the Scholarships for Disadvantaged Students (SDS) program-specific form to collect 3 years of student data instead of 1 year of student data from SDS program applicants. This will assist the agency in making funding decisions for SDS program awards. The form will reflect programmatic changes to the SDS program, made after consideration of the

comments received in response to the request for public comment, published at 84 FR 23571, which will be finalized in the forthcoming SDS Policy Change **Federal Register** Notice.

*Need and Proposed Use of the Information:* The purpose of the SDS Program is to make grant awards to eligible schools to provide scholarships to full-time, financially needy students from disadvantaged backgrounds enrolled in health professions programs. To qualify for participation in the SDS program, a school must be carrying out a program for recruiting and retaining students from disadvantaged backgrounds, including students who are members of racial and ethnic minority groups (section 737(d)(1)(B) of the Public Health Service (PHS) Act). To meet this requirement, a school must show that at least 20 percent of the school’s full-time enrolled students and graduates are from a disadvantaged background. HRSA previously required schools to demonstrate this percentage by submitting 1 year of data; a school must now provide this data for the most recent 3-year period. The proposed revisions to the SDS program-specific form will require applicants to provide the percentage of full-time enrolled students and graduates from a disadvantaged background over a 3-year period, consistent with this policy change.

An additional change to the SDS program is that a 3-year average, instead of a 1-year average, will be used to calculate priority points, which are provided to eligible schools based on the proportion of graduating students going into primary care, the proportion of underrepresented minority students, and the proportion of graduates working in medically underserved communities (section 737(c) of the PHS Act). The proposed revisions to the SDS program-specific form will require applicants to

provide a 3-year average for these percentages, consistent with this policy change, as opposed to the 1 year of data previously required.

**Likely Respondents:** The respondents are institutions that apply for SDS program awards.

**Burden Statement:** Burden in this context means the time expended by

persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing

and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

**TOTAL ESTIMATED ANNUALIZED BURDEN HOURS**

Form	Number of respondents	Number of responses per respondent	Total responses	Hours per response	Total hour burden
Application .....	323	1	323	31	10,013
Total .....	323	.....	323	.....	10,013

From the last submission, the number of respondents has been updated with more recent application figures. There were 400 applications received for the 2012 application cycle and 323 applications from the 2016 cycle.

HRSA specifically requests comments on (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.

**Maria G. Button,**  
 Director, Division of the Executive Secretariat.  
 [FR Doc. 2019-16984 Filed 8-7-19; 8:45 am]  
**BILLING CODE 4165-15-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Meeting of the Advisory Committee on Minority Health**

**AGENCY:** Office of Minority Health, Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice of meeting.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services (HHS) is hereby giving notice that the Advisory Committee on Minority Health (ACMH) will hold a meeting. This meeting will be open to the public. Preregistration is required for both public participation and comment. Any individual who wishes to attend the meeting should email [OMH-ACMH@hhs.gov](mailto:OMH-ACMH@hhs.gov) by August 16, 2019. Information about the meeting is

available from the designated contact person and will be posted on the website for the Office of Minority Health (OMH), [www.minorityhealth.hhs.gov](http://www.minorityhealth.hhs.gov). Information about ACMH activities can be found on the OMH website under the heading *About OMH*.

**DATES:** The meeting will be held on Thursday, August 22, 2019, 9 a.m. to 5 p.m. ET, and Friday, August 23, 2019, 9 a.m. to 3 p.m. ET.

**ADDRESSES:** The meeting will be held at the 5600 Fishers Lane Building, Room 05E29, 5600 Fishers Lane, Rockville, Maryland 20187.

**FOR FURTHER INFORMATION CONTACT:** Violet Woo, Designated Federal Officer, Advisory Committee on Minority Health, Office of Minority Health, Department of Health and Human Services, Tower Building, 1101 Wootton Parkway, Suite 600, Rockville, Maryland 20852. Phone: 240-453-2882; fax: 240-453-2883; email [OMH-ACMH@hhs.gov](mailto:OMH-ACMH@hhs.gov).

**SUPPLEMENTARY INFORMATION:** In accordance with Public Law 105-392, the ACMH was established to provide advice to the Deputy Assistant Secretary for Minority Health on improving the health of each racial and ethnic minority group and on the development of goals and specific program activities of the OMH.

The topics to be discussed during this meeting will include strategies to improve the health of racial and ethnic minority populations through the development of health policies and programs that will help eliminate health disparities with an emphasis on infectious disease, particularly HIV and Hepatitis B. The recommendations will be given to the Deputy Assistant Secretary for Minority Health.

Public attendance at this meeting is limited to space available. Individuals who plan to attend and need special

assistance, such as sign language interpretation or other reasonable accommodations, should contact BLH Technologies, Inc. at (240) 399-8735 and reference this meeting. Requests for special accommodations should be made at least ten (10) business days prior to the meeting.

Members of the public will have an opportunity to provide comments at the meeting. Public comments will be limited to two minutes per speaker during the time allotted. Individuals who would like to submit written statements should email, mail, or fax their comments to the designated contact at least seven (7) business days prior to the meeting.

Any members of the public who wish to have electronic or printed material distributed to ACMH members should email [OMH-ACMH@hhs.gov](mailto:OMH-ACMH@hhs.gov) or mail their materials to the Designated Federal Officer, ACMH, Tower Building, 1101 Wootton Parkway, Suite 600, Rockville, Maryland 20852, prior to close of business on Friday, August 16, 2019.

Dated: July 25, 2019.

**Violet Woo,**  
 Designated Federal Officer, Advisory Committee on Minority Health.

[FR Doc. 2019-16969 Filed 8-7-19; 8:45 am]  
**BILLING CODE 4150-29-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; Independent AITC SEP.

*Date:* August 30, 2019.

*Time:* 10:00 a.m. to 1:00 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:* James T. Snyder, Ph.D. Scientific Review Officer, Scientific Review Program, Division of Extramural Activities/Room 3G31B, National Institutes of Health, NIAID 5601 Fishers Lane, MSC 9823, Rockville, MD 20892, (240) 669-5060, [james.snyder@nih.gov](mailto:james.snyder@nih.gov).

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Planning Grants (R34).

*Date:* September 3, 2019.

*Time:* 3:00 p.m. to 5:00 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:* Priti Mehrotra, Ph.D., Chief, Immunology Review Branch, Scientific Review Program, Division of Extramural Activities, Room #3G40, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892-7616, 240-669-5066, [pmehrotra@niaid.nih.gov](mailto:pmehrotra@niaid.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: August 2, 2019.

**Sylvia L. Neal,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2019-16926 Filed 8-7-19; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Environmental Health Sciences Amended; Notice of Meeting.

Notice is hereby given of a change in the meeting of the National Advisory

Environmental Health Sciences Council, which was published in the **Federal Register** on February 15, 2019, 84 FR, 4502.

This notice is being amended due to change of meeting location. The meeting will be held at Durham Convention Center (Junior Ballroom AB), 301 Morgan Street, Durham, NC 27701. The meeting is partially Closed to the public.

Dated: August 2, 2019.

**Sylvia L. Neal,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2019-16956 Filed 8-7-19; 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; Resource Center for Minority Aging Research (RCMAR) ZAG1 ZIJ-9 J1.

*Date:* October 31–November 1, 2019.

*Time:* October 31, 2019, 6:00 p.m. to 9:00 p.m.

*Agenda:* To evaluate and review grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Time:* November 01, 2019, 8:00 a.m. to 5:00 p.m.

*Agenda:* To evaluate and review grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Time:* 6:00 p.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:* Carmen Moten, Ph.D., MPH, Scientific Review Officer, Scientific Review Branch, National Institute on Aging,

National Institutes of Health, Gateway Bldg., 2C218, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301-402-7703, [cmoten@mail.nih.gov](mailto:cmoten@mail.nih.gov).

*Name of Committee:* National Institute on Aging Special Emphasis Panel; Resource Center for Minority Aging Research (RCMAR) ZAG1 ZIJ-9 J3.

*Date:* October 31–November 1, 2019.

*Time:* October 31, 2019, 6:00 p.m. to 9:00 p.m.

*Agenda:* To evaluate and review grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Time:* November 01, 2019, 8:00 a.m. to 5:00 p.m.

*Agenda:* To evaluate and review grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Time:* 6:00 p.m. to 5:00 p.m.

*Agenda:* To evaluate and review grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Carmen Moten, Ph.D., MPH, Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Bldg., 2C218, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301-402-7703, [cmoten@mail.nih.gov](mailto:cmoten@mail.nih.gov).

*Name of Committee:* National Institute on Aging Special Emphasis Panel; Resource Center for Minority Aging Research (RCMAR) ZAG1 ZIJ-9 J3.

*Date:* October 31–November 1, 2019.

*Time:* October 31, 2019, 6:00 p.m. to 9:00 p.m.

*Agenda:* To evaluate and review grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Time:* November 01, 2019, 8:00 a.m. to 5:00 p.m.

*Agenda:* To evaluate and review grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Time:* 6:00 p.m. to 5:00 p.m.

*Agenda:* To evaluate and review grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Carmen Moten, Ph.D., MPH, Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Bldg., 2C218, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301-402-7703, [cmoten@mail.nih.gov](mailto:cmoten@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: August 2, 2019.

**Sylvia L. Neal,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2019-16923 Filed 8-7-19; 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 Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute on Aging Special Emphasis Panel; T32 and T35 Review, January 2020 Council ZAG1 ZIJ-U (J4).

*Date:* October 18, 2019.

*Time:* 8:00 a.m. to 6:30 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:* Anita H. Undale, MD, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301-827-7428, [anita.undale@nih.gov](mailto:anita.undale@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: August 2, 2019.

**Sylvia L. Neal,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2019-16955 Filed 8-7-19; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of Exclusive Patent License: Lutetium-177 Radiotherapeutics Against Glioblastoma Multiforme and Small-Cell Lung Carcinoma**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to Molecular Targeting Technologies, Inc. (MTTI); a Delaware corporation, with its principle place of business in West Chester, Pennsylvania, to practice the inventions embodied in the patent application listed in the Supplementary Information section of this notice.

**DATES:** Only written comments and/or applications for a license which are received by the NHLBI Office of Technology Transfer and Development August 23, 2019 will be considered.

**ADDRESSES:** Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Michael Shmilovich, Esq., Senior Licensing and Patent Manager, 31 Center Drive, Room 4A29, MSC2479, Bethesda, MD 20892-2479, phone number 301-435-5019, or [shmilovm@mail.nih.gov](mailto:shmilovm@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** The following and all continuing U.S. and foreign patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement to MTTI:

NIH Ref No.	Patent No. or patent application No.	Filing date	Title
E-150-2016-0-US-01 .....	62/333,427 .....	May 9, 2016 .....	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents.
E-150-2016-0-PCT-02 .....	PCT/US2017/031696 .....	May 9, 2017 .....	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents.
E-150-2016-0-CN-03 .....	201780029003X .....	November 9, 2018 .....	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents.
E-150-2016-0-EP-04 .....	17796666.0 .....	November 12, 2018 .....	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents.
E-150-2016-0-JP-05 .....	2018-558662 .....	November 8, 2018 .....	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents.
E-150-2016-0-US-06 .....	16/099,488 .....	November 7, 2018 .....	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents.
E-150-2016-0-SG-07 .....	11201809982R .....	November 9, 2018 .....	Chemical Conjugates of Evans Blue Derivatives and Their Use as Radiotherapy and Imaging Agents.
E-150-2016-1-PCT-01 .....	PCT/US2017/054863 .....	October 3, 2017 .....	Chemical Conjugates of Evans Blue Derivatives And Their Use As Radiotherapy And Imaging Agents.

The patent rights in these inventions have been assigned to the Government of the United States of America. The prospective patent license will be granted worldwide and in a field of use not broader than Lutetium-177 radiotherapeutics containing RGD-peptide moieties targeting integrin  $\alpha\beta3$ -expressing glioblastoma multiforme and small cell lung cancers.

The invention pertains to a radiotherapeutic against cancers that overexpress integrin  $\alpha\beta3$ . RGD peptide-

targeted radionuclide therapy directed against tumors that express integrin  $\alpha\beta3$  has proven effective for the treatment of advanced, low- to intermediate-grade tumors. The subject radiotherapeutic covered by the patent estate includes an RGD peptide (arginylglycylaspartic acid [Arg-Gly-Asp], linear or cyclical), conjugated to an Evans Blue (EB) analog, and further chelated via DOTA to therapeutic radionuclide  $^{177}\text{Lu}$ , a beta emitter. The EB analog reversibly binds to circulating

serum albumin and improves the pharmacokinetics of RGD peptide DOTA conjugated radiotherapeutics and potentially toxicity. The EB analog conjugated has been shown by the inventors to provide reversible albumin binding in vivo and extended half-life in circulation. This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive patent license will be royalty bearing and may be granted unless within fifteen (15) days from the date of this

published notice, the NHLBI receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act*, 5 U.S.C. 552.

Dated: August 1, 2019.

**Michael A. Shmilovich,**

*Senior Licensing and Patenting Manager, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development.*

[FR Doc. 2019-16965 Filed 8-7-19; 8:45 am]

**BILLING CODE 4140-01-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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, 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; Clinical Research Products Management Center (CRPMC).

*Date:* September 3, 2019.

*Time:* 9:30 a.m. to 12:30 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

*Contact Person:* Audrey O. Lau, MPH, Ph.D., Acting Senior Scientific Review Officer, Aids Review Branch SRP, RM 3E70, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9834, Rockville, MD 20852-9834, 240-669-2081, [audrey.lau@nih.gov](mailto:audrey.lau@nih.gov).

*Name of Committee:* National Institute of Allergy and Infectious Diseases, Special Emphasis Panel; NIAID Clinical Trial Planning Grants (R34).

*Date:* September 19, 2019.

*Time:* 1:00 p.m. to 5:00 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:* Priti Mehrotra, Ph.D., Chief, Immunology Review Branch, Scientific Review Program, Division of Extramural Activities, Room #3G40, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892-7616, 240-669-5066, [pmehrotra@niaid.nih.gov](mailto:pmehrotra@niaid.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: August 2, 2019.

**Sylvia L. Neal,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2019-16924 Filed 8-7-19; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Advancing Translational Sciences; 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 Center for Advancing Translational Sciences Special Emphasis Panel; CTSA.

*Date:* September 11-12, 2019.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate cooperative agreement applications.

*Place:* Bethesda North Marriott Hotel & Conference Center, Montgomery County Conference Center Facility, 5701 Marinelli Road, North Bethesda, MD 20852.

*Contact Person:* Victor Henriquez, Ph.D., Scientific Review Officer, Office of Scientific Director, National Center for Advancing Translational Sciences (NCATS), National

Institutes of Health, 6701 Democracy Blvd., Democracy 1, Room 1080, Bethesda, MD 20892-4878, 301-435-0813, [henriqvu@mail.nih.gov](mailto:henriqvu@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: August 2, 2019.

**Sylvia L. Neal,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2019-16925 Filed 8-7-19; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

#### Project: SAMHSA Application for Peer Grant Reviewers (OMB No. 0930-0255)—Revision

Section 501(h) of the Public Health Service (PHS) Act (42 U.S.C. 290aa) directs the Assistant Secretary of the Substance Abuse and Mental Health Services Administration (SAMHSA) to establish such peer review groups as are needed to carry out the requirements of Title V of the PHS Act. SAMHSA administers a large discretionary grants program under authorization of Title V, and, for many years, SAMHSA has funded grants to provide prevention and treatment services related to substance abuse and mental health.

In support of its grant peer review efforts, SAMHSA desires to continue to expand the number and types of reviewers it uses on these grant review committees. To accomplish that end, SAMHSA has determined that it is important to proactively seek the inclusion of new and qualified representatives on its peer review groups. Accordingly, SAMHSA has developed an application form for use by individuals who wish to apply to serve as peer reviewers.

The application form has been developed to capture the essential information about the individual applicants. The most consistent method to accomplish this is through completion of a standard form by all interested persons which captures information about knowledge, education, and experience in a consistent manner from all interested applicants. SAMHSA will use the information provided on the applications to identify appropriate peer grant reviewers. Depending on their experience and qualifications, applicants may be invited to serve as grant reviewers.

The following changes are proposed in the form:

- Added the collection of License # and Expiration Date to meet 21st Century CURES Act requirements.
- Deleted the collection of experienced federal reviewer or non-federal reviewer information.
- Under No SAMHSA Experience section, added collection of whether or not the potential reviewer had completed SAMHSA reviewer training with the date.

**Under the Target Population Section**

- Added the following distinctions: Tribes or Tribal Organizations
- Minorities (African American, Hispanic/Latino, etc)

**Under the Substance Abuse and Clinical Issues Section**

- Added the following distinctions: Medication Assisted Treatment

- Emergency Treatment
- Opioid Use Disorders
- Deleted the following distinctions: Depression/Manic Depression
- Ecstasy
- Fetal Alcohol Syndrome
- Obsessive Compulsive Disorder
- Personality Disorders

**Under the Other Expertise Section**

- Added the following distinctions: Recovery Support Services
- Behavioral Healthcare
- Rural Communities
- Deleted the following distinctions: Faith Based Community Approaches
- Violence Prevention Programs
- Drug Courts

The following table shows the annual response burden estimate.

Number of respondents	Responses/respondent	Burden/responses (hours)	Total burden hours
500	1	1.5	750

Written comments and recommendations concerning the proposed information collection should be sent by September 9, 2019 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: *OIRA\_Submission@omb.eop.gov*. Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202-395-7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

**Summer King,**  
*Statistician.*

[FR Doc. 2019-16986 Filed 8-7-19; 8:45 am]

**BILLING CODE 4162-20-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

**Project: Regulations To Implement SAMHSA's Charitable Choice Statutory Provisions—42 CFR Parts 54 and 54a (OMB No. 0930-0242)—Extension**

Section 1955 of the Public Health Service Act (42 U.S.C. 300x-65), as amended by the Children's Health Act of 2000 (Pub. L. 106-310) and Sections 581-584 of the Public Health Service Act (42 U.S.C. 290kk *et seq.*, as added by the Consolidated Appropriations Act (Pub. L. 106-554)), set forth various provisions which aim to ensure that religious organizations are able to compete on an equal footing for federal funds to provide substance abuse

services. These provisions allow religious organizations to offer substance abuse services to individuals without impairing the religious character of the organizations or the religious freedom of the individuals who receive the services. The provisions apply to the Substance Abuse Prevention and Treatment Block Grant (SABG), to the Projects for Assistance in Transition from Homelessness (PATH) formula grant program, and to certain Substance Abuse and Mental Health Services Administration (SAMHSA) discretionary grant programs (programs that pay for substance abuse treatment and prevention services, not for certain infrastructure and technical assistance activities). Every effort has been made to assure that the reporting, recordkeeping and disclosure requirements of the proposed regulations allow maximum flexibility in implementation and impose minimum burden.

No changes are being made to the regulations or the burden hours.

Information on how states comply with the requirements of 42 CFR part 54 was approved by the Office of Management and Budget (OMB) as part of the Substance Abuse Prevention and Treatment Block Grant FY 2019-2021 annual application and reporting requirements approved under OMB control number 0930-0168.

42 CFR Citation and Purpose	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hours
Part 54—States Receiving SA Block Grants and/or Projects for Assistance in Transition from Homelessness (PATH):					
<b>Reporting</b>					
96.122(f)(5) Annual report of activities the state undertook to comply 42 CFR part 54 (SABG) .....	60	1	60	1	60
54.8(c)(4) Total number of referrals to alternative service providers reported by program participants to States (respondents):					
SABG .....	6	23 (avg.)	135	1	135
PATH .....	10	5	50	1	50
54.8 (e) Annual report by PATH grantees on activities undertaken to comply with 42 CFR part 54 .....	56	1	56	1	56
<b>Disclosure</b>					
54.8(b) State requires program participants to provide notice to program beneficiaries of their right to referral to an alternative service provider:					
SABG .....	60	1	60	.05	3
PATH .....	56	1	56	.05	3
<b>Recordkeeping</b>					
54.6(b) Documentation must be maintained to demonstrate significant burden for program participants under 42 U.S.C. 300x-57 or 42 U.S.C. 290cc-33(a)(2) and under 42 U.S.C. 290cc-21 to 290cc-35. ....	60	1	60	1	60
Part 54—Subtotal .....	115		477		367
Part 54a—States, local governments and religious organizations receiving funding under Title V of the PHS Act for substance abuse prevention and treatment services:					
<b>Reporting</b>					
54a.8(c)(1)(iv) Total number of referrals to alternative service providers reported by program participants to states when they are the responsible unit of government. ....	25	4	100	.083	8
54a(8)(d) Total number of referrals reported to SAMHSA when it is the responsible unit of government. (NOTE: This notification will occur during the course of the regular reports that may be required under the terms of the funding award.) .....	20	2	40	.25	10
<b>Disclosure</b>					
54a.8(b) Program participant notice to program beneficiaries of rights to referral to an alternative service provider .....	1,460	1	1,460	1	1,460
Part 54a—Subtotal .....	1,505		1,600		1,478
Total .....	1,620		2,077		1,845

Written comments and recommendations concerning the proposed information collection should be sent by September 9, 2019 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service,

commenters are encouraged to submit their comments to OMB via email to: *OIRA\_Submission@omb.eop.gov*. Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202-395-7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory

Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

**Summer King,**  
*Statistician.*

[FR Doc. 2019-16983 Filed 8-7-19; 8:45 am]

**BILLING CODE 4162-20-P**

**DEPARTMENT OF HOMELAND SECURITY****Federal Emergency Management Agency**

[Docket ID FEMA-2019-0002; Internal Agency Docket No. FEMA-B-1952]

**Changes in Flood Hazard Determinations****AGENCY:** Federal Emergency Management Agency, DHS.**ACTION:** Notice.

**SUMMARY:** This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Federal Regulations. The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

**DATES:** These flood hazard determinations will be finalized on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Insurance and Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

**ADDRESSES:** The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at <https://msc.fema.gov> for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

**FOR FURTHER INFORMATION CONTACT:** Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646-7659, or (email) [patrick.sacbibit@fema.dhs.gov](mailto:patrick.sacbibit@fema.dhs.gov); or visit the FEMA Map Information eXchange (FMIX) online at [https://www.floodmaps.fema.gov/fhm/fmx\\_main.html](https://www.floodmaps.fema.gov/fhm/fmx_main.html).

**SUPPLEMENTARY INFORMATION:** The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at <https://msc.fema.gov> for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

**Michael M. Grimm,**

*Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.*

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Arkansas: Benton	City of Bentonville (18-06-3818P).	The Honorable Stephanie Orman, Mayor, City of Bentonville, 117 West Central Avenue, Bentonville, AR 72712.	Department of Public Works, 3200 Southwest Municipal Drive, Bentonville, AR 72712.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Nov. 25, 2019 .....	050012
Colorado: Denver .....	City and County of Denver (19-08-0639P).	The Honorable Michael B. Hancock, Mayor, City and County of Denver, 1437 Bannock Street, Suite 350, Denver, CO 80202.	Department of Public Works, 201 West Colfax Avenue, Denver, CO 80202.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Nov. 8, 2019 .....	080046
El Paso .....	City of Colorado Springs (19-08-0188P).	The Honorable John Suthers, Mayor, City of Colorado Springs, 30 South Nevada Avenue, Suite 601, Colorado Springs, CO 80903.	Pikes Peak Regional Building Department, 2880 International Circle, Colorado Springs, CO 80910.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Oct. 15, 2019 .....	080060

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Jefferson .....	City of Westminster (19-08-0502P).	The Honorable Herb Atchison, Mayor, City of Westminster, 4800 West 92nd Avenue, Westminster, CO 80031.	City Hall, 4800 West 92nd Avenue, Westminster, CO 80031.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Nov. 8, 2019 .....	080008
Connecticut: Hartford.	Town of West Hartford (19-01-0295P).	Mr. Matt Hart, Manager, Town of West Hartford, 50 South Main Street, West Hartford, CT 06107.	Planning and Zoning Department, 50 South Main Street, West Hartford, CT 06107.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Sep. 20, 2019 .....	095081
Florida:						
Broward .....	City of Hollywood (19-04-0557P).	Mr. Wazir Ishmael, Manager, City of Hollywood, 2600 Hollywood Boulevard, Room 419, Hollywood, FL 33022.	Public Utilities Department, 2600 Hollywood Boulevard, Room 308, Hollywood, FL 33022.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Nov. 4, 2019 .....	125113
Charlotte .....	Unincorporated areas of Charlotte County (19-04-0669P).	The Honorable Ken Doherty, Chairman, Charlotte County Board of Commissioners, 18500 Murdock Circle, Suite 536, Port Charlotte, FL 33948.	Charlotte County Community, Development Department, 18500 Murdock Circle, Port Charlotte, FL 33948.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Oct. 17, 2019 .....	120061
Hillsborough	Unincorporated areas of Hillsborough County (19-04-1062P).	Mr. Mike Merrill, Hillsborough County Administrator, 601 East Kennedy Boulevard, Tampa, FL 33602.	Hillsborough County Development Services Department, 1400 North Boulevard, Tampa, FL 33607.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Nov. 4, 2019 .....	120112
Manatee .....	City of Bradenton Beach (19-04-3423P).	The Honorable John Chappie, Mayor, City of Bradenton Beach, 107 Gulf Drive North, Bradenton Beach, FL 34217.	Building Department, 107 Gulf Drive North, Bradenton Beach, FL 34217.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Nov. 12, 2019 .....	125091
Miami-Dade	City of Doral (19-04-0513P).	The Honorable Juan C. Bermudez, Mayor, City of Doral, 8401 Northwest 53rd Terrace, 3rd Floor, Doral, FL 33166.	City Hall, 8401 Northwest 53rd Terrace, 3rd Floor, Doral, FL 33166.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Nov. 18, 2019 .....	120041
Monroe .....	City of Marathon (19-04-3625P).	The Honorable John Bartus, Mayor, City of Marathon, 9805 Overseas Highway, Marathon, FL 33050.	Planning Department, 9805 Overseas Highway, Marathon, FL 33050.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Nov. 12, 2019 .....	120681
Monroe .....	Unincorporated areas of Monroe County (19-04-3471P).	The Honorable Sylvia Murphy, Mayor, Monroe County Board of Commissioners, 102050 Overseas Highway, Suite 234, Key Largo, FL 33037.	Monroe County Building Department, 2798 Overseas Highway, Suite 300, Marathon, FL 33050.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Nov. 4, 2019 .....	125129
Monroe .....	Village of Islamorada (19-04-3477P).	The Honorable Deb Gills, Mayor, Village of Islamorada, 86800 Overseas Highway, Islamorada, FL 33036.	Building Department, 86800 Overseas Highway, Islamorada, FL 33036.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Nov. 12, 2019 .....	120424
Sarasota .....	City of Sarasota (19-04-3550P).	The Honorable Liz Alpert, Mayor, City of Sarasota, 1565 1st Street, Room 101, Sarasota, FL 34236.	Development Services Department, 1565 1st Street, Sarasota, FL 34236.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Nov. 13, 2019 .....	125150
Sarasota .....	Unincorporated areas of Sarasota County (19-04-2523P).	The Honorable Charles D. Hines, Chairman, Sarasota County Board of Commissioners, 1660 Ringling Boulevard, Sarasota, FL 34236.	Sarasota County Planning and Development Services Department, 1001 Sarasota Center Boulevard, Sarasota, FL 34240.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Nov. 12, 2019 .....	125144
Montana: Sanders.	Unincorporated areas of Sanders County (19-08-0298P).	The Honorable Anthony B. Cox, Presiding Officer, Sanders County Board of Commissioners, P.O. Box 519, Thompson Falls, MT 59873.	Sanders County Land Services Department, 1111 Main Street.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Nov. 15, 2019 .....	300072
Oklahoma: Pottawatomie.	City of Shawnee (19-06-2167P).	The Honorable Richard Finley, Mayor, City of Shawnee, 16 West 9th Street, Shawnee, OK 74801.	City Hall, 16 West 9th Street, Shawnee, OK 74801.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Oct. 3, 2019 .....	400178
Pennsylvania:						

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Union .....	Borough of Lewisburg (18-03-1763P).	The Honorable Judith T. Wagner, Mayor, Borough of Lewisburg, 127 Spruce Street, Lewisburg, PA 17837.	Borough Hall, 55 South 5th Street, 127 Spruce Street, Lewisburg, PA 17837.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Nov. 12, 2019 .....	480831
Union .....	Township of East Buffalo (18-03-1763P).	The Honorable Char Gray, Chairman, Township of East Buffalo Board of Supervisors, 589 Fairground Road, Lewisburg, PA 17837.	Township Hall, 589 Fairground Road, Lewisburg, PA 17837.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Nov. 12, 2019 .....	421011
Texas:						
Collin and Denton.	City of Celina (19-06-0008P).	The Honorable Sean Terry, Mayor, City of Celina, 142 North Ohio Street, Celina, TX 75009.	City Hall, 142 North Ohio Street, Celina, TX 75009.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Oct. 7, 2019 .....	480133
Collin .....	Unincorporated areas of Collin County (19-06-0008P).	The Honorable Chris Hill, Collin County Judge, 2300 Bloomdale Road, Suite 4192, McKinney, TX 75071.	Collin County Emergency Management Department, 4690 Community Avenue, Suite 200, McKinney, TX 75071.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Oct. 7, 2019 .....	480130
Denton .....	City of Frisco (19-06-0120P).	The Honorable Jeff Cheney, Mayor, City of Frisco, 6101 Frisco Square Boulevard, Frisco, TX 75034.	Engineering Services Department, 6101 Frisco Square Boulevard, Frisco, TX 75034.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Nov. 12, 2019 .....	480134
Denton .....	City of The Colony (19-06-1578P).	The Honorable Joe McCourry, Mayor, City of The Colony, 6800 Main Street, The Colony, TX 75056.	Engineering Department, 6800 Main Street, The Colony, TX 75056.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Nov. 12, 2019 .....	481581
Denton .....	Town of Little Elm (19-06-0120P).	The Honorable David Hillcock, Mayor, Town of Little Elm, 100 West Eldorado Parkway, Little Elm, TX 75068.	Development Services Department, 100 West Eldorado Parkway, Little Elm, TX 75068.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Nov. 12, 2019 .....	481152
Denton .....	Unincorporated areas of Denton County (19-06-0008P).	The Honorable Andy Eads, Denton County Judge, 110 West Hickory Street, 2nd Floor, Denton, TX 76201.	Denton County Public Works, Engineering Department, 1505 East McKinney Street, Suite 175, Denton, TX 76201.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Oct. 7, 2019 .....	480774
Denton .....	Unincorporated areas of Denton County (19-06-0120P).	The Honorable Andy Eads, Denton County Judge, 110 West Hickory Street, 2nd Floor, Denton, TX 76201.	Denton County Public Works, Engineering Department, 1505 East McKinney Street, Suite 175, Denton, TX 76201.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Nov. 12, 2019 .....	480774
Ector .....	City of Odessa (18-06-3857P).	The Honorable David Turner, Mayor, City of Odessa, P.O. Box 4398, Odessa, TX 79760.	City Hall, 411 West 8th Street, 4th Floor, Odessa, TX 79761.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Nov. 18, 2019 .....	480206
McLennan ...	City of Woodway (18-06-3769P).	Mr. Shawn Oubre, Manager, City of Woodway, 922 Estates Drive, Woodway, TX 76712.	Community Services and Development Department, 924 Estates Drive, Woodway, TX 76712.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Nov. 19, 2019 .....	480462
McLennan ...	Unincorporated areas of McLennan County (18-06-3769P).	The Honorable Scott M. Felton, McLennan County Judge, 501 Washington Avenue, Room 214, Waco, TX 76701.	McLennan County Engineering and Mapping Department, 215 North 5th Street, Suite 130, Waco, TX 76701.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Nov. 19, 2019 .....	480456
Potter .....	Unincorporated areas of Potter County (19-06-0488P).	The Honorable Nancy Tanner, Potter County Judge, 500 South Fillmore Street, Suite 103, Amarillo, TX 79101.	Potter County Courthouse, 500 South Fillmore Street, Amarillo, TX 79101.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Nov. 4, 2019 .....	481241
Tarrant .....	City of Fort Worth (19-06-0602P).	The Honorable Betsy Price, Mayor, City of Fort Worth, 200 Texas Street, Fort Worth, TX 76102.	Transportation and Public Works Engineering Department, 200 Texas Street, Fort Worth, TX 76102.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Nov. 14, 2019 .....	480596
Washington:						
Spokane .....	City of Spokane Valley (18-10-1005P).	Mr. Mark Calhoun, Manager, City of Spokane Valley, 10210 East Sprague Avenue, Spokane Valley, WA 99206.	Building and Planning Division, 10210 East Sprague Avenue, Spokane Valley, WA 99206.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Oct. 15, 2019 .....	530342

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Spokane .....	Unincorporated areas of Spokane County (18-10-1005P).	Mr. Gerry Gemmill, Chief Executive Officer, Spokane County, 1116 West Broadway Avenue, Spokane County, WA 99260.	Spokane County Public Works Department, 1026 West Broadway Avenue, Spokane County, WA 99260.	<a href="https://msc.fema.gov/portal/advanceSearch">https://msc.fema.gov/portal/advanceSearch</a> .	Oct. 15, 2019 .....	530174

[FR Doc. 2019-17023 Filed 8-7-19; 8:45 am]  
 BILLING CODE 9110-12-P

**DEPARTMENT OF HOMELAND SECURITY**

**Federal Emergency Management Agency**

[Docket ID FEMA-2019-0002]

**Final Flood Hazard Determinations**

**AGENCY:** Federal Emergency Management Agency, DHS.  
**ACTION:** Notice.

**SUMMARY:** Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below.

The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP). In addition, the FIRM

and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

**DATES:** The date of December 20, 2019 has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

**ADDRESSES:** The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at <https://msc.fema.gov> by the date indicated above.

**FOR FURTHER INFORMATION CONTACT:** Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646-7659, or (email) [patrick.sacbibit@fema.dhs.gov](mailto:patrick.sacbibit@fema.dhs.gov); or visit the FEMA Map Information eXchange (FMIX) online at [https://www.floodmaps.fema.gov/fhm/fmx\\_main.html](https://www.floodmaps.fema.gov/fhm/fmx_main.html).

**SUPPLEMENTARY INFORMATION:** The Federal Emergency Management Agency (FEMA) makes the final determinations

listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at <https://msc.fema.gov>.

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below. (Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

**Michael M. Grimm,**  
*Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.*

Community	Community map repository address
<b>San Diego County, California and Incorporated Areas Docket No.: FEMA-B-1742</b>	
City of Carlsbad .....	Building and Development Department, 1635 Faraday Avenue, Carlsbad, CA 92008.
City of Chula Vista .....	City Hall, 276 4th Avenue, Chula Vista, CA 91910.
City of Coronado .....	City Hall, 1825 Strand Way, Coronado, CA 92118.
City of Del Mar .....	City Hall, 2010 Jimmy Durante Boulevard, Suite 120, Del Mar, CA 92014.
City of Encinitas .....	City Hall, 505 South Vulcan Avenue, Encinitas, CA 92024.
City of Imperial Beach .....	City Hall, 825 Imperial Beach Boulevard, Imperial Beach, CA 91932.
City of National City .....	City Hall, 1243 National City Boulevard, National City, CA 91950.
City of Oceanside .....	City Hall, 300 North Coast Highway, Oceanside, CA 92054.
City of San Diego .....	Engineering Branch, 525 B Street, Suite 750, MS 908A, San Diego, CA 92101.
City of Solana Beach .....	City Hall, 635 South Highway 101, Solana Beach, CA 92075.
Unincorporated Areas of San Diego County .....	Department of Public Works, 5510 Overland Avenue, Suite 410, MS 0326, San Diego, CA 92123.

<b>Clear Creek County, Colorado and Incorporated Areas Docket No.: FEMA-B-1749</b>	
City of Idaho Springs .....	City Hall, 1711 Miner Street, Idaho Springs, CO 80452.
Town of Georgetown .....	Town Hall, 404 6th Street, Georgetown, CO 80444.

Community	Community map repository address
Unincorporated Areas of Clear Creek County .....	Clear Creek County Annex, 1111 Rose Street, Georgetown, CO 80444.
<b>Jefferson County, Colorado and Incorporated Areas Docket No.: FEMA-B-1749</b>	
City of Arvada .....	Engineering Department, 8101 Ralston Road, Arvada, CO 80002.
City of Golden .....	Public Works Department, 1445 10th Street, Golden, CO 80401.
Unincorporated Areas of Jefferson County .....	Jefferson County Planning and Zoning Division, 100 Jefferson County Parkway, Suite 3550, Golden, CO 80419.
<b>Hart County, Georgia and Incorporated Areas Docket No.: FEMA-B-1849</b>	
City of Hartwell .....	City Hall, 456 East Howell Street, Hartwell, GA 30643.
Unincorporated Areas of Hart County .....	Hart County Government Office, 800 Chandler Street, Hartwell, GA 30643.
<b>Benton County, Iowa and Incorporated Areas Docket No.: FEMA-B-1843</b>	
City of Atkins .....	City Hall, 480 3rd Avenue, Atkins, IA, 52206.
City of Belle Plaine .....	City Hall, 1207 8th Avenue, Belle Plaine, IA, 52208.
City of Blainstown .....	City Hall, 305 Locust Street Northwest, Blainstown, IA, 52209.
City of Garrison .....	Garrison Public Library, 201 East Pine Street, Garrison, IA 52229.
City of Keystone .....	City Hall, 208 1st Street, Keystone, IA, 52249.
City of Newhall .....	City Hall, 11 2nd Avenue, Newhall, IA 52315.
City of Norway .....	City Hall, 108 Railroad Street, Norway, IA, 52318.
City of Shellsburg .....	City Hall, 108 Main Street Southeast, Shellsburg, IA, 52332.
City of Urbana .....	City Hall, 102 Capitol Avenue, Urbana, IA, 52345.
City of Van Horne .....	City Hall, 114 Main Street, Van Horne, IA, 52346.
City of Vinton .....	City Hall, 110 West 3rd Street, Vinton, IA, 52349.
Unincorporated Areas of Benton County .....	Benton County Courthouse, 111 East 4th Street, Vinton, IA, 52349.
<b>Grundy County, Iowa and Incorporated Areas Docket No.: FEMA-B-1843</b>	
City of Beaman .....	City Hall, 227 Main Street, Beaman, IA 50609.
City of Conrad .....	City Hall, 204 East Center Street, Conrad, IA 50621.
City of Dike .....	City Hall, 540 Main Street, Dike, IA 50624.
City of Grundy Center .....	City Hall, 703 F Avenue, Suite 2, Grundy Center, IA 50638.
City of Holland .....	City Hall, 106 Main Street, Holland, IA 50642.
City of Morrison .....	City Hall, 204 Sycamore Street, Morrison, IA 50657.
City of Reinbeck .....	City Hall, 414 Main Street, Reinbeck, IA 50669.
City of Wellsburg .....	City Hall, 515 North Adams Street, Wellsburg, IA 50680.
Unincorporated Areas of Grundy County .....	Grundy County Engineer's Office, 22580 M Avenue, Grundy Center, IA 50638.
<b>Hamilton County, Iowa and Incorporated Areas Docket No.: FEMA-B-1843</b>	
City of Ellsworth .....	City Hall, 1528 DeWitt Street, Ellsworth, IA 50075.
City of Jewell .....	City Hall, 701 Main Street, Jewell, IA 50130.
City of Kamrar .....	City Hall, 414 Elm Street, Kamrar, IA 50132.
City of Webster City .....	City Hall, 400 2nd Street, Webster City, IA 50595.
Unincorporated Areas of Hamilton County .....	Hamilton County Courthouse, 2300 Superior Street, Suite 4, Webster City, IA 50595.
<b>Norman County, Minnesota and Incorporated Areas Docket No.: FEMA-B-1843</b>	
City of Halstad .....	Administrative Building, 405 2nd Avenue West, Halstad, MN 56548.
City of Hendrum .....	Administrative Building, 308 Main Street East, Hendrum, MN 56550.
Unincorporated Areas of Norman County .....	County Court House, 16 3rd Avenue East, Ada, MN 56510.
<b>Livingston County, Missouri and Incorporated Areas Docket No.: FEMA-B-1853</b>	
City of Chillicothe .....	City Hall, 715 Washington Street, Chillicothe, MO, 64601.
City of Chula .....	Livingston County Courthouse, 700 Webster Street, Chillicothe, MO, 64601.
City of Wheeling .....	City Hall, 210 North Grant Street, Wheeling, MO, 64688.
Unincorporated Areas of Livingston County .....	Livingston County Courthouse, 700 Webster Street, Chillicothe, MO, 64601.
Village of Utica .....	Livingston County Courthouse, 700 Webster Street, Chillicothe, MO, 64601.
<b>Warren County, Ohio and Incorporated Areas Docket Nos.: FEMA-B-1452 and B-1843</b>	
City of Franklin .....	City Building, 1 Benjamin Franklin Way, Franklin, OH 45005.
Unincorporated Areas of .....	Administration Building, 406 Justice Drive, Lebanon, OH, 45036.
Warren County .....	

Community	Community map repository address
Village of Carlisle .....	Town Hall, 760 Central Avenue, Carlisle, OH 45005.
<b>Aransas County, Texas and Incorporated Areas Docket No.: FEMA-B-1836</b>	
City of Aransas Pass .....	City Hall, 600 West Cleveland Boulevard, Aransas Pass, TX 78336.
<b>Hill County, Texas and Incorporated Areas Docket No.: FEMA-B-1841</b>	
City of Abbott .....	City Hall, 208 East Walnut Street, Abbott, TX 76621.
City of Covington .....	City Hall, 402 Gathings Avenue, Covington, TX 76636.
City of Hillsboro .....	Community Development Department, 214 East Elm Street, Hillsboro, TX 76645.
City of Itasca .....	City Hall, 134 North Hill Street, Itasca, TX 76055.
Unincorporated Areas of Hill County .....	Hill County Courthouse, John W. Erwin Annex, 200 East Franklin Street, Suite 9, Hillsboro, TX 76645.
<b>McLennan County, Texas and Incorporated Areas Docket No.: FEMA-B-1841</b>	
City of Bellmead .....	City Hall, 3015 Bellmead Drive, Bellmead, TX 76705.
City of Hallsburg .....	City Hall, 1115 Wilbanks Drive, Hallsburg, TX 76705.
City of Hewitt .....	Planning and Community Development, 103 North Hewitt Drive, Suite E, Hewitt, TX 76643.
City of Lacy-Lakeview .....	City Hall, 501 East Craven Avenue, Lacy-Lakeview, TX 76705.
City of Leroy .....	City Hall, 10 East Commerce Street, Leroy, TX 76654.
City of Riesel .....	City Hall, 104 North Highway 6, Riesel, TX 76682.
City of Robinson .....	City Hall, 111 West Lyndale Drive, Robinson, TX 76706.
City of Ross .....	Ross City Hall, 1557 Ross Road, Elm Mott, TX 76640.
City of Waco .....	Dr. Mae Jackson Development Center, 401 Franklin Avenue, Waco, TX 76701.
City of West .....	City Hall, 110 North Reagan Street, West, TX 76691.
Unincorporated Areas of McLennan County .....	McLennan County Records Building, 215 North 5th Street, Room 130, Waco, TX 76701.
<b>San Patricio County, Texas and Incorporated Areas Docket No.: FEMA-B-1836</b>	
City of Aransas Pass .....	City Hall, 600 West Cleveland Boulevard, Aransas Pass, TX 78336.
<b>Williamson County, Texas and Incorporated Areas Docket Nos.: FEMA-B-1769 and FEMA-B-1830</b>	
City of Austin .....	Watershed Engineering Division, 505 Barton Springs Road, 12th Floor, Austin, TX 78704.
City of Cedar Park .....	City Hall, 450 Cypress Creek Road, Building 1, Cedar Park, TX 78613.
City of Coupland .....	Coupland Fire Station, 403 FM 1466, Coupland, TX 78615.
City of Georgetown .....	Georgetown Utility Systems, 300-1 Industrial Avenue, Georgetown, TX 78626.
City of Granger .....	City Hall, 119 East Davilla Street, Granger, TX 76530.
City of Hutto .....	Department of Public Works, 210 U.S. 79 East, Suite 203, Hutto, TX 78634.
City of Leander .....	City Hall, 105 North Brushy Street, Leander, TX 78641.
City of Round Rock .....	Utilities and Environment Services, 2008 Enterprise Drive, Round Rock, TX 78664.
City of Taylor .....	City Hall, 400 Porter Street, Taylor, TX 76574.
City of Thrall .....	City Hall, 104 South Main Street, Thrall, TX 76578.
City of Weir .....	City Hall, 2205 South Main Street, Weir, TX 78674.
Unincorporated Areas of Williamson County .....	Williamson County Central Maintenance Facility, 3151 South East Inner Loop, Suite B, Georgetown, TX 78626.

[FR Doc. 2019-17020 Filed 8-7-19; 8:45 am]  
 BILLING CODE 9110-12-P

**DEPARTMENT OF HOMELAND SECURITY**

**U.S. Citizenship and Immigration Services**

[OMB Control Number 1615-NEW]

**Agency Information Collection Activities; New Collection: USCIS Tip Form**

**AGENCY:** U.S. Citizenship and Immigration Services, Department of Homeland Security.

**ACTION:** 30-Day notice.

**SUMMARY:** The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments.

**DATES:** The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until September 9, 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, must be directed to the OMB USCIS Desk Officer via email at [dhsdeskofficer@omb.eop.gov](mailto:dhsdeskofficer@omb.eop.gov). All submissions received must include the agency name and the OMB Control Number 1615-NEW in the subject line.

You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make. For additional information please read the Privacy Act notice that is available via the link in the footer of <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, 20 Massachusetts Avenue NW, Washington, DC 20529-2140, Telephone number (202) 272-8377 (This is not a toll-free number; comments are not accepted via telephone message.). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at <http://www.uscis.gov>, or call the USCIS Contact Center at (800) 375-5283; TTY (800) 767-1833.

**SUPPLEMENTARY INFORMATION:**

**Comments**

The information collection notice was previously published in the **Federal Register** on February 15, 2019, at 84 FR 4518, allowing for a 60-day public comment period. USCIS received 301 comments in connection with the 60-day notice.

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: <http://www.regulations.gov> and enter USCIS-2019-0001 in the search box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including

whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

**Overview of This Information Collection**

(1) *Type of Information Collection Request:* New Collection.

(2) *Title of the Form/Collection:* USCIS Tip Form.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* G-1530; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. The USCIS Tip Form will facilitate the collection of information from the public regarding credible and relevant claims of immigration benefit fraud impacting both open adjudications as well as previously approved benefit requests where the benefit remains valid.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection G-1530 is 55,000 and the estimated hour burden per response is .166 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 9,130 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* There is no public burden cost associated with this collection.

Dated: August 5, 2019.

**Samantha L Deshommes**,  
Chief, Regulatory Coordination Division,  
Office of Policy and Strategy, U.S. Citizenship  
and Immigration Services, Department of  
Homeland Security.

[FR Doc. 2019-17022 Filed 8-7-19; 8:45 am]

**BILLING CODE 9111-97-P**

**DEPARTMENT OF THE INTERIOR**

**Fish and Wildlife Service**

[Docket No. FWS-HQ-IA-2019-0063;  
FXIA1671090000-190-FF09A30000]

**Emergency Exemption; Issuance of  
Emergency Permit To Import  
Endangered Species**

**AGENCY:** Fish and Wildlife Service,  
Interior.

**ACTION:** Notice of issuance of permit.

**SUMMARY:** We, the U.S. Fish and Wildlife Service, have waived the 30-day public notice period and have issued an endangered species permit for activities with four wild-collected eggs from piping plover (*Charadrius melodus*), an endangered bird species. We issue this permit under the Endangered Species Act.

**ADDRESSES:** Materials pertaining to the permit application are available by submitting a Freedom of Information Act (FOIA) request to the Service's FOIA office <https://www.doi.gov/foia/foia-request-form>.

**FOR FURTHER INFORMATION CONTACT:** Brenda Tapia, by phone at 703-358-2104, via email at [DMAFR@fws.gov](mailto:DMAFR@fws.gov), or via the Federal Relay Service at 800-877-8339.

**SUPPLEMENTARY INFORMATION:** We, the U.S. Fish and Wildlife Service (Service), have issued an emergency permit to conduct certain activities with the endangered piping plover (*Charadrius melodus*) in response to a permit application that we received under the authority of section 10(a)(1)(A) of the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*)

We issued the requested permit subject to certain conditions set forth in the permit. For the application, we found that (1) the application was filed in good faith, (2) the granted permit would not operate to the disadvantage of the endangered species, and (3) the granted permit would be consistent with the purposes and policy set forth in section 2 of the ESA.

**PERMIT ISSUED UNDER EMERGENCY  
EXEMPTION**

Permit No.	Applicant	Permit issuance date
44262D	U.S. Fish and Wildlife Service.	June 13, 2019.

The Service's piping plover coordinator requested a permit to import and captive-rear four viable wild-collected piping plover eggs from the Canadian Wildlife Service in

Ontario, Canada, due to the eggs' having been washed out by a storm and abandoned by the parents in the wild. The Service determined that an emergency affecting the viability of the piping plover eggs existed, and that no reasonable alternative was available to the applicant.

On June 13, 2019, the Service issued permit no. PRT-44262D to the U.S. Fish and Wildlife Service, East Lansing, Michigan, to import the four viable wild-collected eggs from piping plover for the purpose of enhancement of the survival of the species. The eggs were salvaged so that the Service could hatch them in captivity at a captive-rearing facility in the United States for eventual release of the fledged birds into the wild.

#### Authorities

We issue this notice under the authority of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and its implementing regulations.

#### Brenda Tapia,

*Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.*

[FR Doc. 2019-16970 Filed 8-7-19; 8:45 am]

BILLING CODE 4333-15-P

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

[Docket No. FWS-HQ-NWRS-2019-0067; FF09R50000-18X-FVRS8451900000]

#### National Wildlife Refuge System; Loess Bluffs National Wildlife Refuge; Possible Name Change

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice; request for comments.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service, we), are considering renaming the Loess Bluffs National Wildlife Refuge. We invite the public to comment on the question of whether or not to rename this refuge.

**DATES:** Interested persons are invited to submit comments that are postmarked on or before August 23, 2019.

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

(1) *Electronically:* Go to the Federal eRulemaking Portal: <http://www.regulations.gov>. Search for FWS-HQ-NWRS-2019-0067, which is the docket number for this rulemaking. Please ensure you have found the correct docket before submitting your comments.

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: Docket No. FWS-HQ-NWRS-2019-0067, U.S. Fish and Wildlife Service, MS: JAO/1N, 5275 Leesburg Pike, Falls Church, VA 22041-3803.

**FOR FURTHER INFORMATION CONTACT:** Ken Fowler, NWRS Division of Realty, U.S. Fish and Wildlife Service, 5275 Leesburg Pike, MS: 3N038D, Falls Church, VA 22041-3803; (703) 358-1713.

**SUPPLEMENTARY INFORMATION:** We are soliciting comments on the question of whether or not to rename the Loess Bluffs National Wildlife Refuge, located in Holt County, Missouri. You may submit your comments and materials concerning this issue by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

#### Background

On January 10, 2017, the Service Director approved a request from the Service Regional Director, Midwest Region, to rename the Squaw Creek National Wildlife Refuge, located in Holt County, Missouri, to Loess Bluffs National Wildlife Refuge. This decision followed a meeting that was held at the refuge on December 19, 2016, with certain interested parties to discuss suitable alternatives for the name change. The majority of the group of stakeholders and Tribal and community leaders present at the meeting concurred that recognizing the loess hills geologic formation would be the best alternative.

Now, in response to congressional direction in House Report 115-765, which accompanied the Consolidated Appropriations Act, 2019 (Pub. L. 116-6), enacted February 15, 2019, the Service is opening a public process on the question of whether or not to rename the Loess Bluffs National Wildlife Refuge. Accordingly, through this **Federal Register** notice, we are inviting the public to comment, for a period of 15 days, on the question of whether or not to rename the Loess Bluffs National Wildlife Refuge.

#### Public Availability of Comments

Written comments we receive will become part of the public record associated with this action. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may request in your

comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

#### Next Steps

After review of any comments received, we will determine whether there is public interest in renaming the Loess Bluffs National Wildlife Refuge. If there is significant public interest in renaming the refuge, we will consult local stakeholders about a new name via another open process.

#### Authority

We provide this notice in accordance with the Congressional direction in House Report 115-765, which accompanied the Consolidated Appropriations Act, 2019 (Pub. L. 116-6).

Dated: July 15, 2019.

#### Margaret E. Everson,

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

[FR Doc. 2019-16966 Filed 8-7-19; 8:45 am]

BILLING CODE 4333-15-P

## DEPARTMENT OF THE INTERIOR

### Bureau of Safety and Environmental Enforcement

[Docket ID BSEE-2018-0004; 190E1700D2 ETISF0000 EAQ000 EEEE500000; OMB Control Number 1014-0002]

#### Agency Information Collection Activities; Oil and Gas Production Measurement, Surface Commingling, and Security

**AGENCY:** Bureau of Safety and Environmental Enforcement, Interior.

**ACTION:** Notice of information collection; request for comment.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, the Bureau of Safety and Environmental Enforcement (BSEE) proposes to renew an information collection.

**DATES:** Interested persons are invited to submit comments on or before October 7, 2019.

**ADDRESSES:** Send your comments on this information collection request (ICR) by either of the following methods listed below:

• Electronically go to <http://www.regulations.gov>. In the Search box, enter BSEE–2018–0004 then click search. Follow the instructions to submit public comments and view all related materials. We will post all comments.

• Email [kye.mason@bsee.gov](mailto:kye.mason@bsee.gov), fax (703) 787–1546, or mail or hand-carry comments to the Department of the Interior; Bureau of Safety and Environmental Enforcement, Regulations and Standards Branch, ATTN: Nicole Mason, 45600 Woodland Road, Sterling, VA 20166. Please reference OMB Control Number 1014–0002 in the subject line of your comments.

**FOR FURTHER INFORMATION CONTACT:** To request additional information about this ICR, contact Nicole Mason by email at [kye.mason@bsee.gov](mailto:kye.mason@bsee.gov) or by telephone at (703) 787–1607.

**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 comments addressing the following issues: (1) Is the collection necessary to the proper functions of BSEE; (2) Will this information be processed and used in a timely manner; (3) Is the estimate of burden accurate; (4) How might BSEE enhance the quality, utility, and clarity of the information to be collected; and (5) How might BSEE 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:** The regulations at 30 CFR part 250, subpart L, concern the Oil and Gas Production Measurement, Surface Commingling, and Security regulatory requirements of oil, gas, and sulphur operations in the Outer Continental Shelf (OCS) and are the subject of this collection. This request also covers any related Notices to Lessees and Operators (NTLs) that BSEE issues to clarify, supplement, or provide additional guidance on some aspects of our regulations.

The BSEE uses the information collected under the Subpart L regulations to ensure that operations on the OCS are carried out in a safe and pollution-free manner, do not interfere with the rights of other users on the OCS, and balance the protection and development of OCS resources. Specifically, we use the information collected to do the following:

In regard to Liquid Hydrocarbon Measurement—

- Determine if measurement equipment is properly installed, provides accurate measurement of production on which royalty is due, and is operating properly;

- Ascertain if all removals of oil and condensate from the lease are reported;
- Obtain rates of production measured at royalty meters, which can be examined during field inspections;

In regard to Gas Measurement—

- Ensure that the sales location is secure and production cannot be removed without the volumes being recorded;

In regard to Surface Commingling—

- Review gas volume statements and compare them with the Oil and Gas Operations Reports to verify accuracy.

In regard to Miscellaneous & Recordkeeping—

- Review proving reports to verify that data on run tickets are calculated and reported accurately.

**Title of Collection:** 30 CFR part 250, subpart L, *Oil and Gas and Sulfur Operations in the OCS—Oil and Gas Production Measurement, Surface Commingling, and Security.*

**OMB Control Number:** 1014–0002.

**Form Number:** None.

**Type of Review:** Extension of a currently approved collection.

**Respondents/Affected Public:** Potential respondents comprise Federal OCS oil, gas, and sulfur lessees/operators and holders of pipeline rights-of-way.

**Total Estimated Number of Annual Respondents:** Not all potential respondents will submit information in any given year and some may submit multiple times.

**Total Estimated Number of Annual Responses:** 102,361.

**Estimated Completion Time per Response:** Varies from 10 minutes to 35 hours, depending on activity.

**Total Estimated Number of Annual Burden Hours:** 39,905.

**Respondent's Obligation:** Most responses are mandatory, while others are required to obtain or retain benefits, or are voluntary.

**Frequency of Collection:** On occasion, monthly, and varies by section.

**Total Estimated Annual Nonhour Burden Cost:** \$322,479.

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.*).

**Stacey Noem,**

*Acting Chief, Office of Offshore Regulatory Programs.*

[FR Doc. 2019–16967 Filed 8–7–19; 8:45 am]

**BILLING CODE 4310–VH–P**

## INTERNATIONAL TRADE COMMISSION

[USITC SE–19–030]

### Sunshine Act Meetings

**AGENCY HOLDING THE MEETING:** United States International Trade Commission.

**TIME AND DATE:** August 20, 2019 at 11:00 a.m.

**PLACE:** Room 101, 500 E Street SW, Washington, DC 20436, Telephone: (202) 205–2000.

**STATUS:** Open to the public.

#### MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: None.
2. Minutes.
3. Ratification List.
4. Vote on Inv. Nos. 701–TA–608 and 731–TA–1420 (Final) (Steel Racks from China). The Commission is currently scheduled to complete and file its determinations and views of
5. *Outstanding action jackets:* None.

The Commission is holding the meeting under the Government in the Sunshine Act, 5 U.S.C. 552(b). In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: August 6, 2019.

**William Bishop,**

*Supervisory Hearings and Information Officer.*

[FR Doc. 2019-17134 Filed 8-6-19; 4:15 pm]

**BILLING CODE 7020-02-P**

## **INTERNATIONAL TRADE COMMISSION**

**[USITC SE-19-031]**

### **Sunshine Act Meetings**

**AGENCY HOLDING THE MEETING:** United States International Trade Commission.

**TIME AND DATE:** August 22, 2019 at 11:00 a.m.

**PLACE:** Room 101, 500 E Street SW, Washington, DC 20436, Telephone: (202) 205-2000..

**STATUS:** Open to the public.

**MATTERS TO BE CONSIDERED:** 1. *Agendas for future meetings:* None.

2. Minutes.

3. Ratification List.

4. Vote on Inv. Nos. 701-TA-627-629 and 731-TA-1458-1461 (Preliminary)(Utility Scale Wind Towers from Canada, Indonesia, Korea, and Vietnam). The Commission is currently scheduled to complete and file its determinations on August 23, 2019; views of the Commission are currently scheduled to be completed and filed on August 30, 2019.

5. *Outstanding action jackets:* None.

The Commission is holding the meeting under the Government in the Sunshine Act, 5 U.S.C. 552(b). In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: August 6, 2019.

**William Bishop,**

*Supervisory Hearings and Information Officer.*

[FR Doc. 2019-17133 Filed 8-6-19; 4:15 pm]

**BILLING CODE 7020-02-P**

## **DEPARTMENT OF JUSTICE**

### **Drug Enforcement Administration**

**[Docket No. 19-19]**

#### **Parth S. Bharill; Decision and Order**

On March 13, 2019, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, Government), issued an Order to Show Cause to Parth S. Bharill, M.D.

(hereinafter, Respondent) of Pittsburgh, Pennsylvania. Order to Show Cause (hereinafter, OSC), at 1. The OSC proposed the revocation of Respondent's Certificate of Registration No. BB3258034 on the ground that Respondent does "not have authority to handle controlled substances in Pennsylvania, the state in which [Respondent is] registered with the DEA." *Id.* (citing 21 U.S.C. 823(f) and 824(a)(3)).

Specifically, the OSC alleged that the Commonwealth of Pennsylvania State Board of Medicine (hereinafter, Board) issued an Order of Temporary Suspension And Notice (hereinafter, Temporary Suspension Order 1) on June 18, 2018. *Id.* This Temporary Suspension Order, according to the OSC, immediately restricted Respondent's license to practice Medicine and Surgery because Respondent's "continued practice of medicine and surgery in Pennsylvania constitutes 'an immediate and clear danger to the public health and safety.'" *Id.* at 1-2. Further, the OSC alleged that on July 13, 2018, the Board "issued an 'Order Granting Continuance with Immediate Temporary Suspension Remaining In Effect' (hereinafter, Temporary Suspension Order 2), whereby the Board maintained the suspension of [Respondent's] medical license." *Id.* at 2.

The OSC notified Respondent of the right to request a hearing on the allegations or to submit a written statement while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 2 (citing 21 CFR 1301.43). The OSC also notified Respondent of the opportunity to submit a corrective action plan. *Id.* at 3 (citing 21 U.S.C. 824(c)(2)(C)).

By letter dated April 12, 2019, Respondent timely requested a hearing. Hearing Request, at 1. According to the Hearing Request, Respondent's interest in the proceedings is to defend his "constitutionally protected right to pursue a gainful occupation" and he objects to the issuance of the OSC because he applied to transfer his certificate of registration (hereinafter, COR) from his Pennsylvania address to a West Virginia address on December 31, 2018, and he "has a current and active Medical License . . . in the State of West Virginia." *Id.* at 1.

Respondent argues that "the use of the phrase 'may be suspended or revoked' [in 21 U.S.C. 824(a)] demonstrates that this is a discretionary authority of the DEA and does not take effect by operation of law based upon the loss of a license." *Id.* at 2 (citations

omitted). He further contends that due to Respondent's request for a change of address to West Virginia, "where an application for modification is received, it must be handled in the same manner as an application for registration." *Id.* (citing 21 U.S.C. 823(f)). He argues that DEA was required to grant the modification because DEA has not found "that Respondent's requested modification was inconsistent with the public interest," and he "has not [sic] disciplinary action taken against his West Virginia Medical License and, therefore, the DEA has not [sic] authority to revoke or suspend his license." *Id.*

The Office of Administrative Law Judges put the matter on the docket and assigned it to Administrative Law Judge Mark M. Dowd (hereinafter, ALJ). The ALJ issued an Order for Prehearing Statements (hereinafter, PH Order) dated April 22, 2019, setting a date by which the Government should file either a Prehearing Statement or a Motion for Summary Disposition, and affording Respondent one additional week to file either its Prehearing Statement or its Reply. PH Order, at 1-2.

The Government filed its Motion for Summary Disposition and Argument in Support of Finding that Respondent Lacks State Authorization to Handle Controlled Substances (hereinafter, Government's Motion) on April 29, 2019. In its motion, the Government stated that Respondent lacks authority to handle controlled substances in Pennsylvania, the state in which he is registered with the DEA, and argued that therefore, DEA must revoke his registration. Government's Motion, at 1.

On May 2, 2019, Respondent filed both a Prehearing Statement and a separate Response in Opposition to the Government's Motion for Summary Disposition (hereinafter, Respondent's Response). In his Prehearing Statement, Respondent requested that the "revocation of his registration be stayed pending a determination on his application for modification, or, in the alternative, that the application for modification be unaffected if revocation is approved." Respondent's Prehearing Statement, at 1. He also requested that "this case be determined on the documents submitted by the parties." *Id.*, at 2, 3. In Respondent's Response, he contends that "prior to seeking to revoke Respondent's registration, the DEA is required to decide the matter of the application of modification," or, in the alternative, if his current registration is revoked, his "application for modification should continue and be granted, unless the Government enters

an order to show cause and demonstrates before an ALJ that granting the application is not in the public interest.” Respondent’s Response, at 4.

I have reviewed and considered Respondent’s Prehearing Statement and Respondent’s Response as part of, and along with, the entire record before me.

On May 3, 2019, the ALJ granted the Government’s Motion, finding that “the subject of the instant litigation is not whether the Respondent has requested to modify his COR to reflect an address in West Virginia, but whether he has state authority to dispense controlled substances in the state in which his COR is currently registered, Pennsylvania, which he concedes, he does not.” Order Granting Summary Disposition and Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (hereinafter, R.D.), at 7–8. “Therefore, summary disposition of an administrative case is warranted where, as here, ‘there is no factual dispute of substance.’” *Id.* at 11 (citing *Veg-Mix, Inc. v. U.S. Dep’t of Agric.*, 832 F.2d 601, 607 (D.C. Cir. 1987)). The ALJ recommended that Respondent’s registration be revoked because Respondent has conceded to his lack of medical license in Pennsylvania and the only “subject COR before this Tribunal . . . has been fatally undermined by the Respondent’s suspension of medical licensure in Pennsylvania.” *Id.* at 10.

By letter dated June 5, 2019, the ALJ certified and transmitted the record to me for final Agency action. In that letter, the ALJ advised that neither party filed exceptions and that the time period to do so had expired.

I issue this Decision and Order based on the entire record before me. 21 CFR 1301.43(e). I make the following findings of fact.

### Findings of Fact

#### *Respondent’s DEA Registration*

Respondent is the holder of DEA Certificate of Registration No. BB3258034 at the registered address of 1350 Locust Street, Suite G102, Pittsburgh, Pennsylvania 15219. Government’s Motion, Attachment 1. Pursuant to this registration, Respondent is authorized to dispense controlled substances in schedules II through V as a practitioner and is also authorized as a DATA-waived practitioner to treat a maximum of 275 patients for narcotic treatment. *Id.*; see 21 CFR 1301.28(a) & (b)(iii). Respondent’s registration expires on July 31, 2019.

Government’s Motion, Attachment 1.

### The Status of Respondent’s State License

On June 18, 2018, the Board issued an Order of Temporary Suspension and Notice of Hearing (hereinafter, Temporary Suspension Order) suspending Respondent’s license effective immediately upon service of the Order. Government’s Motion, Attachment 2, at 1–2. According to the Temporary Suspension Order, the Board determined that if the alleged facts were taken as true, “[r]espondent’s continued practice of medicine and surgery within the Commonwealth of Pennsylvania, along with the exercise of any other . . . ‘authorizations to practice the profession’ . . . make[] Respondent an immediate and clear danger to the public health and safety.” Government’s Motion, Attachment 2, at 1. The Board issued a second Order on July 12, 2018, granting Respondent’s request for a continuance on his preliminary hearing and ordering that the suspension of Respondent’s license to practice as a physician and surgeon remain in effect unless otherwise ordered by the SBM. Government’s Motion, Attachment 3 (Order Granting Continuance with Immediate Temporary Suspension Remaining in Effect), at 1.

A Diversion Investigator assigned to the Pittsburgh District Office, Philadelphia Field Division of this Agency stated that she accessed the public website for the Pennsylvania Bureau of Professional and Occupational Affairs on April 24, 2019, and obtained information from that website showing Respondent’s medical license was listed as under suspension on that date. Declaration of Diversion Investigator, Government’s Motion, Attachment 6, at 2.

According to the Commonwealth of Pennsylvania’s online records, of which I take official notice, Respondent’s license remains suspended. Pennsylvania Licensing System, State Board of Medicine License Verification, <https://www.pals.pa.gov/#/page/searchresult> (last visited July 23, 2019).<sup>1</sup>

<sup>1</sup> Under the Administrative Procedure Act, an agency “may take official notice of facts at any stage in a proceeding—even in the final decision.” United States Department of Justice, Attorney General’s Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), “[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.” Accordingly, Respondent may dispute my finding by filing a properly supported motion for reconsideration within 15 calendar days of the date of this Order. Any such motion shall be filed with the Office of the Administrator and a copy shall be served on the Government. In the event Respondent files a

The Commonwealth of Pennsylvania’s online records show that Respondent’s medical license remains suspended and that Respondent is not authorized in the Commonwealth of Pennsylvania to prescribe controlled substances. *Id.*

Accordingly, I find that Respondent currently is neither licensed to engage in the practice of medicine nor registered to dispense controlled substances in the Commonwealth of Pennsylvania, the State in which he is registered with the DEA.

I further find, consistent with the findings of the ALJ, that Respondent’s application for modification is not the subject of this proceeding, and agree that the Government did not challenge that application modification in its OSC. See R.D., at 9–10.<sup>2</sup>

### Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (hereinafter, CSA), “upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.” *Id.* With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the State in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner’s registration. See, e.g., *James L. Hooper, M.D.*, 76 FR 71,371 (2011), *pet. for rev. denied*, 481 Fed. Appx. 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.*, 43 FR 27,616, 27,617 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress

motion, the Government shall have 15 calendar days to file a response.

<sup>2</sup> Respondent’s COR expires July 31, 2019. See Government’s Motion, Attachment 1. Pursuant to 21 CFR § 1301.51(c), “[n]o fee shall be required for modification . . . . If the modification of registration is granted, the registrant . . . shall maintain it with the old certificate of registration until expiration.” Because the modification is tied to the expiration date of the original COR, the modification will expire on the same date as the COR, unless the applicant renews the COR. See *Craig S. Morris, D.D.S.*, 83 FR 36,966, 36,967 (2018) (“The fact that DEA handles a modification request ‘in the same manner as an application for registration’ pursuant to 21 CFR

[§] 1301.51(c) does not mean that a modification request is the same as an application for a new registration in every respect . . . . [U]nlike a timely renewal application, a request to modify the registration address of an existing registration . . . does not remain pending after that registration expires, nor does it operate to extend when that registration expires.” (citing 21 CFR 1301.51(c)).

defined the term “practitioner” to mean “a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.” 21 U.S.C. 802(21).] Second, in setting the requirements for obtaining a practitioner’s registration, Congress directed that “[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.” 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess State authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner’s registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the State in which he practices. *See, e.g., Hooper, supra*, 76 FR at 71,371–72; *Sheran Arden Yeates, M.D.*, 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.*, 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.*, 53 FR 11,919, 11,920 (1988); *Blanton, supra*, 43 FR at 27,617.

Under the Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act, “no controlled substance . . . may be dispensed without the written prescription of a practitioner.” 35 Pa. Stat. and Const. Stat. Ann. § 780–111(a) (West April 7, 2014 to October 23, 2019). Further, the definition of “practitioner,” as used in the Act, includes a “physician . . . or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance . . . in the course of professional practice . . . in the Commonwealth of Pennsylvania.” *Id.* at 780–102(b).

Here, the undisputed evidence in the record is that Respondent currently lacks authority to practice medicine in the Commonwealth of Pennsylvania. As already discussed, a physician must be a licensed practitioner to dispense a controlled substance in Pennsylvania. Thus, because Respondent lacks authority to practice medicine in the Commonwealth of Pennsylvania and, therefore, is not authorized to handle controlled substances in the Commonwealth of Pennsylvania, Respondent is not eligible to maintain a DEA registration. Accordingly, I will order that Respondent’s DEA registration be revoked.

**Order**

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. BB3258034 issued to Parth S. Bharill, M.D. This Order is effective September 9, 2019.

Dated: July 29, 2019.  
**Uttam Dhillon,**  
*Acting Administrator.*  
 [FR Doc. 2019–17004 Filed 8–7–19; 8:45 am]  
**BILLING CODE 4410–09–P**

**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

[Docket No. DEA–392]

**Bulk Manufacturer of Controlled Substances Application: Alcami Wisconsin Corporation**

**ACTION:** Notice of application.

**DATES:** Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before October 7, 2019.

**ADDRESSES:** Written comments should be sent to: Drug Enforcement Administration, Attention: DEA **Federal Register** Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

**SUPPLEMENTARY INFORMATION:** In accordance with 21 CFR 1301.33(a), this is notice that on March 12 2019, Alcami Wisconsin Corporation, W130N10497 Washington Drive, Germantown, Wisconsin 53022 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Marihuana Extract .....	7350	I
Marihuana .....	7360	I
Tetrahydrocannabinols .....	7370	I
5-Methoxy-N-N-dimethyltryptamine.	7431	I
Thebaine .....	9333	II
Alfentanil .....	9737	II

The company plans to provide bulk active pharmaceutical ingredient to support clinical trials. In reference to drug codes 7350 marihuana extract, 7360 marihuana, and 7360 THC, the company plans to manufacturer these substances synthetically. No other activity for these drug codes is authorized for this registration.

Dated: July 30, 2019.  
**John J. Martin,**  
*Assistant Administrator.*  
 [FR Doc. 2019–17002 Filed 8–7–19; 8:45 am]  
**BILLING CODE 4410–09–P**

**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**Anthony Schapera, M.D.; Decision and Order**

On December 31, 2018, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Anthony Schapera, M.D. (hereinafter, Registrant), of Bishop, California. OSC, at 1. The OSC proposes the revocation of Registrant’s Certificate of Registration No. AS3008213, the denial of any applications for renewal or modification of his registration, and the denial of “any applications for any other DEA registrations” on the ground that he “has no state authority to handle controlled substances.” *Id.* (citing 21 U.S.C. 824(a)(3)).

The substantive ground for the proceeding, as alleged in the OSC, is that Registrant is “without authority to handle controlled substances in the State of California, the state in which . . . [he is] registered with DEA.” *Id.* Specifically, the OSC alleges that the Medical Board of California revoked Registrant’s medical license effective June 22, 2018. *Id.*

The Show Cause Order notified Registrant of his right to request a hearing on the allegations or to submit a written statement while waiving his right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 2 (citing 21 CFR 1301.43). The OSC also notified Registrant of the opportunity to submit a corrective action plan. OSC, at 2–3 (citing 21 U.S.C. 824(c)(2)(C)).

**Adequacy of Service**

In a Declaration dated March 19, 2019 (hereinafter, Declaration), a Diversion Investigator (hereinafter, DI) assigned to the Newark Field Division declared under penalty of perjury that he and another DI “personally served” the OSC on Registrant. Declaration, at 1. Attached to the DI’s Declaration is a DEA–12, Receipt for Cash or Other Items. According to the DI, Registrant acknowledged receipt of the OSC by signing this DEA–12 on January 17, 2019. *Id.*

In its Request for Final Agency Action (hereinafter, RFAA), the Government represents that “at least 30 days have passed since the . . . [OSC] was served on Registrant . . . and Registrant has not requested a hearing and has not otherwise corresponded or communicated with DEA” regarding the OSC “including the filing of any written statement in lieu of a hearing.” RFAA, at 2. The Government requests “a Final Order revoking Registrant’s DEA registration.” *Id.* at 4.

Based on the DI’s Declaration, the Government’s written representations, and my review of the record, I find that the Government accomplished service of the OSC on Registrant on January 17, 2019. I also find that more than 30 days have now passed since the Government accomplished service of the OSC. Further, based on the Government’s written representations, I find that neither Registrant, nor anyone purporting to represent him, requested a hearing, submitted a written statement while waiving Registrant’s right to a hearing, or submitted a corrective action plan. Accordingly, I find that Registrant has waived his right to a hearing and his right to submit a written statement and corrective action plan. 21 CFR 1301.43(d) and 21 U.S.C. 824(c)(2)(C). I, therefore, issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. 21 CFR 1301.43(e).

## Findings of Fact

### *Registrant’s DEA Registration*

Registrant is the holder of DEA Certificate of Registration No. AS3008213 at the registered address of 2385 Apache Drive, Bishop, CA 93514. GX 1 (Certification of Registration History), at 1. Pursuant to this registration, Registrant is authorized to dispense controlled substances in schedules II through V as a practitioner. *Id.* Registrant’s registration is in an “active pending status” and expires on February 28, 2021. *Id.*

### *The Status of Registrant’s State License*

On May 24, 2018, the Medical Board of California (hereinafter, MBC) issued a Decision ordering the revocation of Registrant’s medical license effective June 22, 2018. The MBC Decision adopts the Proposed Decision of Administrative Law Judge Jonathan Lew. ALJ Lew received evidence, heard oral argument, and closed the record before issuing the Proposed Decision. Registrant was represented by counsel before ALJ Lew.

The MBC Decision states that the causes for the revocation are (1) Registrant’s conviction of criminal offenses substantially related to the qualifications, functions, or duties of a physician and surgeon and that also constitute unprofessional conduct, and (2) Registrant’s impairment due to a mental condition that “impacts . . . [his] ability to safely engage in the practice of medicine at this time.” Decision, at 25.

According to California’s online records, of which I take official notice, Registrant’s license is still revoked.<sup>1</sup> Medical Board of California Online License Search, [http://www.mbc.ca.gov/Breeze/License\\_Verification.aspx](http://www.mbc.ca.gov/Breeze/License_Verification.aspx) (last visited July 29, 2019).

Accordingly, I find that Registrant currently is not licensed to engage in the practice of medicine in California, the State in which he is registered with the DEA.

## Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (hereinafter, CSA), “upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.” With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the State in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner’s registration. *See, e.g., James L. Hooper, M.D., 76 FR 71,371 (2011), pet. for rev. denied, 481 Fed. Appx. 826 (4th Cir. 2012); Frederick Marsh Blanton, M.D., 43 FR 27,616, 27,617 (1978).*

This rule derives from the text of two provisions of the CSA. First, Congress

<sup>1</sup> Under the Administrative Procedure Act, an agency “may take official notice of facts at any stage in a proceeding—even in the final decision.” United States Department of Justice, Attorney General’s Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), “[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.” Accordingly, Registrant may dispute my finding by filing a properly supported motion for reconsideration within 15 calendar days of the date of this Order. Any such motion shall be filed with the Office of the Administrator and a copy shall be served on the Government. In the event Registrant files a motion, the Government shall have 15 calendar days to file a response.

defined the term “practitioner” to mean “a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.” 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner’s registration, Congress directed that “[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.” 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess State authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner’s registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the State in which he practices. *See, e.g., Hooper, supra*, 76 FR at 71,371–72; *Sheran Arden Yeates, M.D., 71 FR 39,130, 39,131 (2006); Dominick A. Ricci, M.D., 58 FR 51,104, 51,105 (1993); Bobby Watts, M.D., 53 FR 11,919, 11,920 (1988); Blanton, supra*, 43 FR at 27,617.

According to the California Uniform Controlled Substances Act, “No person other than a physician . . . shall write or issue a prescription.” Cal. Health & Safety Code § 11150 (West, Westlaw current with urgency legislation through Ch. 5 of 2019 Reg. Sess.). Further, “physician,” as defined by California statute, is a person who is “licensed to practice” in California. Cal. Health & Safety Code § 11024 (West, Westlaw current with urgency legislation through Ch. 5 of 2019 Reg. Sess.).

Here, the undisputed evidence in the record is that Registrant currently lacks authority to practice medicine in California. As already discussed, a physician must be licensed to practice medicine in order to write or issue a controlled substance prescription in California. Thus, because Registrant lacks authority to practice medicine in California and, therefore, is not authorized to dispense controlled substances in California, he is not eligible to maintain a DEA registration. Accordingly, I will order that Registrant’s DEA registration be revoked.

## Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f) and 824(a), I hereby revoke DEA Certificate of Registration No. AS3008213 issued to Anthony Schapera, M.D. Further, I hereby deny

any pending application of Anthony Schapera, M.D. to renew or modify this registration, as well as any pending application of Anthony Schapera, M.D. for registration in California. This Order is effective September 9, 2019.

Dated: July 28, 2019.

**Uttam Dhillon,**

*Acting Administrator.*

[FR Doc. 2019-17003 Filed 8-7-19; 8:45 am]

**BILLING CODE 4410-09-P**

## DEPARTMENT OF JUSTICE

### Office of Justice Programs

[OJP (BJA) Docket No. 1763]

#### Notice of Renewal of the Charter for the Public Safety Officer Medal of Valor Review Board

**AGENCY:** Office of Justice Programs (OJP), Bureau of Justice Assistance (BJA), Justice.

**ACTION:** Renewal of the Charter.

**SUMMARY:** The Bureau of Justice Assistance provides notice that the charter of the Public Safety Officer Medal of Valor Review Board has been renewed.

**FOR FURTHER INFORMATION CONTACT:** Visit the website for the Public Safety Officer Medal of Valor Review Board at <https://www.bja.gov/programs/medalofvalor/index.html> or contact Gregory Joy, Policy Advisor, Bureau of Justice Assistance, Office of Justice Programs, 810 7th Street NW, Washington, DC 20531, by telephone at (202) 514-1369, toll free (866) 859-2687, or by email at [Gregory.joy@usdoj.gov](mailto:Gregory.joy@usdoj.gov).

**SUPPLEMENTARY INFORMATION:** The Bureau of Justice Assistance provides notice that the charter of the Public Safety Officer Medal of Valor Review Board has been renewed.

The Charter for the Public Safety Officer Medal of Valor Review Board was submitted to the U.S. Attorney General, who subsequent approved its renewal on April 24, 2019. Following this approval, separate correspondence were mailed June 5, 2019, to: The Honorable Lindsey Graham, Chairman, Committee on the Judiciary, United States Senate; The Honorable Dianne Feinstein, Ranking Member, Committee on the Judiciary, United States Senate; The Honorable Jerrold Nadler, Chairman, Committee on the Judiciary, U.S. House of Representatives; The Honorable Doug Collins, Ranking Member, Committee on the Judiciary, U.S. House of Representatives; and Ms. Sara Striner, Chair, Federal Advisory Committee Desk, Library of Congress.

This completes the process to renew the Charter for an additional 2-year period.

**Gregory Joy,**

*Policy Advisor/Designated Federal Officer, Bureau of Justice Assistance.*

[FR Doc. 2019-16987 Filed 8-7-19; 8:45 am]

**BILLING CODE 4410-18-P**

## DEPARTMENT OF LABOR

### Employment and Training Administration

#### Allocating Grants to States for Reemployment Services and Eligibility Assessments (RESEA) in Accordance With Title III, Section 306 of the Social Security Act (SSA)

**AGENCY:** Office of Unemployment Insurance (OUI), Employment and Training Administration (ETA), Department of Labor (DOL).

**ACTION:** Notice.

**SUMMARY:** The Bipartisan Budget Act of 2018 (BBA), Public Law 115-123 (2018), established permanent authorization for the RESEA program by enacting section 306 of title III, (SSA). This notice announces the formula to allocate base funds for the RESEA program, as provided under Section 306(f)(1), SSA, 42 U.S.C. 506(f)(1).

On April 4, 2019, ETA published a notice in the **Federal Register** (84 FR 13319) requesting public comment concerning the development of a proposed formula that ETA will use to distribute funding to States for RESEA. The notice presented a description of a proposed allocation formula and public comments were requested. The comment period closed on May 6, 2019. This notice summarizes and responds to the comments received and publishes the final allocation formula that will take effect in Fiscal Year (FY) 2021.

**DATES:** The RESEA allocation formula described in this notice will take effect in FY 2021.

**ADDRESSES:** Questions about this notice may be submitted to the U.S. Department of Labor, Employment and Training Administration, Office of Unemployment Insurance, 200 Constitution Avenue NW, Room S-4524, Washington, DC 20210, Attention: Lawrence Burns, or by email at [DOL-ETA-UI-FRN@dol.gov](mailto:DOL-ETA-UI-FRN@dol.gov).

**FOR FURTHER INFORMATION CONTACT:** Lawrence Burns, Division of Unemployment Insurance Operations, at 202-693-3141 (this is not a toll-free number), TTY 1-877-889-5627, or by email at [Burns.Lawrence@dol.gov](mailto:Burns.Lawrence@dol.gov).

**SUPPLEMENTARY INFORMATION:**

## I. Introduction

Since 2005, DOL and participating State workforce agencies have been addressing individual reemployment needs of Unemployment Insurance (UI) claimants and working to prevent and detect UI improper payments through the voluntary UI Reemployment and Eligibility Assessment (REA) program and, beginning in FY 2015, through the voluntary RESEA program.

On February 9, 2018, the President signed the BBA, which included amendments to the SSA creating a permanent authorization for the RESEA program. The RESEA provisions are contained in section 30206 of the BBA, enacting new section 306 of the SSA. 42 U.S.C. 506. Section 306, SSA also contains provisions for funding the RESEA program.

The primary goals of the RESEA program are to: Improve employment outcomes for individuals that receive unemployment compensation (UC) by reducing average duration of receipt of UC through employment; strengthen program integrity and reduce improper payments; promote alignment with the broader vision of the Workforce Innovation and Opportunity Act through increased program integration and service delivery for job seekers; and establish RESEA as an entry point to other workforce system partner programs for individuals receiving UC. Core services that must be provided to RESEA participants are:

- UI eligibility assessment, including review of work search activities, and referral to adjudication, as appropriate, if an issue or potential issue is identified;
- Labor market and career information that address the claimant's specific needs;
- Enrollment in Wagner-Peyser Act funded Employment Services;
- Support to the claimant to develop and implement an individual reemployment plan; and
- Information regarding, and access to, American Job Center services and providing referrals to reemployment services and training, as appropriate, to support the claimant's return to work.

## II. Background

Section 306, SSA, specifies three uses for amounts appropriated for the RESEA program and designates the proportion of annual appropriations to be assigned to these uses: (1) Base funding (84 percent to 89 percent of the appropriation depending on the year) for States to operate the RESEA program, (2) outcome payments (10 percent to 15 percent of the

appropriation depending on the year) designed to reward States meeting or exceeding certain criteria, and (3) up to one percent for the Secretary of Labor to use for research and technical assistance to States. 42 U.S.C. 506(f). With respect to the base funding, section 306(f)(1)(A), SSA, states:

IN GENERAL.— For each fiscal year after fiscal year 2020, the Secretary shall allocate a percentage equal to the base funding percentage<sup>1</sup> for such fiscal year of the funds made available for grants under this section among the States awarded such a grant for such fiscal year using a formula prescribed by the Secretary based on the rate of insured unemployment (as defined in section 203(e)(1) of the federal-State Extended Unemployment Compensation Act of 1970 (26 U.S.C. 3304 note)) in the State for a period to be determined by the Secretary. In developing such formula with respect to a State, the Secretary shall consider the importance of avoiding sharp reductions in grant funding to a State over time. 42 U.S.C § 506(f)(1)(A).

### III. Response to Public Comment

ETA received a total of 19 comments from 14 commenters concerning the RESEA base allocation formula. These comments include: 6 comments regarding the general formula, 3 comments concerning carry-over provisions, 4 comments concerning the proposed hold-harmless provision, 3 comments concerning the establishment of minimum funding levels, and 3 comments concerning administrative and other program cost limits. The following is a summary of these comments and ETA's responses.

#### A. General Formula Comments

Several commenters addressed formula design directly, including general concern expressed by multiple states that provisions must be made to ensure adequate funding levels for small and rural states. Members of the Committee on Ways and Means, U.S. House of Representatives, expressed concern that the proposed formula used elements that eliminated the Insured Unemployment Rate (IUR) rather than relied on the IUR as required in section 306(f), SSA. 42 U.S.C § 506(f)(1)(A). Two States suggested considering additional factors, such as costs per RESEA and program and performance data. One State recommended the use of statistically-adjusted unemployment data over a 10-year period, with an emphasis on more recent data, in place

<sup>1</sup> The term "base funding percentage" as used here is a percentage of the funds appropriated for RESEA grants to operate the program in a fiscal year. Section 306(f)(1)(B), SSA, defines the base funding percentage for fiscal years 2021 through 2026 as 89 percent and for fiscal years after 2026 as 84 percent.

of the IUR as a means of providing more stable funding levels. One State expressed support for the proposed formula allocation methodology, but recommended revisiting the formula if future legislation expanded program eligibility to additional populations. One State recommended ETA reserve a portion of RESEA funds to respond to sudden economic changes or other unforeseen circumstances that would require a one-time influx of additional funding.

In response to these comments, as discussed more fully below, ETA has developed a revised allocation formula that uses two primary input variables: the IUR and the civilian labor force (CLF). These two factors are included in the formula because section 306, SSA, requires the formula to be based on the IUR and the CLF addresses the differences in state size. 42 U.S.C. 506(f)(1). It also includes additional provisions, discussed below, that are intended to prevent significant State funding fluctuations over time and to provide minimum funding for smaller or rural States. The use of additional data factors, such as cost per RESEA, were considered, but not included because of the increased burden of collecting and maintaining this data and the risk of creating additional funding fluctuations as States change their program design from year to year. The RESEA legislation does not authorize ETA to maintain a RESEA funding reserve. The final allocation formula is described below.

#### B. Carry-Over Provisions Comments

Three States commented on the proposed 25 percent carry-over limit, expressing preference to have it increased to 30 or 35 percent, or eliminated altogether. States also suggested that the formula should allow for a higher carry-over limit upon special request by a State. In response to these comments, ETA has increased the carry-over limit to 30 percent. This change ensures the majority of funds continue to be used to provide RESEA services in a timely manner while also providing States with additional flexibility to support program costs that may span across years, such as contractual costs.

#### C. Hold-Harmless Provision Comments

ETA received four comments from four commenters on the proposed five percent hold-harmless provision. Two comments expressed concern that the hold-harmless provision would not be applied in the initial distribution under the allocation formula. One commenter expressed concern that a fixed hold-

harmless provision would negatively impact States with a stable IUR. The final comment recommended a gradual, tiered-approach to implementing the hold-harmless provision that would increase the hold-harmless rate over several years until it is fully implemented at the maximum five percent level.

In response to these comments, ETA incorporated the recommended gradual, phased implementation strategy in which the maximum potential reduction increases from 3 to 5 percent over a 3-year period. This phased implementation results in a longer transition period for states that may face reductions resulting from the new allocation formula to adjust their program design and will help prevent significant disruptions in service delivery. ETA is also clarifying that the hold-harmless provision will be applied during the initial formula allocation of funds in FY 2021 and each State, after applying the hold-harmless provision, will receive a FY 2021 allotment that is no less than an amount equal to at least 97 percent of its FY 2020 maximum RESEA grant award. Each State's FY 2020 maximum RESEA grant award will be provided in forthcoming FY 2020 RESEA operating guidance.

#### D. Minimum Funding Level Comments

Three States provided comments pertaining to the absence of a minimum funding level for rural and less populated States. Two States provided comments recommending inclusion of a minimum funding level and a third State expressed concern that an additional "leveling factor" beyond the hold-harmless provision must be included to further protect small States from potential funding fluctuations associated with changes in the IUR. In response to these comments, ETA has incorporated a minimum funding level into the allocation formula as described below. The inclusion of a minimum funding level will allow all states, regardless of size, population density, or economic conditions, to implement or maintain an RESEA program.

#### E. Administrative Costs and Other Funding Limitations.

Three States provided comments on RESEA requirements that are not related to the formula allocation. One State submitted a comment recommending greater flexibility in administrative cost limits to support alternative approaches to grant management, such as the use of cost allocation plans. One State commented that all limits on RESEA funds should be removed to provide States with maximum flexibility in

determining how to administer the RESEA program. A third State recommended providing States that are pursuing program automation with additional program administration resources. Because none of these comments are related to the proposed formula allocation methodology, ETA made no changes to the proposed formula allocation.

#### IV. Description of Base Allocation Formula

The final base allocation formula has been modified in response to the public comments. The new formula uses two primary input variables: The IUR and the CLF. Under this formula, each State's average IUR for the 12 months ending June 30 will be divided by the national average IUR. The two resulting ratios will be multiplied together, producing a combined IUR–CLF weighting factor. A State's allotment of the available RESEA funding will reflect the proportion of its State-specific combined weighting factor compared to the sum of all States combined weighting factors. Use of the IUR ensures that States with high IURs, and hence greater unemployment, receive a higher proportion of RESEA funds. Use of the CLF as a factor controls for State size.

#### V. Description of the Hold-Harmless Provision

The statutory language requires the Secretary to consider the importance of avoiding sharp reductions in grant funding to a state over time. 42 U.S.C. § 506(f)(1)(A). To satisfy this requirement, DOL will incorporate a phased hold-harmless provision as follows:

(1) In FY 2021, each State will receive no less than an amount equal to at least 97 percent of its FY 2020 maximum grant award;

(2) In FY 2022, each State will receive no less than an amount equal to at least 96 percent of its FY 2021 allotment;

(3) In FY 2023 and subsequent years, each State will receive no less than an amount equal to at least 95 percent of its previous year's allotment.

#### VI. Minimum Funding Provisions

No State will receive an amount equal to less than 0.28 percent of the total available funding for FY2021 RESEA's base funding level. This approach mirrors the minimum funding provisions in the Wagner-Peyser Act (29 U.S.C. 49e) and acknowledges that all States have certain fixed costs to administer the program.

#### VII. Carry-Over Threshold

If a State has a balance of up to 30 percent of its previous year's award, the

State may carry that amount over from one year to the next. However, a State agency carrying over an amount in excess of 30 percent will have any amount in excess of the 30 percent reduced from its subsequent year's allocation, and the resulting additional resources will be included in the distribution to States that are under the 30 percent threshold. This provision is intended to ensure States are using the majority of funds to provide reemployment services to claimants in the year for which it is allocated and provide States with flexibility to support costs and activities that may span across years.

#### VIII. Conclusion

The RESEA funding formula articulated in this notice will be utilized beginning in FY 2021. It is ETA's intent to provide States with funding planning targets annually in advance of the actual guidance and allocation.

**John Pallasch,**

*Assistant Secretary for Employment and Training, Labor.*

[FR Doc. 2019–16988 Filed 8–7–19; 8:45 am]

**BILLING CODE 4510–FW–P**

### DEPARTMENT OF LABOR

#### Employment and Training Administration

#### Workforce Information Advisory Council

**AGENCY:** Employment and Training Administration, Labor.

**ACTION:** Notice of Renewal of the Workforce Information Advisory Council

*Authority:* Pursuant to the Wagner-Peyser Act of 1933, as amended, 29 U.S.C. 49 *et seq.*; Workforce Innovation and Opportunity Act, Public Law 113–128; Federal Advisory Committee Act, as amended, 5 U.S.C. App. **SUMMARY:** The Department of Labor (Department) announces the renewal of the Workforce Information Advisory Council (WIAC) charter.

#### SUPPLEMENTARY INFORMATION:

##### I. Background and Authority

Section 15 of the Wagner-Peyser Act, 29 U.S.C. 49l–2, as amended by section 308 of the Workforce Innovation and Opportunity Act of 2014 (WIOA), Public Law 113–128 requires the Secretary of Labor (Secretary) to establish and maintain the WIAC.

The statute, as amended, requires the Secretary, acting through the Commissioner of Labor Statistics and

the Assistant Secretary for Employment and Training, to formally consult at least twice annually with the WIAC to address: (1) Evaluation and improvement of the nationwide workforce and labor market information system established by the Wagner-Peyser Act, and of the statewide systems that comprise the nationwide system, and (2) how the Department and the States will cooperate in the management of those systems. The Secretary, acting through the Bureau of Labor Statistics (BLS) and the Employment and Training Administration (ETA), and in consultation with the WIAC and appropriate Federal agencies, must also develop a 2-year plan for management of the system, with subsequent updates every two years thereafter. The statute generally prescribes how the plan is to be developed and implemented, outlines the contents of the plan, and requires the Secretary to submit the plan to designated authorizing committees in the House and Senate.

By law, the Secretary must “seek, review, and evaluate” recommendations from the WIAC, and respond to the recommendations in writing to the WIAC. The WIAC must make written recommendations to the Secretary on the evaluation and improvement of the workforce and labor market information system, including recommendations for the 2-year plan. The 2-year plan, in turn, must describe WIAC recommendations and the extent to which the plan incorporates them.

The WIAC accomplishes its objectives by, for example: (1) Studying workforce and labor market information issues; (2) seeking and sharing information on innovative approaches, new technologies, and data to inform employment, skills training, and workforce and economic development decision making and policy; and (3) advising the Secretary on how the workforce and labor market information system can best support workforce development, planning, and program development.

##### II. Structure

The Wagner-Peyser Act at section 15(d)(2)(B), requires the WIAC to have 14 representative members, appointed by the Secretary, consisting of:

(i) Four members who are representatives of lead State agencies with responsibility for workforce investment activities, or State agencies described in Wagner-Peyser Act Section 4 (agency designated or authorized by Governor to cooperate with the Secretary), who have been nominated by such agencies or by a national

organization that represents such agencies;

(ii) Four members who are representatives of the State workforce and labor market information directors affiliated with the State agencies responsible for the management and oversight of the workforce and labor market information system as described in Wagner-Peyser Act Section 15(e)(2), who have been nominated by the directors;

(iii) One member who is a representative of providers of training services under WIOA section 122 (Identification of Eligible Providers of Training Services);

(iv) One member who is a representative of economic development entities;

(v) One member who is a representative of businesses, who has been nominated by national business organizations or trade associations;

(vi) One member who is a representative of labor organizations, who has been nominated by a national labor federation;

(vii) One member who is a representative of local workforce development boards, who has been nominated by a national organization representing such boards; and

(viii) One member who is a representative of research entities that use workforce and labor market information.

The Secretary must ensure that the membership of the WIAC is geographically diverse, and that no two members appointed under clauses (i), (ii), and (vii), above, represent the same State. Each member will be appointed for a term of three years and the Secretary will not appoint a member for any more than two consecutive terms. Any member whom the Secretary appoints to fill a vacancy occurring before the expiration of the predecessor's term will be appointed only for the remainder of that term. Members of the WIAC will serve on a voluntary and generally uncompensated basis, but will be reimbursed for travel expenses to attend WIAC meetings, including per diem in lieu of subsistence, as authorized by the Federal travel regulations.

**FOR FURTHER INFORMATION CONTACT:** Steve Rietzke, Division of National Programs, Tools, and Technical Assistance, Office of Workforce Investment (address above); (202) 693-

3912; or use email address for the WIAC, [WIAC@dol.gov](mailto:WIAC@dol.gov).

**John Pallasch,**

*Assistant Secretary, Employment and Training Administration.*

[FR Doc. 2019-16989 Filed 8-7-19; 8:45 am]

**BILLING CODE 4510-FN-P**

## DEPARTMENT OF LABOR

### Office of the Secretary

#### **Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple Worksite Report and the Report of Federal Employment and Wages**

**ACTION:** Notice of availability; request for comments.

**SUMMARY:** The Department of Labor (DOL) is submitting the Bureau of Labor Statistics (BLS) sponsored information collection request (ICR) titled, "Multiple Worksite Report and the Report of Federal Employment and Wages," to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

**DATES:** The OMB will consider all written comments that agency receives on or before September 9, 2019.

**ADDRESSES:** A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the *RegInfo.gov* website at [http://www.reginfo.gov/public/do/PRAViewICR?ref\\_nbr=201903-1220-003](http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201903-1220-003) (this link will only become active on the day following publication of this notice) or by contacting Frederick Licari by telephone at 202-693-8073, TTY 202-693-8064, (these are not toll-free numbers) or by email at [DOL\\_PRA\\_PUBLIC@dol.gov](mailto:DOL_PRA_PUBLIC@dol.gov).

Submit comments about this request by mail to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL-BLS, Office of Management and Budget, Room 10235, 725 17th Street NW, Washington, DC 20503; by Fax: 202-395-5806 (this is not a toll-free number); or by email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov). Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301,

200 Constitution Avenue NW, Washington, DC 20210; or by email: [DOL\\_PRA\\_PUBLIC@dol.gov](mailto:DOL_PRA_PUBLIC@dol.gov).

**FOR FURTHER INFORMATION CONTACT:** Frederick Licari by telephone at 202-693-8073, TTY 202-693-8064, (these are not toll-free numbers) or by email at [DOL\\_PRA\\_PUBLIC@dol.gov](mailto:DOL_PRA_PUBLIC@dol.gov).

**SUPPLEMENTARY INFORMATION:** This ICR seeks to extend PRA authority for the Multiple Worksite Report and the Report of Federal Employment and Wages information collection. States use the Multiple Worksite Report to collect employment and wages data from non-Federal businesses engaged in multiple operations within a State and subject to State Unemployment Insurance laws. The Report of Federal Employment and Wages is designed for Federal establishments covered under the Unemployment Compensation for Federal Employees program. These data are used for sampling, benchmarking, and economic analysis. BLS Authorizing Statute sections 1 and 2 and Social Security Act section 303 authorize this information collection. See 29 U.S.C. 1 and 2, and 42 U.S.C. 503.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB under the PRA approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1220-0134.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on August 31, 2019. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on March, 21, 2019 (84 FR 10550).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at

the address shown in the **ADDRESSES** section within thirty-(30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1220-0134. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: DOL-BLS.

Title of Collection: Multiple Worksite Report and the Report of Federal Employment and Wages.

OMB Control Number: 1220-0134.

Affected Public: Business or other for-profit institutions; not-for-profit institutions; and the Federal Government.

Total Estimated Number of Respondents: 147,139.

Total Estimated Number of Responses: 588,556.

Total Estimated Annual Time Burden: 217,765 hours.

Total Estimated Annual Other Costs Burden: \$0.

Authority: 44 U.S.C. 3507(a)(1)(D).

Dated: August 2, 2019.

Frederick Licari,

Departmental Clearance Officer.

[FR Doc. 2019-16944 Filed 8-7-19; 8:45 am]

BILLING CODE 4510-24-P

## NUCLEAR REGULATORY COMMISSION

[NRC-2016-0238]

### Managing Aging Processes in Storage (MAPS) Report

AGENCY: Nuclear Regulatory Commission.

ACTION: NUREG; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing NUREG-

2214, "Managing Aging Processes in Storage (MAPS) Report." The NUREG provides guidance to the NRC technical review staff and establishes a technical basis for the safety review of renewal applications for specific licenses of independent spent fuel storage installations (ISFSIs) and certificates of compliance of dry storage systems.

DATES: NUREG-2214 is available on August 8, 2019.

ADDRESSES: Please refer to Docket ID NRC-2016-0238 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this action using any of the following methods:

- *Federal Rulemaking Website*: Go to <https://www.regulations.gov/> and search for Docket ID NRC-2016-0238. Address questions about NRC docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301-287-9127; email: [Jennifer.Borges@nrc.gov](mailto:Jennifer.Borges@nrc.gov). For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *NRC's Agencywide Documents Access and Management System (ADAMS)*: You may obtain publicly-available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.

- *NRC's PDR*: You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

**FOR FURTHER INFORMATION CONTACT:** John Wise, Office of Nuclear Material Safety and Safeguards, telephone: 301-415-8085, email: [John.Wise@nrc.gov](mailto:John.Wise@nrc.gov); U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

#### SUPPLEMENTARY INFORMATION:

##### I. Discussion

The NRC is issuing NUREG-2214 (ADAMS Accession No. ML19214A111) to provide a technical basis for the staff's safety review of aging degradation mechanisms and aging management programs in renewal applications for specific ISFSI licenses and certificates of compliance of spent fuel dry storage systems.

NUREG-2214 evaluates aging degradation mechanisms to determine if they could affect the ability of dry storage system components to fulfill their safety functions in the period of extended operation. The guidance also provides examples of aging management programs that are considered generically acceptable to address the credible aging mechanisms to ensure that the design bases of dry storage systems will be maintained.

##### II. Additional Information

The staff considered public comments received on the draft report in preparing the final NUREG. The NRC published a notice of the availability of the draft report for comment on October 24, 2017 (82 FR 49233). The public comment period closed on December 26, 2017. The public comments and staff responses are available in ADAMS under Accession No. ML19072A016.

##### III. Regulatory Analysis

The NRC has prepared a final regulatory analysis on this action. The analysis examines the costs and benefits of the alternatives considered by the NRC. The regulatory analysis is available in ADAMS under Accession No. ML19130A192.

##### IV. Backfitting and Issue Finality Provisions

NUREG-2214 provides guidance to the NRC staff for the safety review of aging degradation mechanisms and aging management programs in renewal applications for specific ISFSI licenses and certificates of compliance of spent fuel dry storage systems. The issuance of this NUREG would not constitute backfitting as defined in the backfitting provisions in section 72.62 of title 10 of the *Code of Federal Regulations* (10 CFR), which are applicable to specific ISFSI licensees. Issuance of the NUREG would also not constitute backfitting under 10 CFR 50.109, or otherwise be inconsistent with the issue finality provisions in 10 CFR part 52, which are applicable to general ISFSI licensees using the certificates of compliance. The NRC's position is based upon the following considerations.

1. The NUREG positions do not constitute backfitting, inasmuch as the NUREG is internal guidance directed at the NRC staff with respect to their regulatory responsibilities.

The NUREG provides guidance to the staff on how to review an application for the NRC's regulatory approval in the form of licensing. The issuance of internal staff guidance is not a matter for which ISFSI applicants or general ISFSI licensees using certificates of

compliance are protected under the backfitting provisions in 10 CFR 72.62 and 10 CFR 50.109, or the issue finality provisions of 10 CFR part 52.

2. The NRC staff has no intention to impose the NUREG positions on existing licensees and regulatory approvals, either now or in the future.

The staff does not intend to impose or apply the positions described in the NUREG to existing (already issued) licenses and regulatory approvals. Therefore, the issuance of this NUREG—even if considered guidance which is within the purview of the issue finality provisions in 10 CFR part 52—need not be evaluated as if it were a backfit or as being inconsistent with issue finality provisions. If, in the future, the staff seeks to impose a position in the NUREG on holders of already issued licenses in a manner which does not provide issue finality as described in the applicable issue finality provision, then the staff must make the showing as set forth in the backfitting provisions in 10 CFR 72.62 and 10 CFR 50.109, or address the criteria for avoiding issue finality as described in the applicable issue finality provision in 10 CFR part 52.

3. Backfitting and issue finality do not—with limited exceptions not applicable here—protect current or future applicants.

Applicants and potential applicants are not, with certain exceptions, protected by the backfitting provisions in 10 CFR 72.62 or 10 CFR 50.109, or any issue finality provisions under 10 CFR part 52. This is because neither of the backfitting provisions in 10 CFR parts 72 and 50, nor the issue finality provisions under part 52—with certain exclusions discussed below—were intended to apply to every NRC action which substantially changes the expectations of current and future applicants. The exceptions to the general principle are applicable whenever an applicant references a part 52 license (*e.g.*, an early site permit) and/or NRC regulatory approval (*e.g.*, a design certification rule) with specified issue finality provisions. However, the matters address in this NUREG are not subject matters or issues for which issue finality protection is provided.

#### V. Congressional Review Act

This NUREG is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

Dated at Rockville, Maryland, this 5th day of August, 2019.

For the Nuclear Regulatory Commission.

**Michael C. Layton,**

*Director, Division of Spent Fuel Management, Office of Nuclear Material Safety and Safeguards.*

[FR Doc. 2019–17021 Filed 8–7–19; 8:45 am]

**BILLING CODE 7590-01-P**

#### NUCLEAR REGULATORY COMMISSION

[NRC–2019–0057]

#### Information Collection: NRC Policy Statement, “Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement,” Maintenance of Existing Agreement State Programs, Requests for Information Through the Integrated Materials Performance Evaluation Program (IMPEP) Questionnaire, and Agreement State Participation in IMPEP

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Renewal of existing information collection; request for comment.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, “Policy Statement for the ‘Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement,’ Maintenance of Existing Agreement State Programs, Request for Information Through the Integrated Materials Performance Evaluation Program (IMPEP) Questionnaire, and Agreement State Participation in IMPEP.”

**DATES:** Submit comments by October 7, 2019. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

**ADDRESSES:** You may submit comments by any of the following methods:

- *Federal Rulemaking website:* Go to <https://www.regulations.gov/> and search for Docket ID NRC–2019–0057. Address questions about NRC docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: [Jennifer.Borges@nrc.gov](mailto:Jennifer.Borges@nrc.gov). For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Mail comments to:* David Cullison, Office of the Chief Information Officer,

Mail Stop: T6–A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:** David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: [Infocollects.Resource@nrc.gov](mailto:Infocollects.Resource@nrc.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Obtaining Information and Submitting Comments

###### A. Obtaining Information

Please refer to Docket ID NRC–2019–0057 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking website:* Go to <https://www.regulations.gov/> and search for Docket ID NRC–2019–0057. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2019–0057 on this website.

- *NRC’s Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). The supporting statement is available in ADAMS under Accession No. ML19112A064.

- *NRC’s PDR:* You may examine and purchase copies of public documents at the NRC’s PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

- *NRC’s Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting NRC’s Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: [Infocollects.Resource@nrc.gov](mailto:Infocollects.Resource@nrc.gov).

###### B. Submitting Comments

Please include Docket ID NRC–2019–0057 in the subject line of your comment submission, to ensure that the

NRC is able to make your comment submission available to the public in this docket.

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

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

## II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

1. *The title of the information collection:* Policy Statement for the "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof By States Through Agreement," Maintenance of Existing Agreement State Programs, Request for Information Through the Integrated Materials Performance Evaluation Program (IMPEP) Questionnaire, and Agreement State Participation in IMPEP.

2. *OMB approval number:* 3150-0183.

3. *Type of submission:* Extension.

4. *The form number, if applicable:* Not applicable.

5. *How often the collection is required or requested:* Every four years for completion of the IMPEP questionnaire in preparation for an IMPEP review. One time for new Agreement State applications. Annually for participation by Agreement States in the IMPEP reviews and fulfilling requirements for Agreement States to maintain their programs.

6. *Who will be required or asked to respond:* All Agreement States (38 Agreement States who have signed Agreements with NRC under Section 274b. of the Atomic Energy Act (Act)) and any non-Agreement State seeking to

sign an Agreement with the Commission.

7. *The estimated number of annual responses:* 65.

8. *The estimated number of annual respondents:* 40 (38 existing Agreement States, one Agreement State Application currently being reviewed by the NRC, and one anticipated new application).

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 298,194 hours (an average of 7,455 hours per respondent). This includes 636 hours to complete the IMPEP questionnaires; 2,250 hours to prepare one new Agreement State application, 468 hours for participation in IMPEP reviews; and 294,840 hours for maintaining Existing Agreement State programs.

10. *Abstract:* The States wishing to become Agreement States are requested to provide certain information to the NRC as specified by the Commission's Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof By States Through Agreement." The Agreement States need to ensure that the radiation control program under the Agreement remains adequate and compatible with the requirements of Section 274 of the Act and must maintain certain information. The NRC conducts periodic evaluations through IMPEP to ensure that these programs are compatible with the NRC's program, meet the applicable parts of the Act, and adequate to protect public health and safety.

## III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the estimate of the burden of the information collection accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated at Rockville, Maryland, this 5th day of August, 2019.

For the Nuclear Regulatory Commission.

**David C. Cullison,**

*NRC Clearance Officer, Office of the Chief Information Officer.*

[FR Doc. 2019-16978 Filed 8-7-19; 8:45 am]

**BILLING CODE 7590-01-P**

## POSTAL SERVICE

### International Product Change— Inbound Competitive Non-Published Rate Agreements With Foreign Postal Operators

**AGENCY:** Postal Service™.

**ACTION:** Notice.

**SUMMARY:** The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add Inbound Competitive Non-Published Rate Agreements with Foreign Postal Operators to the Competitive Products List.

**DATES:** *Date of notice:* August 8, 2019.

**FOR FURTHER INFORMATION CONTACT:** Christopher C. Meyerson, 202-268-7820.

**SUPPLEMENTARY INFORMATION:** The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642, on August 2, 2019, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to add Inbound Competitive Non-Published Rate Agreements with Foreign Postal Operators to the Competitive Products List and Notice of Filing Inbound Competitive NPR-FPO 1 Model Contract and Application for Non-Public Treatment of Materials Filed Under Seal*. Documents are available at [www.prc.gov](http://www.prc.gov), Docket Nos. MC2019-180 and CP2019-202.

**Christopher C. Meyerson,**

*Attorney, Corporate and Postal Business Law.*

[FR Doc. 2019-16971 Filed 8-7-19; 8:45 am]

**BILLING CODE 7710-12-P**

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-86557; File No. SR-CboeBZX-2019-057]]

### Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To List and Trade Shares of the American Century Focused Dynamic Growth ETF and American Century Focused Large Cap Value ETF Under Currently Proposed Rule 14.11(k)

August 2, 2019.

On June 6, 2019, Cboe BZX Exchange, Inc. filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934

(“Act”)<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> a proposed rule change to list and trade shares of the American Century Focused Dynamic Growth ETF and American Century Focused Large Cap Value ETF under proposed Rule 14.11(k) (Managed Portfolio Shares). The proposed rule change was published for comment in the **Federal Register** on June 25, 2019.<sup>3</sup> The Commission has received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act<sup>4</sup> 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 August 9, 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,<sup>5</sup> designates September 23, 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-CboeBZX-2019-057).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>6</sup>

**Jill M. Peterson,**

*Assistant Secretary.*

[FR Doc. 2019-16941 Filed 8-7-19; 8:45 am]

**BILLING CODE 8011-01-P**

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-86554; File No. SR-DTC-2019-005]

### Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing of Proposed Rule Change To Amend the Settlement Guide To Implement a New Algorithm for Transactions Processed in the Night Cycle

August 2, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”)<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on July 22, 2019, The Depository Trust Company (“DTC”) 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. 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<sup>3</sup> of DTC consists of amendments to the Procedures<sup>4</sup> set forth in the Settlement Guide<sup>5</sup> to implement a new processing algorithm for book-entry Deliveries<sup>6</sup> and Payment Orders<sup>7</sup> processed in the DTC night cycle (“Night Cycle”), as described in greater detail below.

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> Capitalized terms not defined herein are defined in the Rules, By-Laws and Organization Certificate of DTC (“Rules”), available at [www.dtcc.com/-/media/Files/Downloads/legal/rules/dtc\\_rules.pdf](http://www.dtcc.com/-/media/Files/Downloads/legal/rules/dtc_rules.pdf), and the DTC Settlement Service Guide (“Settlement Guide”), available at <http://www.dtcc.com/-/media/Files/Downloads/legal/service-guides/Settlement.pdf>.

<sup>4</sup> Pursuant to the Rules, the term “Procedures” means the Procedures, service guides, and regulations of DTC adopted pursuant to Rule 27, as amended from time to time. See Rule 1, Section 1, *supra* note 3. Pursuant to Rule 27, each Participant and DTC is bound by the Procedures and any amendment thereto in the same manner as it is bound by the Rules. See Rule 27, *supra* note 3.

<sup>5</sup> *Supra* note 3.

<sup>6</sup> Pursuant to Rule 1, the term “Delivery” as used with respect to a Security held in the form of a Security Entitlement on the books of DTC, means debiting the Security from an Account of the Deliverer and crediting the Security to an Account of the Receiver. *Supra* note 3.

<sup>7</sup> Pursuant to the Settlement Guide, “Payment Order” means a transaction in which a Participant charges another Participant for changes in value for outstanding stock loans or option contract premiums. See Settlement Guide, *supra* note 3, at 5.

#### 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

The purpose of this proposed rule change is to amend the Settlement Guide to implement a new processing algorithm for Deliveries and Payment Orders processed in the Night Cycle.

###### (i) Background

Pursuant to the proposed rule change, DTC is proposing to make enhancements to its processing of transactions in the Night Cycle (“Night Cycle Reengineering”), as more fully described below. Night Cycle Reengineering is designed to maximize transaction throughput by optimizing available positions and controlling the order in which transactions are attempted for settlement within existing Night Cycle timeframes. The reengineered Night Cycle would introduce a new, advanced settlement processing algorithm capable of evaluating each Participant’s transaction obligations, available positions, transaction priorities and risk management controls, including Net Debit Cap and Collateral Monitor,<sup>8</sup> to identify the transaction processing order that maximizes Night Cycle settlement rates. DTC believes that the proposed rule change would facilitate more efficient processing of Deliveries and Payment Orders in the Night Cycle and increase the percentage of transactions that have been processed for settlement

<sup>8</sup> In managing its credit risk, DTC uses the Collateral Monitor and Net Debit Cap. These two controls work together to protect the DTC settlement system in the event of Participant default. The Collateral Monitor requires net debit settlement obligations, as they accrue intraday, to be fully collateralized; the Net Debit Cap limits the amount of any Participant’s net debit settlement obligation to an amount that can be satisfied with DTC liquidity resources (the Participants Fund and the committed line of credit from a consortium of lenders). See Settlement Guide, *supra* note 3, at 64-67.

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> See Securities Exchange Act Release No. 86155 (June 19, 2019), 84 FR 29912.

<sup>4</sup> 15 U.S.C. 78s(b)(2).

<sup>5</sup> *Id.*

<sup>6</sup> 17 CFR 200.30-3(a)(31).

prior to the start of regular daytime processing.

#### DTC Transaction Processing

When a Deliver Order<sup>9</sup> or Payment Order has been submitted to DTC for processing, the transaction must be approved by the Receiver through the Receiver Authorized Delivery function (“RAD”), before it will be staged for DTC settlement processing in accordance with the Rules and the Settlement Guide.<sup>10</sup> After a Receiver approves a Delivery or Payment Order using RAD, DTC checks risk controls, including the Net Debit Cap and Collateral Monitor of the Participants to the transaction.<sup>11</sup> DTC also checks whether or not the Participant that would make the Delivery has a sufficient position in the subject Securities available in the Participant’s Account.<sup>12</sup> If a transaction satisfies DTC risk controls, namely the Net Debit Cap and Collateral Monitor, and the Delivering Participant has sufficient position in the applicable Securities, then the transaction will be processed by DTC and will become complete if the Receiver satisfies its end-of-day funds settlement obligation.<sup>13</sup> If a transaction is not processed, *i.e.*, because DTC risk controls are not met, or if the Deliverer has insufficient position in the applicable Securities, this would result in an Exception such that the transaction will pend in DTC’s system and recycle until the condition causing the pend is satisfied.<sup>14</sup>

An incomplete transaction recycles in DTC’s system until the end of the day, and if it remains incomplete at the end of the day it will not be processed, will

<sup>9</sup>Pursuant to the Settlement Guide, “Deliver Order” is the term used to define a book-entry movement of shares of a particular Security between two DTC Participants. See Settlement Guide, *supra* note 3, at 4. DTC acts in accordance with duly authorized instructions from a Participant to effect transfers by a Participant of its Deposited Securities to another Participant or Participants. See Rule 6, *supra* note 3. Any Participant making a Delivery Versus Payment of Securities through the facilities of DTC shall provide DTC with an instruction specifying the amount of the payment therefor in accordance with the Procedures. After receipt of such instruction, DTC is authorized to, and shall (subject to the right of DTC to cease to act for a Participant pursuant to the Rules and the Procedures), credit the Account of the Deliverer with the amount specified and debit the Account of the Receiver with the same amount. See Rule 9(A), Section 1, *supra* note 3.

<sup>10</sup>RAD allows Participants to review and either approve or reject incoming Deliveries before they are processed. See Settlement Guide, *supra* note 3, at 53. RAD limits a Participant’s exposure from misdirected or erroneously entered transactions. See Settlement Guide, *supra* note 3, at 5.

<sup>11</sup> See Settlement Guide, *supra* note 3, at 64–68.

<sup>12</sup> See Settlement Guide, *supra* note 3, at 55.

<sup>13</sup> See Rules 9(A) and 9(B), *supra* note 3.

<sup>14</sup> See Settlement Guide, *supra* note 3, at 55.

be removed from processing and will not settle.<sup>15</sup> If the Participants to the transaction wish to settle the transaction through DTC, it will need to be resubmitted.

DTC currently processes transactions in real-time from approximately 8:30 p.m. Eastern Time (“ET”) on the night before settlement day until 3:30 p.m. ET on settlement day for valued transactions and until 6:35 p.m. ET for free transactions.<sup>16</sup> The Night Cycle starts at approximately 8:30 p.m. ET on the Business Day prior to settlement date and runs until approximately 10 p.m. ET each Business Day. Transactions that cannot satisfy DTC’s controls at the time they are introduced to DTC will recycle throughout the day and be continuously reattempted until approximately 3:10 p.m. for valued transactions, and 6:35 p.m. for free transactions.<sup>17</sup> Transactions that satisfy DTC’s controls are processed immediately as described above. The end-of-day settlement process for valued transactions typically concludes between approximately 4 p.m. and 4:30 p.m.<sup>18</sup>

#### Proposed Night Cycle Reengineering Processing Rules

Other than a limited look-ahead process as described below, DTC does not employ a processing mechanism that is designed to proactively optimize the percentage of available transactions that are processed for settlement on

<sup>15</sup> *Id.*

<sup>16</sup> Valued transactions are processed as Deliveries Versus Payment, as defined in Rule 1, *supra* note 3, with the related payments settled through end-of-day settlement. Free transactions do not have an associated payment. Processing of valued transactions must be completed earlier on settlement date than free transactions so that DTC can settle the related payments of funds in accordance with established timeframes for the DTC end-of-day settlement process as set forth in the Settlement Guide. See Settlement Guide, *supra* note 3, at 17–20. In accordance with the Settlement Processing Schedule, valued transactions must be approved in RAD by the Receiver by 3:30 p.m. ET. Any valued transactions not approved by the Receiver by this time are removed from the system. See Settlement Guide, *supra* note 3, at 24–27.

<sup>17</sup> Certain Participants manage their securities inventory by controlling when securities transactions are submitted to DTC for processing, *i.e.*, they may hold off submitting outgoing transactions (deliveries) until incoming transactions (receives) are processed. The window between 3:10 p.m. ET and 3:30 p.m. ET provides such Participants with an opportunity to react to receive transactions and submit applicable delivery transactions. The cutoff for all valued transactions is 3:30 p.m. ET, which allows DTC to calculate final settlement balances and complete end of day funds settlement. Free transactions are allowed to recycle until 6:35 p.m. ET since many free transactions are blocked intraday by the Collateral Monitor until end of day funds settlement is complete and the Collateral Monitor controls are “released.” See Settlement Guide, *supra* note 3, at 24–27.

<sup>18</sup> See Settlement Guide, *supra* note 3, at 17–20.

settlement date. As described below, DTC proposes to implement a process that would facilitate a higher percentage of available transactions being processed for settlement during the Night Cycle.<sup>19</sup>

Pursuant to the proposed rule change, DTC would introduce an algorithm that would test multiple scenarios that would incorporate all transactions available for processing at the start of the Night Cycle as a single batch (“Night Batch Process”), to determine the order of processing of those transactions that allows for the optimal percentage of the transactions to satisfy risk and position controls (*i.e.*, the Collateral Monitor and Net Debit Cap controls), and therefore be processed for settlement in the Night Cycle. Consistent with DTC’s existing processing environment, the scenarios used would only involve processing of the transactions on a bilateral basis (*i.e.*, no netting of Deliveries).<sup>20</sup> Once the optimal order of processing has been identified, the results reflecting this optimal processing order would be incorporated into DTC’s core processing environment on a transaction-by-transaction basis, and member output would be produced using existing DTC output facilities. Delivery instructions provided to DTC after the Night Batch Process has begun would be submitted for daytime processing.

#### Inventory Management System Submission Order

Participants can use a profile in the Inventory Management System (“IMS”) that allows them to define the order in which their transactions get submitted for processing during the Night Cycle.<sup>21</sup>

Specifically, IMS provides Participants with two (2) different types of transaction ordering: Submission ordering and recycle ordering. The submission ordering allows Participants to control the order in which different transaction types are submitted into DTC’s core processing system. The

<sup>19</sup> Approximately 50 percent of transactions available for processing at the start of the Night Cycle are processed for settlement during the Night Cycle. DTC anticipates that the proposal would increase the percentage of transactions processed for settlement during the Night Cycle to approximately 65 percent.

<sup>20</sup> The proposed rule change relates only to the processing order of Deliveries and does not impact DTC’s funds settlement process, by which associated funds debits and credits in the Participant’s settlement account are netted intraday to calculate, at any time, a net debit balance or net credit balance, resulting in an end-of-day settlement obligation or right to receive payment.

<sup>21</sup> See Securities Exchange Act Release No. 52450 (September 15, 2005), 70 FR 55641 (September 22, 2005) (File No. SR-DTC-2005-07) and Securities Exchange Act Release No. 50944 (December 29, 2004), 70 FR 1927 (January 11, 2005) (File No. SR-DTC-2004-10).

submission order functionality allows Participants to prioritize transactions by transaction types. The recycle ordering allows Participants to control how DTC attempts to process recycling, or pending, transactions. Similar to the submission ordering, Participants can also prioritize transactions by transaction types under recycle ordering. Additionally, Participants can instruct DTC to (i) attempt transactions in the defined order but complete any transaction that can be completed, (ii) only complete transactions in the defined order, or (iii) not complete any transactions until instructed to do so.

Because the proposed Night Batch Process would attempt to maximize settlement regardless of transaction type, the IMS profile would become obsolete with respect to transactions processed in the Night Cycle.

#### Look-Ahead Processing

Pursuant to the Settlement Guide, DTC's look-ahead process ("Look-Ahead Process") runs throughout the processing day at fifteen-minute intervals and selects pairs of transactions that when processed simultaneously will not violate the involved Participants' Net Debit Cap, Collateral Monitor and other risk management system controls.<sup>22</sup>

The Look-Ahead Process reduces transaction blockage for Securities by identifying a receive transaction pending due to a Net Debit Cap insufficiency, and determines whether the processing of an offsetting delivery transaction pending because of a quantity deficiency in the same Security would permit both transactions to be completed in compliance with DTC's risk management system controls.<sup>23</sup> DTC's processing system calculates the net effect to the Collateral Monitor and Net Debit Cap controls for all three Participants involved and if the net effect will not result in a deficit in the Collateral Monitor or Net Debit Cap for any of the three Participants, the system processes the transactions simultaneously.<sup>24</sup>

Pursuant to the proposed rule change, because the Night Batch Process would provide an algorithm to maximize settlement for all transactions processed in the Night Cycle, the Look-Ahead Process would become obsolete for Night Cycle processing and would not be utilized for processing of transactions in the Night Batch Process.

#### (ii) Proposed Rule Changes

Pursuant to the proposed rule change, DTC would add a section to the Settlement Guide titled "Batch Processing" that would set forth the following text:

During the Night Batch Process, DTC evaluates each Participant's available positions, transaction priority and risk management controls and identifies the transaction processing order that optimizes the number of transactions processed for settlement. The Night Batch Process allows DTC to run multiple processing scenarios until it identifies an optimal processing scenario.

At approximately 8:30 p.m. on S-1, DTC will subject all transactions eligible for processing to the Night Batch Process. The Night Batch Process will be run in an "off-line" batch that will not be visible to Participants, allowing DTC to run multiple processing scenarios until the optimal processing scenario is identified. Once the optimal scenario is identified, the results of the Night Batch Process will be incorporated back into DTC's core processing environment on a transaction-by-transaction basis, and Participant output will be produced using existing DTC output facilities.

In addition, the proposed rule change would add a definition for the Night Batch Process to the Settlement Guide to state that it is a process that operates to control the order of processing of transactions in the Night Cycle.

The proposed rule change would also add a sentence to the section of the Settlement Guide describing the Look-Ahead Process to state that the Look-Ahead Process would not be utilized during the Night Batch Process.

As described above, the IMS profile that allows Participants to define the order in which their transactions get submitted for settlement during the Night Cycle would become obsolete. DTC's Procedures relating to the implementation of rule changes relating to this profile were set forth in two DTC Important Notices<sup>25</sup> ("IMS Important Notices") that were included in the applicable rule filings cited above,<sup>26</sup> and these Procedures were not added to the text of any other DTC Rule or Procedure, including the Rules and Settlement Guide. Therefore, no amendment to the text of the Rules or a service guide is proposed with respect to the proposed rule change relating to this IMS profile. DTC would describe the proposed change relating to IMS in an Important

Notice issued at the time of implementation of the proposed rule change with a citation to the two IMS Important Notices, cited above.

#### (iii) Participant Outreach

Beginning in March 2018, DTC has conducted ongoing outreach with Participants to provide them with notice of the proposed changes. As of the date of this filing, no written comments relating to the proposed changes have been received in response to this outreach. The Commission will be notified of any written comments received.

#### (iv) Implementation Timeframe

Pending Commission approval, DTC expects to implement this proposal by September 26, 2019 and would announce the effective date of the proposed change by an Important Notice posted to its website. As proposed, a legend would be added to the Settlement Guide stating there are changes that have been approved by the Commission but have not yet been implemented. The proposed legend also would include a date by which such changes would be implemented and the file number of this proposal, and state that, once this proposal is implemented, the legend would automatically be removed from the Settlement Guide.

## 2. Statutory Basis

DTC believes this proposal is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a registered clearing agency. Specifically, DTC believes this proposal is consistent with Section 17A(b)(3)(F) of the Act<sup>27</sup> for the reasons described below.

Section 17A(b)(3)(F) of the Act requires, in part, that the Rules be designed to promote the prompt and accurate clearance and settlement of Securities transactions.<sup>28</sup> DTC believes that the proposed changes to implement the Night Batch Process, which would test the entire batch of transactions available for processing at the start of the Night Batch Process to determine the optimal order to process transactions in the Night Cycle, such that they may satisfy risk and position controls, would help maximize the number of transactions processed for settlement during the Night Cycle. Therefore, DTC believes that the proposed changes to implement the Night Batch Process would promote the prompt and accurate clearance and settlement of Securities transactions,

<sup>22</sup> See Settlement Guide, *supra* note 3, at 43.

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> See DTC Important Notice No. B#6329 (September 7, 2004) and DTC Important Notice No. B#7594 (April 25, 2005).

<sup>26</sup> See *supra* note 21.

<sup>27</sup> 15 U.S.C. 78q-1(b)(3)(F).

<sup>28</sup> *Id.*

consistent with Section 17A(b)(3)(F) of the Act.

*(B) Clearing Agency's Statement on Burden on Competition*

DTC believes the proposed changes could burden competition. This is because by implementing the Night Batch Process, Participants would no longer be able to use IMS to direct the prioritization of the processing of their transactions in the Night Cycle. DTC does not believe any burden on competition presented by the proposal would be significant, because the benefit that would be realized from the processing of a higher percentage of transactions during the Night Cycle through the optimized process described above would offset the burden of a Participant not being able to determine the order of processing on its own, and therefore render as insignificant any residual burden of a Participant no longer being able to use IMS to direct prioritization of transactions.

DTC believes any burden on competition that is created by these proposed changes would be necessary and appropriate in furtherance of the purposes of the Act, as permitted by Section 17A(b)(3)(I) of the Act.<sup>29</sup>

The proposed changes to implement the Night Batch Process would be necessary in furtherance of the purposes of the Act because the Rules must be designed to promote the prompt and accurate clearance and settlement of Securities transactions.<sup>30</sup> As described above, DTC believes that the proposed changes would promote the prompt and accurate clearance and settlement of Securities transactions by maximizing the number of settled transactions during the Night Cycle. As such, DTC believes these proposed changes would be necessary in furtherance of the purposes of the Act, as permitted by Section 17A(b)(3)(I) of the Act.<sup>31</sup>

DTC believes any burden on competition that is created by the proposed changes to implement the Night Batch Process would also be appropriate in furtherance of the purposes of the Act. The proposed changes would enable DTC to optimize the available Securities positions and their settlement order. Having the ability to optimize the available Securities positions and their settlement order would help DTC to maximize the number of settled transactions during the Night Cycle. As such, DTC believes these proposed changes would be

appropriate in furtherance of the purposes of the Act, as permitted by Section 17A(b)(3)(I) of the Act.<sup>32</sup>

*(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

Written comments relating to this proposed rule change have not been solicited or received. DTC will notify the Commission of any written comments received by DTC.

**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](mailto:rule-comments@sec.gov). Please include File Number SR-DTC-2019-005 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-DTC-2019-005. 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 DTC 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-DTC-2019-005 and should be submitted on or before August 29, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>33</sup>

**Jill M. Peterson,**

*Assistant Secretary.*

[FR Doc. 2019-16939 Filed 8-7-19; 8:45 am]

**BILLING CODE 8011-01-P**

**SECURITIES AND EXCHANGE COMMISSION**

**Sunshine Act Meetings**

**TIME AND DATE:** Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94-409, that the Securities and Exchange Commission Small Business Capital Formation Advisory Committee will hold a public meeting on Tuesday August 13, 2019, at 9:30 a.m. (CT)

**PLACE:** The meeting will be held at Creighton University, in The President's Fitzgerald Boardroom on the fourth floor of the Mike and Josie Harper Center, located at 602 North 20th Street, Omaha, Nebraska 68178.

**STATUS:** The meeting will be open to the public. Seating will be on a first-come, first-served basis. The meeting will be webcast on the Commission's website at [www.sec.gov](http://www.sec.gov).

**MATTERS TO BE CONSIDERED:** On July 9, 2019, the Commission issued a press release indicating where the meeting would be held and that it would open

<sup>29</sup> 15 U.S.C. 78q-1(b)(3)(I).

<sup>30</sup> 15 U.S.C. 78q-1(b)(3)(F).

<sup>31</sup> 15 U.S.C. 78q-1(b)(3)(I).

<sup>32</sup> *Id.*

<sup>33</sup> 17 CFR 200.30-3(a)(12).

to the public. On August 2, 2019, the Commission published notice of the Committee meeting (Release No. 33-10666), indicating that the meeting is open to the public and inviting the public to submit written comments to the Committee. This Sunshine Act notice is being issued because a majority of the Commission may attend the meeting.

The agenda for the meeting includes matters relating to rules and regulations affecting small and emerging companies under the federal securities laws.

**CONTACT PERSON FOR MORE INFORMATION:** For further information, please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551-5400.

Dated: August 6, 2019.

**Vanessa A. Countryman,**  
Secretary.

[FR Doc. 2019-17103 Filed 8-6-19; 4:15 pm]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-86558; File No. SR-FINRA-2019-022]

### Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of a Proposed Rule Change To Amend FINRA Rule 5130 (Restrictions on the Purchase and Sale of Initial Equity Public Offerings) and FINRA Rule 5131 (New Issue Allocations and Distributions)

August 2, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”)<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on July 26, 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, II, and III below, which Items have been prepared by FINRA. 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 amend FINRA Rule 5130 (Restrictions on the Purchase and Sale of Initial Equity Public Offerings) and FINRA Rule 5131 (New Issue Allocations and Distributions) to exempt additional persons from the

scope of the rules, modify current exemptions to enhance regulatory consistency, address unintended operational impediments and exempt certain types of offerings from the scope of the rules.

Specifically, the proposed rule change would: (1) Incorporate the definitions of “family member” and “family client” under the Investment Advisers Act of 1940 (“Advisers Act”)<sup>3</sup> and the rules promulgated thereunder<sup>4</sup> into the definition of “family investment vehicle” under FINRA Rule 5130(i)(4); (2) exclude sovereign entities that own broker-dealers from the categories of restricted persons under FINRA Rule 5130(i)(10)(E); (3) exempt foreign employee retirement benefits plans that meet specified conditions from FINRA Rules 5130 and 5131(b) (Spinning); (4) provide alternative conditions for satisfying the foreign investment company exemption under FINRA Rule 5130(c)(6); (5) exclude offerings that are conducted pursuant to Regulation S under the Securities Act of 1933 (“Securities Act”)<sup>5</sup> and other offerings outside of the United States and its territories from the definition of “new issue” in FINRA Rules 5130 and 5131; (6) align FINRA Rule 5130(d) (Issuer-Directed Securities) with a similar provision in FINRA Rule 5131.01 (Issuer Directed Allocations); (7) exclude unaffiliated charitable organizations from the definition of “covered non-public company” in FINRA Rule 5131(e)(3); and (8) add an anti-dilution provision for purposes of FINRA Rule 5131(b), similar to the provision in FINRA Rule 5130(e) (Anti-Dilution Provisions).

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 Rule 5130 protects the integrity of the public offering process by ensuring that: (1) Members make bona fide public offerings of securities at the offering price; (2) members do not withhold securities in a public offering for their own benefit or use such securities to reward persons who are in a position to direct future business to members; and (3) industry insiders, including members and their associated persons, do not take advantage of their insider position to purchase new issues<sup>6</sup> for their own benefit at the expense of public customers. Paragraph (a) of Rule 5130 provides that, except as otherwise permitted under the rule: (1) A member (or an associated person) may not sell a new issue to an account in which a restricted person<sup>7</sup> has a beneficial interest;<sup>8</sup> (2) a member (or an associated person) may not purchase a new issue in any account in which such member or associated person has a beneficial interest; and (3) a member may not continue to hold new issues acquired as an underwriter, selling group member, or otherwise.

FINRA Rule 5131 addresses abuses in the allocation and distribution of new issues. Among other things, the rule prohibits the practice of “spinning,” which is the allocation of new issues by a firm to executive officers and directors of the firm’s current, former or prospective investment banking clients.

In April 2017, FINRA published *Regulatory Notice* 17-14 (Capital Formation) seeking comment on the effectiveness and efficiency of its rules, operations and administrative processes governing broker-dealer activities related to the capital-raising process and their impact on capital formation.<sup>9</sup> In

<sup>6</sup> “New issue” means any initial public offering (“IPO”) of an equity security as defined in Section 3(a)(11) of the Act, made pursuant to a registration statement or offering circular, subject to some exceptions. See FINRA Rules 5130(i)(9) and 5131(e)(7).

<sup>7</sup> The term “restricted person” includes the following categories of persons: (1) Broker-dealers; (2) broker-dealer personnel; (3) finders and fiduciaries; (4) portfolio managers; and (5) persons owning a broker-dealer. See FINRA Rule 5130(i)(10).

<sup>8</sup> “Beneficial interest” means any economic interest, such as the right to share in gains or losses. The receipt of a management or performance based fee for operating a collective investment account, or other fees for acting in a fiduciary capacity, is not considered a beneficial interest in the account. See FINRA Rule 5130(i)(1).

<sup>9</sup> The comment period closed on May 30, 2017.

FINRA received 11 comment letters in response to

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> 15 U.S.C. 80b-2(a)(11)(G).

<sup>4</sup> 17 CFR 205.202(a)(11)(G)-1.

<sup>5</sup> 17 CFR 230.901, *et seq.*

response to the *Notice*, two commenters requested that FINRA consider amending Rules 5130 and 5131 to remove certain impediments to capital formation that are unnecessary to protect investors.<sup>10</sup> In addition, based on FINRA's experience with the rules since their adoption, FINRA believes that amendments to Rules 5130 and 5131 are appropriate to address the impact of the rules on family offices, sovereign entities, foreign employee retirement benefits plans, foreign investment companies and executive officers and directors of charitable organizations. FINRA is proposing to amend Rules 5130 and 5131 in response to the comments it received based on *Regulatory Notice* 17-14 as well as FINRA's experience with the rules.

#### Family Offices

The definition of "restricted person" in FINRA Rule 5130 includes portfolio managers, who are persons with the authority to buy or sell securities for, among other entities, a collective investment account.<sup>11</sup> The term "collective investment account"<sup>12</sup> currently excludes a "family investment vehicle," which, in turn, is defined as a legal entity that is beneficially owned solely by immediate family members.<sup>13</sup> Accordingly, under the rule, a person with the authority to buy or sell securities for an account that is beneficially owned only by "immediate family members," as defined, is not considered a portfolio manager based solely on that investment authority and, therefore, is not a restricted person. FINRA excluded such persons from the definition of "portfolio manager" because family investment vehicles are often established for tax and estate

planning purposes and do not manage money for unrelated persons.<sup>14</sup>

FINRA is proposing to expand the definition of "family investment vehicle" under Rule 5130 to include entities that are beneficially owned solely by "family members" and "family clients," which are terms used in the family office context and are defined in Advisers Act Rule 202(a)(11)(G)-1.<sup>15</sup> FINRA believes that an expansion that will further regulatory consistency without undermining investor protection is appropriate. As a result, the proposed rule change will incorporate these definitions into the definition of "family investment vehicle" under Rule 5130, subject to some limitations.

Family offices are entities established by families to manage their wealth and provide other services to family members and are excluded from the definition of "investment adviser" and, thus, are not subject to regulation under the Advisers Act.<sup>16</sup> The Advisers Act defines a "family office" as a company that, among other conditions, is wholly owned by family clients.<sup>17</sup> The term "family client"<sup>18</sup> includes, among other defined persons, "family members"<sup>19</sup> as well as "key employees"<sup>20</sup> of the family office.

<sup>14</sup> See Securities Exchange Act Release No. 42325 (January 10, 2000), 5 FR 2656, 2660 (January 18, 2000) (Notice of Filing File No. SR-NASD-99-60) ("Notice of New Issue Rule Filing").

<sup>15</sup> See 17 CFR 275.202(a)(11)(G)-1.

<sup>16</sup> See 15 U.S.C. 80b-2(a)(11)(G); *Family Offices*, Advisers Act Release No. 3220 (June 22, 2011), 76 FR 37983 (June 29, 2011).

<sup>17</sup> 17 CFR 275.202(a)(11)(G)-1(b)(2).

<sup>18</sup> 17 CFR 275.202(a)(11)(G)-1(d)(4).

<sup>19</sup> The term "family member" is defined as all lineal descendants (including by adoption, stepchildren, foster children, and individuals that were a minor when another family member became a legal guardian of that individual) of a common ancestor (who may be living or deceased), and such lineal descendants' spouses or spousal equivalents; provided that the common ancestor is no more than 10 generations removed from the youngest generation of family members. See 17 CFR 275.202(a)(11)(G)-1(d)(6).

<sup>20</sup> The term "key employee" is defined as any natural person (including any key employee's spouse or spouse equivalent who holds a joint, community property, or other similar shared ownership interest with that key employee) who is an executive officer, director, trustee, general partner, or person serving in a similar capacity of the family office or its affiliated family office or any employee of the family office or its affiliated family office (other than an employee performing solely clerical, secretarial, or administrative functions with regard to the family office) who, in connection with his or her regular functions or duties, participates in the investment activities of the family office or affiliated family office, provided that such employee has been performing such functions and duties for or on behalf of the family office or affiliated family office, or substantially similar functions or duties for or on behalf of another company, for at least 12 months. See 17 CFR 275.202(a)(11)(G)-1(d)(8).

Although they overlap in significant respects, differences exist between a family investment vehicle under FINRA Rule 5130 and the family office concept under the Advisers Act. These differences create inconsistencies, which do not further the purposes of FINRA Rule 5130, with respect to the treatment of family offices under the two regimes. For example, the definition of "immediate family member" under FINRA Rule 5130 includes a person's parents, mother-in-law or father-in-law, spouse, brother or sister, brother-in-law or sister-in-law, son-in-law or daughter-in-law and children, whereas the definition of "family member" under the Advisers Act includes lineal descendants of a common ancestor and the lineal descendants' spouses or spousal equivalents.<sup>21</sup> As a result, and by way of example, the inclusion of grandchildren or grandparents in a collective investment account will not disqualify the account from the family office designation under the Advisers Act on that basis, but would cause such an account to fall outside of the definition of "family investment vehicle" under FINRA Rule 5130.

Another difference is that the terms "immediate family member" and "family client" each address categories of non-family members; however, they do so in different ways. Specifically, the definition of "immediate family member" under FINRA Rule 5130 includes any individual to whom the person provides material support, which could encompass non-family members.<sup>22</sup> The definition of "family client" under the Advisers Act includes key employees of the family office, which may also cover non-family members but not necessarily only those non-family members who receive material support.<sup>23</sup> As a result of this difference, a person who has the authority to buy or sell securities for an account that is beneficially owned by family clients could be considered a portfolio manager based exclusively on that investment authority, and thus a restricted person under FINRA Rule 5130.

Given the significant overlap between these concepts, and FINRA's belief that the differences do not serve the purposes of the rule, FINRA is proposing to incorporate the definitions of "family member" and "family client" under the Advisers Act into the definition of "family investment vehicle" under Rule 5130, subject to

<sup>21</sup> See 17 CFR 275.202(a)(11)(G)-1(d)(6); *supra* note 19.

<sup>22</sup> See *supra* note 13.

<sup>23</sup> See *supra* note 20.

the *Notice*. The *Notice* and the comment letters are available at <http://www.finra.org/industry/notices/17-14>.

<sup>10</sup> Sean Davy, Managing Director, Capital Markets Division, Securities Industry and Financial Markets Association ("SIFMA") and Sullivan & Cromwell LLP ("Sullivan & Cromwell").

<sup>11</sup> See FINRA Rule 5130(i)(10)(D) (Portfolio Managers). The definition of "portfolio manager" also includes any immediate family member of a portfolio manager who materially supports, or receives material support from, the portfolio manager. The term "material support" is defined as directly or indirectly providing more than 25 percent of a person's income in the prior calendar year. Members of the immediate family living in the same household are deemed to be providing each other with material support. See FINRA Rule 5130(i)(8).

<sup>12</sup> See FINRA Rule 5130(i)(2).

<sup>13</sup> See FINRA Rule 5130(i)(4). The term "immediate family member" is defined as a person's parents, mother-in-law or father-in-law, spouse, brother or sister, brother-in-law or sister-in-law, son-in-law or daughter-in-law, and children, and any other individual to whom the person provides material support. See FINRA Rule 5130(i)(5).

some limitations. Specifically, the proposed rule change would amend FINRA Rule 5130(i)(4) to define a “family investment vehicle” as a legal entity that is beneficially owned solely by one or more of the following persons: (1) “immediate family members” as defined under FINRA Rule 5130(i)(5); (2) “family members” as defined under Advisers Act Rule 202(a)(11)(G)–1(d)(6); or (3) “family clients” as defined under Advisers Act Rule 202(a)(11)(G)–1(d)(4);<sup>24</sup> provided, however, that where the beneficial owners of such an entity include family clients, the person who has the sole authority to buy or sell securities for such an entity is an “immediate family member” as defined in FINRA Rule 5130(i)(5) or a “family member” as defined in Advisers Act Rule 202(a)(11)(G)–1(d)(6).

The first category would preserve the current exception in FINRA Rule 5130 and would provide relief from portfolio manager status under the rule for a person who has the authority to buy or sell securities for an account that is beneficially owned only by immediate family members. The second category would provide relief from portfolio manager status under the rule for a person who has the authority to buy or sell securities for an account that is beneficially owned only by “family members,” as defined in the Advisers Act. The third category would provide relief from portfolio manager status under the rule for a person who has the authority to buy or sell securities for an account that is owned only by “family clients,” as defined in the Advisers Act. In addition, the proposed rule change would provide relief to a legal entity that is beneficially owned by any combination of these categories.

However, the proposed rule change contains an important caveat where the beneficial owners are not solely immediate family members or family members under FINRA Rule 5130(i)(5) or Advisers Act Rule 202(a)(11)(G)–1(d)(6), respectively. Specifically, in such cases, the proposed rule change would only provide relief from portfolio manager status if the person who has the authority to buy or sell securities for the account is an “immediate family member,” as defined in FINRA Rule 5130, or a “family member,” as defined in the Advisers Act.<sup>25</sup> FINRA believes

<sup>24</sup> As noted above, the term “family client” includes not only family members but others, including key employees. See 17 CFR 275.202(a)(11)(G)–1(d)(4). Therefore, a family investment vehicle that is beneficially owned solely by family clients may include beneficial owners that are not family members.

<sup>25</sup> Further, the proposed relief is only with respect to a person’s status as a portfolio manager under

that it is necessary to impose this condition to safeguard against the abuses the rule is designed to address and to ensure that, for purposes of Rule 5130, the person who has the authority to buy or sell securities for the account is more closely aligned with the family than with key employees or others associated with the family office. FINRA believes that the proposed rule change strikes the proper balance between the treatment of family investment vehicles in FINRA Rule 5130 and the recognition of the family office exemption under the Advisers Act.

#### Sovereign Entities

The definition of “restricted person” in FINRA Rule 5130 includes, among others, direct and indirect owners of broker-dealers that are listed, or required to be listed, on Schedules A and B of Form BD (Uniform Application for Broker-Dealer Registration) and that have an ownership interest above specified thresholds.<sup>26</sup> The definition of “restricted person” includes owners of broker-dealers because the prohibition on purchases of new issues by a broker-dealer could be circumvented if the owners of a broker-dealer were permitted to purchase new issues.<sup>27</sup>

A sovereign wealth fund (“SWF”) is a pool of capital or an investment fund owned or controlled by a sovereign nation and created for the purpose of making investments on behalf of the sovereign nation.<sup>28</sup> Occasionally, an SWF or sovereign nation (collectively, a “sovereign entity”) may acquire a direct or an indirect ownership stake in a registered broker-dealer, requiring the sovereign entity to be listed on Schedule A or B of Form BD. Moreover, the sovereign entity’s ownership interest

FINRA Rule 5130. The proposed relief does not extend to a person who has a beneficial interest in a family investment vehicle and is a restricted person based on his or her other activities, such as an associated person of a member.

<sup>26</sup> See FINRA Rule 5130(i)(10)(E) (Persons Owning a Broker-Dealer). FINRA Rule 5130 also provides an exception for an owner of a “limited business broker-dealer,” which is defined as a broker-dealer whose authorization to engage in the securities business is limited solely to the purchase and sale of investment company/variable contracts securities and direct participation program securities. See FINRA Rules 5130(i)(7) and 5130(i)(10)(E).

<sup>27</sup> See Securities Exchange Act Release No. 48701 (October 24, 2003), 68 FR 62126, 62133 (October 31, 2003) (Order Approving File No. SR–NASD–99–60) (“New Issue Rule Approval Order”).

<sup>28</sup> There is no standard definition of the term “sovereign wealth fund,” and the term is not defined under the federal securities laws. See, e.g., Celeste Cecelia Moles Lo Turco, *Sovereign Wealth Funds: From Transparency to Sustainability*, Sovereign Wealth Funds Law Centre, Bi-Annual Legal Report, October 2013 (noting the absence of a commonly accepted definition of “sovereign wealth fund”).

could exceed the specified thresholds in FINRA Rule 5130(i)(10)(E), which would make the sovereign entity a restricted person.

Rule 5130(i)(10)(E) was not intended to encompass sovereign entities that acquire an ownership interest in a registered broker-dealer. Instead, as discussed above, the inclusion of owners of broker-dealers in the categories of restricted persons was intended to prevent circumvention of the prohibition on purchases of new issues by broker-dealers. FINRA believes that sovereign entities are unlikely to circumvent the rule’s prohibition by reallocating new issue shares to broker-dealers and are inherently not designed for such a purpose. Further, FINRA notes that significant investments by sovereign entities currently are subject to distinct legal and regulatory requirements.<sup>29</sup>

To address the unintended application of FINRA Rule 5130 to sovereign entities, the proposed rule change would exclude sovereign entities from the scope of owners of broker-dealers under Rule 5130(i)(10)(E). The proposed exclusion would not apply to affiliates of sovereign entities that are otherwise restricted. Accordingly, while a sovereign entity that owns a broker-dealer would not be considered a restricted person under the proposed rule change, the broker-dealer would continue to be a restricted person under FINRA Rule 5130.

The proposed rule change would also amend FINRA Rule 5130(i) (Definitions) to define the term “sovereign entity” for purposes of the rule as “a sovereign nation or a pool of capital or an investment fund owned or controlled by a sovereign nation and created for the purpose of making investments on behalf of the sovereign nation.” The proposed rule change would further define the term “sovereign nation” as “a sovereign nation or its political subdivisions, agencies or instrumentalities.”

#### Foreign Employee Retirement Benefits Plans

FINRA Rule 5130(c)(7) provides a general exemption from the rule’s prohibitions for an Employee Retirement Income Security Act

<sup>29</sup> For example, specific investments by sovereign entities in the United States that raise national security concerns are subject to review by the Committee on Foreign Investment in the United States (CFIUS). CFIUS is an interagency committee of the federal government chaired by the Department of the Treasury and authorized to review transactions that could result in control of a U.S. business by a foreign person to determine the effect of such transactions on the national security of the United States. See 31 CFR 800.

("ERISA") benefits plan that is qualified under Section 401(a) of the Internal Revenue Code ("IRC"), provided that the plan is not sponsored solely by a broker-dealer. Employee retirement benefits plans that are organized under and governed by foreign laws, even when similar to qualifying ERISA plans in all material respect, are not subject to ERISA and do not qualify for the exemption in FINRA Rule 5130(c)(7).<sup>30</sup> Because foreign employee retirement benefits plans may invest in assets on behalf of potentially hundreds of thousands of participants and beneficiaries, such plans may be unable to determine whether persons with a beneficial interest are restricted persons under FINRA Rule 5130. As a result, such plans may find it impossible to assess whether they may permissibly invest in new issues. Currently, FINRA Rule 5130 does not include a general exemption for foreign employee retirement benefits plans, although FINRA has previously acknowledged that such an exemption may be appropriate.<sup>31</sup>

In recent years, FINRA staff has granted several requests for exemption from the rule for foreign employee retirement benefits plans.<sup>32</sup> In each case, the foreign employee retirement benefits plans were organized under and governed by foreign laws, had an extensive number of participants and beneficiaries and significant assets in the employer's retirement fund or family of retirement funds, and were administered by trustees and managers that have a fiduciary obligation to administer the funds in the best interests of the participants and beneficiaries. Under these circumstances, the plans stated that the funds plainly could not serve as a conduit for restricted persons to

purchase new issues. FINRA staff agreed that the concerns underlying the rule were not served in light of those circumstances and, as such, FINRA staff granted exemptions from FINRA Rule 5130 in connection with the foreign employee retirement benefits plans.

FINRA is proposing to codify this position by amending FINRA Rule 5130(c) (General Exemptions) to provide an exemption for an employee retirement benefits plan organized under and governed by the laws of a foreign jurisdiction, provided that such a plan or family of plans: (1) Has, in aggregate, at least 10,000 participants and beneficiaries and \$10 billion in assets; (2) is operated in a non-discriminatory manner insofar as a wide range of employees, regardless of income or position, are eligible to participate without further amendment or action by the plan sponsor;<sup>33</sup> (3) is administered by trustees and managers that have a fiduciary obligation to administer the funds in the best interests of the participants and beneficiaries; and (4) is not sponsored by a broker-dealer. Under these conditions, FINRA believes that the plan(s) are not likely to serve as a conduit for circumventing the rule. In addition, FINRA believes that the rationale for exempting ERISA benefits plans applies equally to foreign benefits plans when these conditions are met, and such plans should be afforded similar treatment under the rule.

Finally, FINRA Rule 5131(b)(2) sets forth the exemptions applicable to the spinning provision. The exemptions generally correspond to those under FINRA Rule 5130(c). Therefore, in conjunction with adding foreign employee retirement benefits plans to Rule 5130(c), FINRA is also proposing to amend Rule 5131(b)(2) to add a corresponding exemption to that rule. This proposed change will minimize unnecessary regulatory burdens without undermining the rule's stated objective, as the practice of spinning is unlikely to occur in connection with a covered person's beneficial interest in a foreign employee retirement benefits plan.

#### Alternative Conditions for Foreign Investment Company Exemption

Paragraph (c)(6) of FINRA Rule 5130 currently exempts sales to and

purchases by an investment company organized under the laws of a foreign jurisdiction, provided that: (1) The investment company is listed on a foreign exchange for sale to the public or authorized for sale to the public by a foreign regulatory authority; and (2) no person owning more than five percent of the shares of the investment company is a restricted person. The foreign investment company exemption is intended to apply to foreign investment companies that are similar to U.S. registered investment companies, which are currently exempt from FINRA Rule 5130's prohibitions.<sup>34</sup>

The purpose of the five percent condition is to prevent purchases of new issues by foreign investment companies with concentrated ownership interests of restricted persons.<sup>35</sup> However, based on FINRA's experience with the rule, including informal discussions with industry groups and market participants in the years since the rule's adoption, FINRA understands that it is operationally impractical for a foreign investment company to determine whether an investor owns more than five percent of its shares where the investor acquires his or her interest through an intermediary that then holds the shares for multiple investors in an omnibus or nominee account as distinguished from an account that holds shares of a single investor. Further, an investor may acquire shares of a foreign investment company through multiple intermediaries or through multiple omnibus or nominee accounts at the same intermediary. In such cases, foreign investment companies are not able to satisfy the five percent condition.

When FINRA (then NASD) originally proposed the foreign investment company exemption as part of NASD Rule 2790 (Restrictions on the Purchase and Sale of Initial Equity Public Offerings), the exemption included an additional condition that required the foreign investment company to have 100 or more investors.<sup>36</sup> During the rulemaking process, however, FINRA determined to simplify the exemption by eliminating the 100 investor requirement because the condition addressed the same concerns about concentration of ownership as the five percent condition.<sup>37</sup>

Given the operational issues raised by the five percent condition, FINRA is

<sup>30</sup> ERISA explicitly excludes from coverage employee benefit plans that are "maintained outside of the United States primarily for the benefit of persons substantially all of whom are nonresident aliens." 29 U.S.C. 1003(b)(4).

<sup>31</sup> See Restrictions on the Purchase and Sale of Initial Equity Public Offerings Amendment No. 3, File No. SR-NASD-99-60 (March 19, 2001), <http://www.finra.org/sites/default/files/RuleFiling/p000150.pdf>.

<sup>32</sup> See Letter from Gary L. Goldsholle, FINRA, to Edward A. Kwalwasser, Proskauer Rose LLP, dated December 7, 2010, <http://www.finra.org/industry/exemptive-letters/december-7-2010-1200am>; Letter from Afshin Atabaki, FINRA, to Christopher M. Wells, Proskauer Rose LLP, dated November 2, 2012, <http://www.finra.org/industry/exemptive-letters/november-2-2012-1200am>; Letter from Meredith Cordisco, FINRA, to Amy Natterson Kroll, Morgan, Lewis & Bockius LLP, dated July 23, 2015, <http://www.finra.org/industry/exemptive-letters/july-23-2015-1200am>; and Letter from Meredith Cordisco, FINRA, to Amy Natterson Kroll, Morgan, Lewis & Bockius LLP, dated April 16, 2018, <http://www.finra.org/industry/exemptive-letters/april-16-2018-1200am>.

<sup>33</sup> The definition of "broad-based foreign retirement plan" under Section 409A of the IRC includes a substantially similar condition. See 26 CFR 1.409A-1(a)(3)(v)(A). Section 409A imposes restrictions on the deferral of compensation by employees, directors and independent contractors. Section 409A provides an exemption for compensation deferred under certain broad-based foreign retirement plans.

<sup>34</sup> See FINRA Rule 5130(c)(1).

<sup>35</sup> See New Issue Approval Order, 68 FR at 62138.

<sup>36</sup> See Notice of New Issue Rule Filing, 5 FR at 2657.

<sup>37</sup> See New Issue Approval Order, 68 FR at 62137.

proposing to amend Rule 5130(c)(6) to provide the following two alternative methods to establish that a foreign investment company is widely held for purposes of the rule: (1) The investment company has 100 or more direct investors; or (2) the investment company has 1,000 or more indirect investors.<sup>38</sup> FINRA believes that satisfying either of these two conditions would also assuage concerns about concentration of ownership. The proposed rule change would also add a condition to paragraph (c)(6) to ensure that the foreign investment company is not formed for the specific purpose of investing in new issues.

Therefore, as proposed, paragraph (c)(6) of FINRA Rule 5130 would exempt sales to and purchases by an investment company organized under the laws of a foreign jurisdiction, provided that: (1) The investment company is listed on a foreign exchange for sale to the public or authorized for sale to the public by a foreign regulatory authority; (2) no person owning more than five percent of the shares of the investment company is a restricted person, the investment company has 100 or more direct investors, or the investment company has 1,000 or more indirect investors; and (3) the investment company was not formed for the specific purpose of investing in new issues.<sup>39</sup>

#### Exclusion for Foreign Offerings

As noted above, for purposes of FINRA Rules 5130 and 5131, the term “new issue” means any IPO of an equity security as defined in Section 3(a)(11) of the Act, made pursuant to a registration statement or offering circular, subject to some exceptions.<sup>40</sup> Currently, the definition is not expressly limited to domestic securities offerings. Accordingly, the rules could apply to foreign offerings, even if a safe harbor is available for those offerings under the Securities Act, to the extent that a

<sup>38</sup> As noted above, in some jurisdictions, investors may invest through layers of intermediaries, with the legal ownership held by nominees. FINRA believes that a foreign investment company would be considered to be widely held on an indirect basis if it has 1,000 or more indirect investors.

<sup>39</sup> The proposed rule change also impacts an identical exemption cross referenced in paragraph (b)(2) of FINRA Rule 5131. The proposed rule change would not undermine the objectives of the spinning provision, as spinning would be unlikely to occur in connection with a foreign investment company when the proposed conditions are met.

<sup>40</sup> See Rules 5130(i)(9) and 5131(e)(7). The definition of “new issue” does not include, among others, offerings made pursuant to an exemption under Section 4(1), 4(2) or 4(6) of the Securities Act, or Securities Act Rule 504 if the securities are “restricted securities” under Securities Act Rule 144(a)(3), or Rule 144A or Rule 505 or Rule 506 adopted thereunder. See Rule 5130(i)(9)(A).

member or an associated person is participating in the offering or receiving allocations of new issues as an investor.<sup>41</sup>

In connection with *Regulatory Notice* 17–14, SIFMA and Sullivan & Cromwell requested that FINRA expressly exclude from Rules 5130 and 5131 offerings that are conducted pursuant to Regulation S, which provides a safe harbor from the registration requirements of the Securities Act for offshore offers and sales of securities. SIFMA suggested that FINRA’s goals of investor protection and fostering fair public capital markets are not present when members are participating in transactions conducted wholly offshore, and Sullivan & Cromwell stated that such a carve-out would provide clarity to the industry.<sup>42</sup> Some foreign jurisdictions may not restrict market participants, such as broker-dealers, from purchasing IPO shares for their own account. By prohibiting members and associated persons from purchasing IPO shares in foreign offerings, the current rule may indirectly impede the capital formation process in those foreign jurisdictions. Further, Regulation S offerings are currently excluded from the definition of “public offering” for purposes of FINRA Rules 5110 (Corporate Financing Rule—Underwriting Terms and Arrangements) and 5121 (Public Offerings of Securities With Conflicts of Interest). FINRA believes that an exclusion from Rules 5130 and 5131 for Regulation S offerings is also appropriate. In addition, FINRA believes that the exclusion should be extended to other offerings made outside of the United States or its territories and not just those that are expressly designated as Regulation S offerings.

#### Issuer-Directed Securities

FINRA Rules 5130(d) and 5131.01 each contain exemptive provisions for new issue allocations that are directed by an issuer, when specified conditions are met, because the regulatory concerns that the rules are designed to address are not present with respect to allocations of securities that are not controlled by an underwriter. However, these exemptions are not identical, in that FINRA Rule 5131 exempts allocations directed by affiliates and selling shareholders, while FINRA Rule 5130 does not.

In response to *Regulatory Notice* 17–14, SIFMA requested better alignment of

<sup>41</sup> See *Notice to Members* 03–79 (December 2003) at n.13.

<sup>42</sup> See SIFMA at 8; Sullivan & Cromwell at 7–8.

these provisions.<sup>43</sup> FINRA agrees that a conforming change to FINRA Rule 5130(d) to more closely align the rule with the issuer-directed provision in FINRA Rule 5131.01 will provide regulatory consistency without negatively impacting investor protection or the integrity of the market for new issues and would not impact the spinning provision of Rule 5131. Specifically, the proposed rule change would amend paragraphs (d)(1) and (d)(2) of Rule 5130 to expand the exemption for issuer-directed securities to allocations directed by affiliates and selling shareholders of the issuer. The change will also clarify that the exemption applies to shares that are specifically directed in writing by the issuer.

#### Exclusion for Unaffiliated Charitable Organizations

As noted above, paragraph (b) of FINRA Rule 5131 prohibits the practice of “spinning,” which is the allocation of new issues to executive officers and directors of current and certain former or prospective investment banking clients. The spinning provision provides that no member or person associated with a member may allocate shares of a new issue to any account in which an executive officer or director of a public company<sup>44</sup> or a covered non-public company,<sup>45</sup> or a person materially supported<sup>46</sup> by such executive officer or director, has a beneficial interest:<sup>47</sup> (1) If the company is currently an investment banking services client of the member or the member has received compensation from the company for investment banking services in the past 12 months; (2) if the person responsible for making the allocation decision knows or has reason to know that the

<sup>43</sup> See SIFMA at 7, n.10.

<sup>44</sup> FINRA Rule 5131(e)(1) defines “public company” as “any company that is registered under Section 12 of the Exchange Act or files periodic reports pursuant to Section 15(d) thereof.” See FINRA Rule 5131(e)(1).

<sup>45</sup> The term “covered non-public company” means any non-public company satisfying the following criteria: (1) Income of at least \$1 million in the last fiscal year or in two of the last three fiscal years and shareholders’ equity of at least \$15 million; (2) shareholders’ equity of at least \$30 million and a two-year operating history; or (3) total assets and total revenue of at least \$75 million in the latest fiscal year or in two of the last three fiscal years. See FINRA Rule 5131(e)(3).

<sup>46</sup> Similar to the definition in FINRA Rule 5130(i)(8), FINRA Rule 5131 defines “material support” to mean directly or indirectly providing more than 25 percent of a person’s income in the prior calendar year. Persons living in the same household are deemed to be providing each other with material support. See FINRA Rule 5131(e)(6).

<sup>47</sup> The term “beneficial interest” has the same meaning as in FINRA Rule 5130. See FINRA Rule 5131(e)(2).

member intends to provide, or expects to be retained by the company for, investment banking services within the next three months; or (3) on the express or implied condition that such executive officer or director, on behalf of the company, will retain the member for the performance of future investment banking services.

Because executive officers and directors are often in a position to hire members on behalf of the companies they serve, allocating new issues to such persons creates the appearance of impropriety and has the potential to divide the loyalty of the executive officers and directors from the company on whose behalf they must act. Industry groups and market participants have noted that these same concerns are not implicated in the case of executive officers and directors of charitable organizations. However, due to their asset size, some charitable organizations fall within the definition of a covered non-public company, making executives or directors of such organizations the subject of the rule's prohibition. FINRA believes that charitable organizations are not likely to generate significant investment banking business and, thus, there is a low risk, if any, that improper incentives would motivate a member's or an associated person's decision to allocate shares to the account of executive officers or directors of such organizations.

FINRA is proposing to amend paragraph (e)(3) of Rule 5131 (Definitions) to exclude unaffiliated charitable organizations, as that term is elsewhere defined in the rule,<sup>48</sup> from the definition of "covered non-public company." As a result of this proposed amendment, an executive officer or director of a charitable organization that is not affiliated with the member allocating IPO shares would not become the subject of the rule's spinning provision solely on the basis of that service.

#### Addition of Anti-Dilution Provision to FINRA Rule 5131

FINRA Rule 5130 allows restricted persons that are existing equity owners of an issuer to purchase shares of the issuer in a public offering in order to maintain their equity ownership

<sup>48</sup> An "unaffiliated charitable organization" is a tax-exempt entity organized under Section 501(c)(3) of the IRC that is not affiliated with the member and for which no executive officer or director of the member, or person materially supported by such executive officer or director, is an individual listed or required to be listed on Part VII of Internal Revenue Service Form 990 (*i.e.*, officers, directors, trustees, key employees, highest compensated employees and certain independent contractors). See FINRA Rule 5131(e)(9).

position. However, FINRA Rule 5131 currently does not include a similar anti-dilution provision for executive officers and directors who are subject to the prohibition on spinning set forth in Rule 5131(b). In response to *Regulatory Notice* 17–14, SIFMA urged FINRA to create symmetry between the rules by adding an anti-dilution provision for purposes of Rule 5131(b).<sup>49</sup> FINRA agrees that executive officers and directors of public companies and covered non-public companies who are subject to Rule 5131's spinning provision should be able to maintain the same equity ownership level that they held prior to the offering. Accordingly, the proposed rule change would amend Rule 5131 to add an anti-dilution provision to the rule similar to the one in Rule 5130(e), and would thus allow an executive officer or director of a public company or a covered non-public company (or a person materially supported by such a person) to retain the percentage equity ownership in the issuer at a level up to the ownership interest as of three months prior to the filing of the registration statement, provided that the other conditions are met.

If the Commission approves the proposed rule change, FINRA will announce the effective date of the proposed rule change in a *Regulatory Notice* to be published no later than 60 days following Commission approval. The effective date will be no later than 30 days following publication of the *Regulatory Notice* announcing Commission approval.

#### 2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,<sup>50</sup> 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. FINRA believes that the proposed rule change will further these purposes by promoting capital formation and aiding member compliance efforts, while maintaining

<sup>49</sup> See SIFMA at 7, n.10. In addition, SIFMA requested that FINRA consider amending Rule 5131(d)(3) (Agreement Among Underwriters) relating to the treatment of returned shares to allow members the option of selling such shares in the secondary market and donating profits anonymously to an unaffiliated charity when a syndicate short position exists, consistent with a similar option when no syndicate short position exists. See SIFMA 8–9. FINRA considered this comment and has determined not to proceed with any changes to Rule 5131(d)(3).

<sup>50</sup> 15 U.S.C. 78o–3(b)(6).

the integrity of the public offering process and investor confidence in the capital 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.

#### Economic Impact Assessment

FINRA has undertaken an economic impact assessment, as set forth below, to further analyze the regulatory need for the proposed rule change, the economic baseline of analysis, the economic impact and the alternatives considered.

##### 1. Regulatory Need

Based upon FINRA's experience with Rules 5130 and 5131, as well as input from industry groups and market participants regarding practical and operational issues relating to the rules, FINRA is proposing amendments to reduce the regulatory burden on firms and remove certain impediments to capital formation without impacting investor protection. The proposed rule change aims to foster capital formation and to bring regulatory clarity and consistency. Specifically, FINRA is proposing to exempt additional persons from the scope of the rules, modify current exemptions to enhance regulatory consistency, address unintended operational impediments and exempt certain types of offerings from the scope of the rules.

##### 2. Economic Baseline

The economic baseline for the proposed rule change is the current requirements and provisions of FINRA Rules 5130 and 5131, which are intended to protect the integrity of the public offering process. To this end, Rule 5130 sets forth categories of persons that are restricted from purchasing new issues. In addition, Rule 5131 places restrictions on the allocation of new issues to executive officers and directors of a member's current, former or prospective investment banking clients.

To assess the current economic baseline, FINRA has analyzed the current groups potentially affected by the various aspects of the proposed rule change. FINRA believes that there are thousands of family offices that, along with the family members and family clients served by those offices, are potentially impacted by the proposed

rule change.<sup>51</sup> With respect to sovereign entities, there are approximately 195 independent states in the world,<sup>52</sup> many of which operate one or more sovereign wealth funds, and the number is believed to be on the rise.<sup>53</sup> FINRA understands that there are thousands of foreign pension plans (including both state- and privately-operated foreign plans) as well as millions of beneficiaries and participants of those plans. Similarly, FINRA understands that there are thousands of foreign investment companies and millions of investors in such companies. As of 2013, there were over one million organizations with Section 501(c)(3) status in the United States, though the number of charitable organizations that are large enough to fall within the current definition of “covered non-public company” in Rule 5131(e)(3) is likely smaller than that figure.<sup>54</sup>

### 3. Economic Impact

For purposes of this discussion, FINRA has identified the potentially material impacts of the proposed amendments on the affected parties.

FINRA believes that the proposed amendments to Rules 5130 and 5131 will remove unnecessary impediments to capital formation and lessen burdens in the public offering process. The proposed amendments will generally have a beneficial impact on issuers, underwriters and selling group members and certain categories of investors.

FINRA believes that a significant impact of the proposed amendments will be a reduction in both the costs and uncertainty in determining whether an investor is subject to the restrictions of Rules 5130 and 5131. The proposed rule change also may increase the pool of investors eligible to purchase new issues and, thus, encourage capital formation. FINRA believes that the proposed amendments would not alter the original purpose of Rules 5130 and 5131 in ensuring the integrity of a public offering.

FINRA Rule 5130 restricts members and associated persons from purchasing new issues for their own account or

selling new issues to an account in which other restricted persons have a beneficial interest. Currently the definition of “restricted person” in Rule 5130(i)(10) captures certain persons that were not intended to be included in the definition. To address this issue, the proposed rule change would exempt from the definition of “restricted person”: (1) A person with the authority to buy or sell securities for an account beneficially owned by a family office, subject to specified conditions; and (2) sovereign entities that acquire an ownership interest in a registered broker-dealer. These persons would benefit from the proposed rule change by eliminating their restrictions from purchasing new issues, thus increasing their set of potential investments. To the extent that new issues provide a unique risk-return profile from other types of securities investments, the inclusion of them in these persons’ portfolios would be value enhancing. The proposed rule change would also better align with the Advisers Act’s treatment of family offices.

FINRA Rule 5130 currently does not include a general exemption for foreign employee retirement benefits plans. Rather, FINRA staff has granted exemptive relief to certain foreign employee retirement benefits plans that have demonstrated that they cannot serve as a conduit for restricted persons to purchase new issues. The proposed rule change codifies the criteria upon which the staff granted exemptive relief. The proposed rule change would allow plans that meet specified criteria to invest in new issues without having to determine the eligibility of hundreds of thousands of participants and beneficiaries. By providing such plans additional flexibility to invest in new issues, the proposed rule change would enhance the investment options for their equity portfolios. The codification of the criteria would also improve regulatory uniformity and reduce compliance costs.

The foreign investment company exemption in FINRA Rule 5130(c)(6) is intended to apply to foreign investment companies that are similar to U.S. registered investment companies, which are currently exempt from FINRA Rule 5130’s prohibitions. In order to satisfy the current exemption, the foreign investment company, among other conditions, must establish that no person owning more than five percent of the shares of the investment company is a restricted person. However, where an investor acquires his or her interest in a foreign investment company through an intermediary that then holds the shares for multiple investors in an

omnibus or nominee account, the foreign investment company may not be able to determine whether the investor owns more than five percent of its shares. The proposed rule change would address this operational issue and create two alternative conditions that the foreign investment company have 100 or more direct investors or 1,000 or more indirect investors. The proposed alternative conditions would provide additional flexibility to foreign investment companies to demonstrate their eligibility for the exemption, and thereby enhance their ability to purchase new issues.

FINRA Rules 5130 and 5131 are primarily concerned with fostering fair public capital markets within the United States. However, because the definition of “new issue” is not expressly limited to domestic offerings, the rules could apply to foreign offerings, even if a safe harbor is available for those offerings under the Securities Act, if a member or an associated person is participating in the offering or receiving allocations as an investor. The proposed rule change would clarify the scope of Rules 5130 and 5131 by excluding Regulation S offerings and other offerings made outside of the United States or its territories from the scope of the rules. The proposed rule change would also harmonize Rules 5130 and 5131 with other FINRA rules relating to securities offerings, FINRA Rules 5110 and 5121, which currently exclude foreign offerings. FINRA believes that the proposed rule change will remove the burdens associated with complying with both U.S. and foreign regulatory regimes relating to public offerings and will lead to an increase in the pool of eligible investors for offshore offerings of new issues without undermining the fairness of U.S. public capital markets. Further, an increase in the pool of eligible investors could lead to a lower cost of capital for issuers engaged in foreign offerings.

The issuer-directed provisions in FINRA Rules 5130 and 5131 are similar, but have differences that do not further the purposes of the rules. The proposed rule change would better align the issuer-directed provisions of Rules 5130 and 5131, provide regulatory consistency across the rules and remove the compliance costs of applying different standards, without negatively impacting the purposes of the rules.

Charitable organizations may not generate significant investment banking business. However, due to their asset size, some charitable organizations may fall within the definition of a “covered non-public company” under FINRA

<sup>51</sup> The exact number of family offices in the United States is not known; however, it is estimated that there are between 3,000 and 5,000 single family offices operating in the United States. See, e.g., Mary Pollack, Family Office Exchange, <https://www.familyoffice.com/insights/how-many-family-offices-are-there-united-states>.

<sup>52</sup> See U.S. Department of State, Fact Sheet, Bureau of Intelligence and Research, Independent States in the World, <https://www.state.gov/s/inr/rls/4250.htm>.

<sup>53</sup> See Sovereign Wealth Fund Institute, Sovereign Wealth Fund Rankings, <http://www.swfinstitute.org/sovereign-wealth-fund-rankings/>.

<sup>54</sup> See National Center for Charitable Statistics, <http://nccs.urban.org>.

Rule 5131, making executives or directors of such organizations the subject of the rule's prohibition. FINRA believes that the concerns addressed by the rule are not implicated with respect to executive officers or directors of charitable organizations that are not affiliated with a member. The proposed rule change, therefore, would exclude "unaffiliated charitable organizations," as currently defined in Rule 5131, from the definition of "covered non-public company." FINRA believes that this proposed change will ease the burden on firms as they will no longer be required to consider whether an investment banking relationship exists vis-à-vis the member and an unaffiliated charitable organization when an individual with a beneficial interest in an account is an executive officer or director (or materially supported by such a person) of such an organization. FINRA believes that the proposed rule change would provide benefits by reducing the uncertainty of whether a particular relationship is problematic and by reducing the time and costs associated with making that determination. The proposed rule change will also impact individuals who are executive officers or directors of unaffiliated charitable organizations (and those materially supported by such individuals) as they will no longer be subject to the rule's prohibitions on that basis. Finally, the proposed rule change will benefit issuers by increasing the pool of prospective investors, thus potentially leading to a lower cost of capital for the issuers.

Finally, the anti-dilution provision of FINRA Rule 5130 allows restricted persons to maintain the equity ownership interest they had before a public offering, but FINRA Rule 5131 has no similar provision. An unintentional result of this is that officers or directors of public companies and covered non-public companies may experience diminished ownership interest upon a public offering and a transfer of wealth from them to those investors that are able to purchase shares in the new offering. The proposed rule change would add an anti-dilution provision to Rule 5131 similar to that of Rule 5130 and ameliorate this inconsistency. This would reduce the regulatory uncertainty and create a level playing field for all investors.

#### 4. Alternatives Considered

FINRA considered various alternatives to the proposed rule change. When assessing foreign pension plans, FINRA considered whether to impose a requirement that the plan, or family of

plans, have a greater number of participants and beneficiaries than the proposed 10,000. However, the 10,000 participants and beneficiaries figure is appropriate, particularly when viewed along with the condition that the plan have at least \$10 billion in assets, and exceeds participant thresholds contained in other parts of the rule.<sup>55</sup>

With respect to the foreign investment company exemption, FINRA considered allowing foreign investment companies to establish dilution of the fund solely by satisfying the current five percent condition. However, allowing the foreign investment company to satisfy either the five percent condition, the 100 or more direct investor condition, or the 1,000 or more indirect investor condition, in addition to the other conditions, achieves the purpose of the rule while providing greater flexibility for foreign investment companies to meet the conditions of the exemption.

In assessing the appropriateness of an exclusion for charitable organizations from the definition of "covered non-public company" in Rule 5131(e)(3), FINRA considered whether to extend the exclusion to all nonprofit organizations, including, for example, civic leagues or social welfare entities organized pursuant to other sections of the IRC.<sup>56</sup> However, FINRA determined not to extend the definition in this manner and notes that, unlike Section 501(c)(3) organizations, such organizations are not prohibited from substantially engaging in other activities. In addition, limiting the exclusion to Section 501(c)(3) charitable organizations is consistent with the treatment of such entities in the context of other provisions of Rules 5130 and 5131.<sup>57</sup>

#### 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 on the proposed rule change. As noted above, in April 2017, FINRA published *Regulatory Notice 17-14* seeking comment on the effectiveness and efficiency of its rules

<sup>55</sup> See, e.g., Rule 5130(c)(3)(A) (exempting sales to and purchases of new issues by an insurance company general, separate or investment account, provided that, among other conditions, the account is funded by premiums from 1,000 or more policyholders).

<sup>56</sup> Civic leagues and social welfare organizations may be organized pursuant to Section 501(c)(4) of the IRC.

<sup>57</sup> See, e.g., Rule 5130(c)(9) (exempting Section 501(c)(3) tax exempt charitable organizations from Rule 5130); Rule 5131(e)(9) (defining unaffiliated charitable organization as a tax-exempt entity organized under Section 501(c)(3) of the IRC).

relating to the capital-raising process, including FINRA Rules 5130 and 5131 generally, and, in response, two commenters requested that FINRA consider certain amendments to Rules 5130 and 5131.<sup>58</sup>

In addition to comments received in response to *Regulatory Notice 17-14*, FINRA has experience with the rules since their adoption that has informed the proposed rule change. During that time, FINRA has generally engaged in discussions with industry groups and market participants regarding: (1) Persons with authority to buy or sell securities on behalf of accounts beneficially owned by family offices; (2) sovereign entities that own broker-dealers; (3) foreign employee retirement benefits plans; (4) executive officers and directors of unaffiliated charitable organizations; and (5) foreign investment companies whose shares are held in omnibus or nominee accounts. The proposed rule change also reflects FINRA's experience and years of informal discussions with market participants.

FINRA believes that the proposed rule change strikes the appropriate balance by promoting capital formation and aiding member compliance efforts while maintaining the protections that Rules 5130 and 5131 are designed to provide, as discussed above.

#### 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 (i) as the Commission may designate up to 90 days of such date 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:

<sup>58</sup> See *supra* notes 9 and 10.

*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](mailto:rule-comments@sec.gov). Please include File Number SR-FINRA-2019-022 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-2019-022. 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-2019-022 and should be submitted on or before August 29, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>59</sup>

**Jill M. Peterson,**

*Assistant Secretary.*

[FR Doc. 2019-16942 Filed 8-7-19; 8:45 am]

**BILLING CODE 8011-01-P**

**SECURITIES AND EXCHANGE COMMISSION****Sunshine Act Meetings**

**TIME AND DATE:** Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94-409, that the Commission will host the SEC Government-Business Forum on Small Business Capital Formation on Wednesday, August 14, 2019 beginning at 9:00 a.m. (CT).

**PLACE:** The forum will be held at Creighton University, Hixson-Lied Auditorium in the Mike and Josie Harper Center, 602 North 20th Street, Omaha, NE 68178. The panel discussions will be webcast on the Commission's website at [www.sec.gov](http://www.sec.gov).

**STATUS:** This meeting will be open to the public.

**MATTERS TO BE CONSIDERED:** The forum will include remarks by SEC Commissioners and panel discussions that Commissioners may attend. The panel discussions will explore capital formation in the Silicon Prairie area and the Commission's request for public comment on ways to harmonize private securities offering exemptions. This Sunshine Act notice is being issued because a majority of the Commission may attend the meeting.

**CONTACT PERSON FOR MORE INFORMATION:** For further information, please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551-5400.

Dated: August 6, 2019.

**Vanessa A. Countryman,**

*Secretary.*

[FR Doc. 2019-17120 Filed 8-6-19; 4:15 pm]

**BILLING CODE 8011-01-P**

**SECURITIES AND EXCHANGE COMMISSION**

[Release No. 34-86556; File No. SR-NSCC-2019-002]

**Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing of a Proposed Rule Change To Amend Procedure VII With Respect to the Receipt of CNS Securities and Make Other Changes**

August 2, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on July 22, 2019, National Securities Clearing Corporation ("NSCC") 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. 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 would amend Procedure VII of NSCC's Rules & Procedures ("Rules")<sup>3</sup> with respect to the receipt of securities from NSCC's Continuous Net Settlement ("CNS") System<sup>4</sup> and make technical changes, as described in greater detail 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

The purpose of this proposed rule change is to amend Procedure VII (CNS Accounting Operation) with respect to the receipt of securities from the CNS System in order to reflect a change in the allocation algorithm used during the night cycle.<sup>5</sup> The proposed rule change would also make technical changes.

(i) Background

NSCC's CNS System is an automated accounting and securities settlement system that centralizes and nets the settlement of compared and recorded securities transactions and maintains an orderly flow of security and money balances. The CNS System provides clearance for equities, corporate bonds,

<sup>3</sup> Capitalized terms not defined herein are defined in the Rules, available at [http://www.dtcc.com/-/media/Files/Downloads/legal/rules/nsccl\\_rules.pdf](http://www.dtcc.com/-/media/Files/Downloads/legal/rules/nsccl_rules.pdf).

<sup>4</sup> The CNS System and its operation are described in Rule 11 (CNS System) and Procedure VII (CNS Accounting Operation) of the Rules. *Id.*

<sup>5</sup> Night cycle is sometimes also referred to as "evening cycle" in the Rules. To ensure consistent terminology usage, NSCC is proposing technical changes to replace references to "evening cycle" with "night cycle" as described in greater detail below.

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>59</sup> 17 CFR 200.30-3(a)(12).

unit investment trusts, and municipal bonds that are eligible for book-entry transfer at The Depository Trust Company (“DTC”), an NSCC affiliate.

Under the CNS System, all eligible compared and recorded transactions for a particular settlement date are netted by CUSIP<sup>6</sup> number into one position per Member. The position can be net long (buy), net short (sell) or flat. As a continuous net system, those positions are further netted with positions of the same CUSIP number that remain open after their original scheduled settlement date (usually two business days after the trade date or T+2), so that transactions scheduled to settle on any day are netted with fail positions (*i.e.*, positions that have failed in delivery or receipt on the settlement date), which results in a single deliver or receive obligation for each Member for each CUSIP number in which the Member has activity.

CNS relies on an interface with DTC for the book-entry movement of securities. Procedure VII (CNS Accounting Operation) describes the receipt and delivery of CNS Securities. CNS short positions are compared against Members’ DTC accounts to determine availability of securities for delivery. If securities are available, they are transferred from the Member’s account at DTC to NSCC’s account at DTC to cover the Member’s short obligations to CNS. In contrast, the allocation of CNS long positions to receiving Members is processed in an order determined by an algorithm built into the system. CNS long positions are allocated to Members as the securities are received by NSCC, *i.e.*, CNS long positions are transferred from the NSCC account at DTC to the accounts of NSCC Members at DTC, in accordance with the algorithm.

For CNS Securities, NSCC uses a modified delivery versus payment mechanism in that when a Member delivers securities to CNS, the Member receives a credit, and when NSCC delivers securities to the long receiving Member (a long allocation), the securities deliveries/movements are not final until the “effective time” occurs pursuant to Rule 12 (Settlement).<sup>7</sup> Specifically, under the Rules, a CNS

delivery transaction is complete and final as to the delivering Member once the securities are debited from the delivering Member’s account at DTC and credited to NSCC’s CNS account at DTC; however, a CNS delivery transaction does not become final as to the receiving “long” Member until the “effective time.”

The current settlement processing cycle spans two business days, with a night cycle that begins at approximately 8:30 p.m. Eastern Time (“ET”) on the day prior to settlement date and runs until approximately 10 p.m. ET, and a day cycle that begins at approximately 6:30 a.m. ET on settlement date and runs until approximately 3:10 p.m. ET. The night cycle and the day cycle settlement processes are essentially the same, except that the night cycle settlement process runs in batches and the day cycle settlement process runs continuously. Transactions that do not get processed for settlement during the night cycle are carried into the following day cycle for settlement processing.

#### Current Allocation Algorithm

NSCC employs an algorithm to determine the order in which Members with long allocations receive positions from CNS; however, Members can submit priority requests that override NSCC’s algorithm when they have special needs to receive securities owed to them (*e.g.*, the security is undergoing a corporate action or the Member has an urgent customer delivery). The priority requests can be submitted for the night cycle, the day cycle, or both.

Pursuant to Procedure VII, subsection E (Influencing Receipts from CNS), Members can request that they receive priority for some or all issues on a standing or override basis. NSCC’s Rules also permit a Member to buy-in long positions that have not been delivered to it by the close of business on the scheduled settlement date. Submission of buy-in notices and other specified activity will also affect the priority of a Member’s long position.

The current priority groups are as follows—

First, long positions in a CNS Reorganization Sub-Account established pursuant to paragraph H.4 of Procedure VII of the Rules;<sup>8</sup>

Second, long positions against which Buy-In Intent<sup>9</sup> notices are due to expire

<sup>8</sup> *Supra* note 3.

<sup>9</sup> Section 7 of Rule 11 (CNS System) and subsection J of Procedure VII (CNS Accounting Operation) of the Rules provide that in the event a Member has a Long Position in a CNS Security, the Member may demand immediate delivery thereof by submitting to NSCC a Buy-In Intent notice in

that day but which were not filled the previous day;

Third, long positions against which Buy-In Intent<sup>10</sup> notices are due to expire the following day;

Fourth, (i) long positions in a receiving ID Net Subscriber’s agency account established at a Qualified Securities Depository,<sup>11</sup> and (ii) long positions against the component securities of index receipts;

Fifth, in descending sequence, priority levels as specified by Standing Priority Requests and as modified by Priority Overrides.

Currently, when more than one long position in a given CNS Security exists within the same priority group, the positions are allocated based on their age, *i.e.*, the “oldest” position is allocated first.<sup>12</sup> In addition, when more than one long position in a given CNS Security exists within the same priority group all of which have been long the same number of consecutive days (*i.e.*, within the same age group), the allocation rank is determined by a computer generated random number.

The allocation algorithm currently used for the night and day cycles is the same but is computed separately.

#### (ii) Proposed Changes to Allocation Algorithm

NSCC, together with DTC,<sup>13</sup> is looking to improve processing efficiency and maximize the number of securities transactions processed for settlement during the night cycle.

Currently, approximately 50 percent (50%) of the CNS transactions are processed for settlement during the night cycle. In order to improve processing efficiency and maximize the number of CNS transactions that would get processed for settlement during the night cycle, NSCC is proposing a modification to the allocation algorithm used during the night cycle. NSCC anticipates that the proposal would increase the percentage of CNS

such form and within such times as determined by NSCC. *Supra* note 3.

<sup>10</sup> *Id.*

<sup>11</sup> ID Net Service and its operation are described in Rule 65 (ID Net Service) and Procedure XVI (ID Net Service) of the Rules. *Supra* note 3.

<sup>12</sup> Age is defined in Procedure VII, subsection E, as the number of consecutive days during which the position has been long, irrespective of quantity. *Supra* note 3.

<sup>13</sup> On July 22, 2019, DTC submitted a proposed rule change to implement a new algorithm to optimize its settlement processing of transactions during the night cycle (“DTC settlement optimization algorithm”). The proposal is designed to maximize the number of transactions processed for settlement during the night cycle. See SR-DTC-2019-005, which was filed with the Commission. A copy of the proposed rule change is available at <http://www.dtcc.com/legal/sec-rule-filings.aspx>.

<sup>6</sup> CUSIP is a registered trademark of the American Bankers Association. The term “CUSIP number” refers to the Committee on Uniform Securities Identification Procedures identifying number.

<sup>7</sup> Pursuant to Rule 12 (Settlement), the “effective time” generally occurs when it is clear that NSCC has either been paid, or is in a credit position with respect to a Member or its Settling Bank, and NSCC has no obligation due with respect to a Member pursuant to the Clearing Agency Cross-Guaranty Agreement. Until the effective time has occurred in accordance with the Rules, NSCC retains ownership rights in the long allocations. *Supra* note 3.

transactions processed for settlement during the night cycle to approximately 65 percent (65%).

As described above, the current allocation sequence for day cycle and night cycle is as follows: priority groups, age of positions, and random number within an age group. Under the proposal, NSCC is proposing changes to the allocation algorithm so that age of positions and random number within an age group would no longer be considered as factors when allocating CNS long positions within the same priority group during the night cycle.<sup>14</sup> Instead, allocation of CNS long positions within the same priority group during the night cycle would be determined by the DTC settlement optimization algorithm.<sup>15</sup>

NSCC believes eliminating the age of positions and random number within an age group from being considered as factors when allocating CNS long positions within the same priority group during the night cycle would help maximize the number of transactions processed for settlement during the night cycle. Specifically, removing the requirement to process transactions for settlement during the night cycle in an order based on the age of positions and random number within an age group would help the DTC settlement optimization algorithm<sup>16</sup> perform more effectively in identifying the optimal order by which transactions are processed for settlement, which in turn would help maximize the number of transactions processed for settlement during the night cycle.

NSCC is not proposing changes to the allocation algorithm used during the day cycle.

#### (iii) Proposed Rule Changes

NSCC is proposing to add a clause to subsection C.4 of Procedure VII (CNS Accounting Operation) to make it clear that there would be differences in the allocation algorithm used for receipts from CNS between the day cycle and the night cycle processes. NSCC is also proposing to add a parenthetical regarding subsection E of Procedure VII for ease of reference.

In order to reflect the proposed elimination of random number within an age group as a factor when allocating CNS long positions within the same priority group during the night cycle, NSCC is proposing to modify the first

paragraph of subsection E of Procedure VII by deleting the references to an algorithm which changes daily.

NSCC is also proposing to revise subsection E.4 of Procedure VII to reflect the proposed changes to the allocation algorithm used during the night cycle by adding (i) “and, for the day cycle only,” to the first paragraph in subsection E.4 and (ii) “For the day cycle only,” to the third and fourth paragraphs of subsection E.4. These changes are being proposed in order to make it clear that age of positions and random number within an age group would only be considered as factors when allocating CNS long positions during the day cycle.

In addition, NSCC is proposing to modify the last paragraph of subsection E.4 of Procedure VII to make it clear that the allocation algorithm used for the night and day cycles is computed separately to allow for the use of different allocation factors in those respective cycles.

NSCC is proposing technical changes by replacing references to “evening cycle” with “night cycle” in subsections A, C.3, E.1, E.2, E.4, E.5, and H.5 of Procedure VII. Similarly, NSCC is proposing to replace references to (i) “evening allocation” with “night allocation” in subsections C.3, C.4, and J.1 of Procedure VII, (ii) “evening and day delivery cycles” with “night and day delivery cycles” in subsection E.4 of Procedure VII and (iii) “evening allocation cycle” with “night cycle” in Section I of Addendum G. These changes are being proposed to ensure consistency in terminology usage in the Rules. NSCC is also proposing technical changes to correct cross references in subsections E.3 and E.4(a) of Procedure VII.

#### (iv) Member Outreach

Beginning in March 2018, NSCC has conducted ongoing outreach with Members in order to provide them with notice of the proposed changes. As of the date of this filing, no written comments relating to the proposed changes have been received in response to this outreach. The Commission will be notified of any written comments received.

#### (v) Implementation Timeframe

Pending Commission approval, NSCC expects to implement this proposal by September 26, 2019 and would announce the effective date of the proposed change by an Important Notice posted to its website. As proposed, a legend would be added to Procedure VII and Addendum G stating there are changes that have been approved by the

Commission but have not yet been implemented. Each proposed legend also would include a date by which such changes would be implemented and the file number of this proposal, and state that, once this proposal is implemented, the legend would automatically be removed from Procedure VII and Addendum G, as applicable.

#### 2. Statutory Basis

NSCC believes this proposal is consistent with the requirements of the Act, and the rules and regulations thereunder applicable to a registered clearing agency. Specifically, NSCC believes this proposal is consistent with Section 17A(b)(3)(F)<sup>17</sup> of the Act for the reasons described below.

Section 17A(b)(3)(F) of the Act requires, in part, that the Rules be designed to promote the prompt and accurate clearance and settlement of securities transactions.<sup>18</sup> NSCC believes that the proposed changes to the allocation algorithm used during the night cycle would promote prompt and accurate clearance and settlement of securities transactions. This is because the proposed changes would remove the requirement to process transactions for settlement during the night cycle in an order based on the age of positions and random number within an age group. Eliminating the requirement to process transactions in an order based on the age of positions and random number within an age group would help enhance the effectiveness of the DTC settlement optimization algorithm in identifying the optimal order to process transactions for settlement. Being able to effectively identify the optimal order to process transactions for settlement would help maximize the number of transactions processed for settlement during the night cycle. Therefore, NSCC believes that the proposed changes to the allocation algorithm used during the night cycle would promote the prompt and accurate clearance and settlement of securities transactions, consistent with Section 17A(b)(3)(F) of the Act.

NSCC also believes that the proposal to make technical changes would promote prompt and accurate clearance and settlement of securities transactions. This is because the proposed technical changes would help ensure consistency in terminology usage and correct cross references in the Rules, both of which would ensure the Rules are clear and accurate. Having clear and accurate Rules would help Members to better understand their

<sup>14</sup> Based on data from January through April 2019, aged positions (*i.e.*, positions that have failed in delivery or receipt on their respective scheduled settlement dates for one or more days) comprised approximately 0.21 percent of the value of all transactions received before netting.

<sup>15</sup> *Supra* note 13.

<sup>16</sup> *Id.*

<sup>17</sup> 15 U.S.C. 78q-1(b)(3)(F).

<sup>18</sup> *Id.*

rights and obligations regarding NSCC's clearance and settlement services. NSCC believes that when Members better understand their rights and obligations regarding NSCC's clearance and settlement services, they can act in accordance with the Rules. NSCC believes that better enabling Members to comply with the Rules would promote the prompt and accurate clearance and settlement of securities transactions by NSCC. As such, NSCC believes the proposal to make technical changes is consistent with Section 17A(b)(3)(F) of the Act.<sup>19</sup>

*(B) Clearing Agency's Statement on Burden on Competition*

NSCC believes the proposed changes to the allocation algorithm used during the night cycle could burden competition. This is because by eliminating the age of positions and random number within an age group from being considered as factors when allocating CNS long positions during the night cycle, Members with the oldest positions would no longer receive priority during the night cycle. While Members with aged positions would no longer be prioritized over other Members within the same priority group, NSCC does not believe such change in priority would in and of itself mean that the burden on competition is significant. This is because, as described above, aged positions only comprised approximately 0.21 percent of the value of all transactions received before netting. Accordingly, NSCC does not believe the burden on competition would be significant.

Regardless of whether the burden on competition is deemed significant, NSCC believes any burden on competition that is created by these proposed changes would be necessary and appropriate in furtherance of the purposes of the Act, as permitted by Section 17A(b)(3)(I) of the Act.<sup>20</sup>

The proposed changes to the allocation algorithm used during the night cycle would be necessary in furtherance of the purposes of the Act because the Rules must be designed to promote the prompt and accurate clearance and settlement of securities transactions.<sup>21</sup> As described above, NSCC believes that the proposed changes would promote the prompt and accurate clearance and settlement of securities transactions by maximizing the number of transactions processed for settlement during the night cycle. As such, NSCC believes these proposed

changes would be necessary in furtherance of the purposes of the Act, as permitted by Section 17A(b)(3)(I) of the Act.<sup>22</sup>

NSCC believes any burden on competition that is created by the proposed changes to the allocation algorithm used during the night cycle would also be appropriate in furtherance of the purposes of the Act. The proposed changes would eliminate the age of positions and random number within an age group from being considered as factors when allocating CNS long positions within the same priority group during the night cycle, which would in turn enhance the effectiveness of the DTC settlement optimization algorithm in identifying the optimal order by which to process transactions for settlement during the night cycle. Being able to effectively identify the optimal order by which to process transactions for settlement during the night cycle would in turn help maximize the number of transactions processed for settlement during the night cycle. As such, NSCC believes these proposed changes would be appropriate in furtherance of the purposes of the Act, as permitted by Section 17A(b)(3)(I) of the Act.<sup>23</sup>

NSCC does not believe the proposal to make technical changes would impact competition. These changes are being proposed to ensure consistency in terminology usage in the Rules and to correct cross references. They would not change NSCC's current practices or affect Members' rights and obligations. As such, NSCC believes the proposal to make technical changes would not have any impact on competition.

*(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

Written comments relating to this proposed rule change have not been solicited or received. NSCC will notify the Commission of any written comments received by NSCC.

**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](mailto:rule-comments@sec.gov). Please include File Number SR-NSCC-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-NSCC-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 NSCC 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-NSCC-

<sup>19</sup> *Id.*

<sup>20</sup> 15 U.S.C. 78q-1(b)(3)(I).

<sup>21</sup> 15 U.S.C. 78q-1(b)(3)(F).

<sup>22</sup> 15 U.S.C. 78q-1(b)(3)(I).

<sup>23</sup> *Id.*

2019-002 and should be submitted on or before August 29, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>24</sup>

**Jill M. Peterson,**

*Assistant Secretary.*

[FR Doc. 2019-16940 Filed 8-7-19; 8:45 am]

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## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-86553; File No. SR-FICC-2019-003]

### Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing of Proposed Rule Change To Revise the MBS VaR Floor

August 2, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”)<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on July 18, 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. 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 a proposal to change the calculation of the VaR Floor (as defined below) and the corresponding description in the FICC Mortgage-Backed Securities Division (“MBS”) Clearing Rules (“MBS Rules”)<sup>3</sup> to: (i) Allow FICC, subject to the governance process set forth in the Clearing Agency Model Risk Management Framework (“Framework”)<sup>4</sup> (as described below),

to adjust the “VaR Floor percentage” (as defined below) within a proposed range when FICC’s review of the VaR Floor percentage indicates that the VaR Floor percentage is not sufficient to cover FICC’s credit exposure to each Clearing Member fully with a high degree of confidence, (ii) state that Clearing Members would be notified in advance of any such adjustment to the VaR Floor percentage, (iii) designate that the VaR Floor percentage would be subject to at least monthly model performance monitoring, and (iv) make certain technical changes.

The proposed changes would necessitate changes to the Methodology and Model Operations Document—MBS Quantitative Risk Model (the “QRM Methodology”).<sup>5</sup> FICC is requesting confidential treatment of the QRM Methodology and has filed it separately with the Secretary of the Commission.<sup>6</sup>

#### 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

The purpose of the proposed rule change is to change the calculation of the VaR Floor (as defined below) and the corresponding description in the MBS Rules to: (i) Allow FICC, subject to the governance process set forth in the Framework (as described below), to

procedures; (v) model approval process; and (vi) model performance procedures.

<sup>5</sup> Because FICC requested confidential treatment, the QRM Methodology was filed separately with the Commission as part of proposed rule change SR-FICC-2016-007 (the “VaR Filing”). See Securities Exchange Act Release No. 79868 (January 24, 2017), 82 FR 8780 (January 30, 2017) (SR-FICC-2016-007) (“VaR Filing Approval Order”). FICC also filed the VaR Filing proposal as an advance notice pursuant to Section 806(e)(1) of the Payment, Clearing, and Settlement Supervision Act of 2010 (12 U.S.C. 5465(e)(1)) and Rule 19b-4(n)(1)(i) under the Act (17 CFR 240.19b-4(n)(1)(i)), with respect to which the Commission issued a Notice of No Objection. See Securities Exchange Act Release No. 79843 (January 19, 2017), 82 FR 8555 (January 26, 2017) (SR-FICC-2016-801).

<sup>6</sup> 17 CFR 240.24b-2.

adjust the VaR Floor percentage (as defined below) within a proposed range when FICC’s review of the VaR Floor percentage indicates that the VaR Floor percentage is not sufficient to cover FICC’s credit exposure to each Clearing Member fully with a high degree of confidence, (ii) state that Clearing Members would be notified in advance of any such adjustment to the VaR Floor percentage, (iii) designate that the VaR Floor percentage would be subject to at least monthly model performance monitoring, and (iv) make certain technical changes. The proposed changes would necessitate changes to the QRM Methodology. The proposed changes are described in detail below.

#### Background

On January 24, 2017, the Commission approved FICC’s VaR Filing to make certain enhancements to the MBS value-at-risk (“VaR”) margin calculation methodology.<sup>7</sup> The VaR Filing amended the definition of VaR Charge to include the VaR Floor.<sup>8</sup> The VaR Charge comprises the largest portion of a Clearing Member’s Required Fund Deposit amount. The VaR Charge is calculated using a risk-based margin methodology that is intended to capture the market price risk associated with the securities in a Clearing Member’s portfolio. The methodology is designed to project the potential gains or losses that could occur in connection with the liquidation of a defaulting Clearing Member’s portfolio, assuming that a portfolio would take three days to hedge or liquidate in normal market conditions. The projected liquidation gains or losses are used to determine the amount of the VaR Charge, which is calculated to cover projected liquidation losses at a 99 percent confidence level.<sup>9</sup>

FICC uses the VaR Floor as an alternative to the VaR Charge amount calculated by the VaR model for Clearing Members’ portfolios where the VaR Floor calculation is greater than the model-based calculation. The VaR Floor addresses the risk that the VaR model may calculate too low a VaR Charge for certain portfolios where the VaR model applies substantial risk offsets among long and short positions in different classes of mortgage-backed securities that have a high degree of historical price correlation. FICC applies the VaR

<sup>7</sup> See VaR Filing Approval Order, *supra* note 5.

<sup>8</sup> The term “VaR Floor” is defined within the definition of VaR Charge. See MBS Rule 1, *supra* note 3.

<sup>9</sup> Unregistered Investment Pool Clearing Members are subject to a VaR Charge with a minimum targeted confidence level assumption of 99.5 percent. See MBS Rule 4, Section 2(c), *supra* note 3.

<sup>24</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> Capitalized terms not defined herein are defined in the MBS Rules, available at <http://www.dtcc.com/legal/rules-and-procedures>.

<sup>4</sup> See Securities Exchange Act Release No. 81485 (August 25, 2017), 82 FR 41433 (August 31, 2017) (SR-DTC-2017-008; SR-FICC-2017-014; SR-NSCC-2017-008). The Framework sets forth the model risk management practices adopted by FICC, National Securities Clearing Corporation, and The Depository Trust Company. The Framework is designed to help identify, measure, monitor, and manage the risks associated with the design, development, implementation, use, and validation of quantitative models. The Framework describes: (i) Governance of the Framework; (ii) key terms; (iii) model inventory procedures; (iv) model validation

Floor at the Clearing Member portfolio level. Because the historical price correlation may not persist in future market conditions,<sup>10</sup> FICC believes that it is prudent to apply a VaR Floor that is based upon the market value of the gross unsettled positions in the Clearing Member's portfolio in order to protect FICC against such risk in the event that FICC is required to liquidate a mortgage-backed securities portfolio in stressed market conditions.

(i) Proposed Rule Changes Allowing FICC To Adjust the VaR Floor Percentage

The MBS Rules currently define the VaR Floor as "5 basis points of the market value of a Clearing Member's gross unsettled positions."<sup>11</sup> Therefore, the VaR Floor is utilized as the Clearing Member's VaR Charge if the VaR model yields an amount that is lower than 5 basis points (referred to herein as the "VaR Floor percentage") of the market value of a Clearing Member's gross unsettled positions.

FICC is proposing to revise the definition of the VaR Floor to allow FICC, subject to the governance process set forth in the Framework, to adjust the VaR Floor percentage within a proposed range when FICC's review of the VaR Floor percentage indicates that the VaR Floor percentage is not sufficient to cover FICC's credit exposure to each Clearing Member fully with a high degree of confidence. FICC is proposing that the VaR Floor percentage would be no less than 5 basis points and no more than 30 basis points of the gross unsettled positions.

FICC believes that the range of 5 to 30 basis points would allow FICC to effectively set a floor on the VaR Charge at a level that has historically impacted only a small number of Clearing Members based on the impact study discussed below.<sup>12</sup> In order to

<sup>10</sup> For example, certain TBAs may have highly correlated historical price returns despite having different coupons and, although the net risk exposure may be adequately modeled under current market conditions, future market conditions could cause the risk relationship to change in a way that may not be adequately captured by the model. TBA is defined in MBS Rule 1. See MBS Rule 1, *supra* note 3.

<sup>11</sup> See definition of "VaR Charge." See MBS Rule 1, *supra* note 3.

<sup>12</sup> For the period February 27, 2017 through February 28, 2019, a 5 basis point VaR Floor would impact less than 0.4% of Clearing Members on average daily who have a VaR Charge, a 10 basis point VaR Floor would impact less than 2.3%, a 15 basis point VaR Floor would impact less than 5.0%, a 20 basis point VaR Floor would impact less than 8.2%, a 25 basis point VaR Floor would impact less than 11.4%, a 30 basis point VaR Floor would impact less than 14.4%, a 45 basis point VaR Floor would impact less than 22.3%, and a 60 basis point VaR Floor would impact less than 30.6%.

determine the specific VaR Floor percentage within the permissible range, FICC would review, on at least an annual basis, the impact of alternative VaR Floor parameters within the proposed range of 5 to 30 basis points to the backtesting performance and to Clearing Members' margin charges. Upon approval of this filing, FICC proposes to initially set the VaR Floor at 10 basis points based on observed backtesting coverage on actual Clearing Members' positions and hypothetical portfolios<sup>13</sup> that could result in low VaR Charges.<sup>14</sup>

As stated above, any adjustment to the VaR Floor percentage would be subject to the governance process set forth in the Framework. Specifically, the Framework provides that all model performance concerns will be escalated by the Model Validation and Control Group ("MVC") to the Model Risk Governance Committee ("MRGC"), including model performance enhancement concerns and the MRGC may further recommend certain matters for further escalation to the Management Risk Committee and/or Risk Committee of the Board.

(ii) Proposed Clearing Member Notifications Regarding Adjustments to the VaR Floor Percentage

For adjustments to the VaR Floor percentage that would fall within the proposed range, FICC would provide Clearing Members with 10 Business Days' notice prior to the implementation of such adjustment. Clearing Members would be notified of the applicable VaR Floor percentage by an Important Notice issued no later than 10 Business Days prior to the implementation of the adjustment. For adjustments that would fall outside of the proposed range, FICC would submit a rule filing to the Commission. As proposed, FICC would not apply a VaR Floor percentage that is less than 5 basis points (which is the current VaR Floor percentage); however, the proposed change would allow FICC to adjust such VaR Floor percentage above 5 basis points (up to 30 basis points).

<sup>13</sup> For example, FICC can create hypothetical settlement portfolios with long/short positions where the net market value is zero to identify potential settlement portfolios where historical price changes of different classes of mortgage-backed securities did not experience offsetting price moves (commonly referred to as "basis risk").

<sup>14</sup> FICC's coverage at the Clearing Agency level is at 99%. The issue has arisen with respect to certain Clearing Members whose portfolios are achieving below 99% coverage on a 12-month rolling basis.

(iii) Proposed Rule Changes To Designate that the VaR Floor Percentage Would Be Subject to at Least Monthly Model Performance Monitoring

The Framework provides that, as part of model performance monitoring, on at least a monthly basis, sensitivity analysis is performed on FICC's margin model, the key parameters and assumptions for backtesting are reviewed, and modifications are considered to ensure FICC's backtesting practices are appropriate for determining the adequacy of the applicable margin resources of FICC. The Framework also describes that MVC performs a model validation for each FICC model approved for use in production not less than annually, including, among other things, on its margin systems and related models.<sup>15</sup>

The VaR Floor percentage is currently subject to periodic model validations as part of FICC's margin model validation on at least an annual basis to determine if the VaR Floor percentage would remain adequate to cover FICC's credit exposure to Clearing Members with certain types of portfolios fully with a high degree of confidence. FICC would propose, as part of model performance monitoring, to designate the VaR Floor percentage as a parameter of its VaR model that will be reviewed on at least a monthly basis per the Framework. As such, FICC proposes to amend the QRM Methodology to reference the at least monthly model performance monitoring of the VaR Floor percentage.

(iv) Proposed Technical Changes

The proposed rule change would also make technical changes to restate the calculation of the VaR Floor to provide more detail than the current provision and to use defined terms (that is, the terms Long Positions<sup>16</sup> and Short Positions<sup>17</sup>).

Specifically, FICC would (i) delete "5 basis points of the market value of a Clearing Member's gross unsettled positions" and replace it with "an amount designated by the Corporation" and (ii) add a new sentence that would read: "Such VaR Floor will be determined by multiplying the sum of the absolute values of Long Positions and Short Positions, at market value, by

<sup>15</sup> *Supra* note 4.

<sup>16</sup> The term "Long Position" means a Member's obligations with respect to the purchase of an Eligible Security or an Option Contract, as determined pursuant to the MBS Rules. MBS Rule 1, *supra* note 3.

<sup>17</sup> The term "Short Position" means a Member's obligation with respect to the sale of an Eligible Security or an Option Contract, as determined pursuant to the MBS Rules. MBS Rule 1, *supra* note 3.

a percentage designated by the Corporation that is no less than 0.05% and no greater than 0.30%. The Corporation shall determine the percentage within this range to be applied based on factors including but not limited to a review performed at least annually of the impact of the VaR Floor parameter at different levels within the range to the backtesting performance and to Clearing Members' margin charges. The Corporation shall inform Clearing Members of the applicable percentage utilized by the VaR Floor by an Important Notice issued no later than 10 Business Days prior to the implementation of such percentage."

In addition, FICC proposes a technical change to the QRM Methodology to reference that there will be at least annual model validation of the VaR Floor percentage; the QRM methodology currently provides that the VaR Floor percentage is reviewed annually and updated.

#### (v) Review and Need for VaR Floor Percentage Adjustment

FICC conducted a review of the VaR Floor percentage in June 2017 and conducted impact studies beginning in February 2017, which found that an increase in the VaR Floor percentage to 10 basis points is necessary to bring the VaR Charge to a level that would cover FICC's credit exposure to certain Clearing Members that have long-short portfolios fully with a high degree of confidence.<sup>18</sup> The review, performed in June 2017, found that portfolios that contained long-short positions, for example, where a portfolio was long the GNMA II/FNMA basis at a higher coupon and short the GNMA II/FNMA basis at a lower coupon, were not adequately covered by a VaR Floor percentage of 5 basis points during periods of market volatility. Increasing the VaR Floor percentage to 10 basis points would improve the backtesting coverage of this group to 99.8%. As a result, FICC began monitoring all portfolios with a VaR Charge below 10 basis points of the portfolio's gross positions for a potential Intraday Mark-to-Market Charge to ensure sufficient margin coverage during periods of market volatility. Although a recent impact study for the twelve months ended February 2019 found the backtesting coverage of the VaR Charge for certain Clearing Members with long-short portfolios had improved to the 99% confidence level without the change to the VaR Floor percentage,

<sup>18</sup> These are portfolios that net down to a low VaR Charge amount but represent large gross positions.

FICC believes it is prudent to make the change to ensure the VaR Charge remains adequate if market conditions change. The June 2017 review of the VaR Floor percentage that included a period of market volatility also found that an increase in the VaR Floor percentage to 20 basis points if the alternative volatility calculation (which was referred to as the "Margin Proxy" in the VaR Filing<sup>19</sup>) is applied would better cover risks of portfolios with offsetting long and short positions within the same agency program, given that the Margin Proxy allows for further netting among positions within the same agency program than would occur within the VaR model.<sup>20</sup> The recent impact study for the twelve months ended February 2019 found if the VaR Floor percentage were increased to 20 basis points, the backtesting coverage of the Margin Proxy<sup>21</sup> would improve to 99% for eleven of the fourteen portfolios that would otherwise have been below the 99% confidence level target. Additionally, the backtesting deficiencies of the three small portfolios that would have remained below the 99% confidence target would be reduced to an average 11 backtesting deficiencies if the VaR Floor percentage were increased to 20 basis points, from an average 45 backtesting deficiencies utilizing the current VaR Floor percentage of 5 basis points. If Margin Proxy were invoked as an alternative volatility calculation, FICC would utilize the Backtesting Charge<sup>22</sup> to further mitigate exposure to FICC caused by settlement risks that may not be adequately captured by the alternative volatility model. Upon Commission approval of this proposed rule change, FICC would provide Clearing Members with 10 Business Days' notice of the increase of the VaR Floor percentage to 10 basis points. The notice would also inform Clearing Members that in the event that the alternative volatility calculation (the Margin Proxy) would be employed, the

<sup>19</sup> The Margin Proxy is used as an alternative volatility calculation in the event that the requisite data used for the methodology (*i.e.*, sensitivity approach) that is used to calculate the VaR Charge is unavailable for an extended period of time. See VaR Filing Approval Order, 82 FR at 8781.

<sup>20</sup> FICC proposed and received Commission approval to increase the look-back period and apply a historical stressed period to the Margin Proxy calibration. See Securities Exchange Act Release No. 85944 (May 24, 2019), 84 FR 25315 (May 31, 2019) (SR-FICC-2019-001).

<sup>21</sup> The Margin Proxy study was calibrated using a 10-year historical look-back period plus 1-year stress period.

<sup>22</sup> See definition of "Backtesting Charge." See MBSD Rule 1, *supra* note 3.

VaR Floor percentage would be increased to 20 basis points.

#### (vi) Impact Study

FICC performed an impact study on Clearing Members' portfolios for the period beginning February 27, 2017, when the changes in the VaR Filing were implemented, to February 28, 2019, that showed increasing the VaR Floor percentage to 10 basis points would impact a small number of Clearing Members, and the total MBSD Clearing Fund impact would be small. Nevertheless, FICC believes this change is necessary to maintain sufficient financial resources to cover FICC's credit exposures to certain Clearing Members' portfolios fully with a high degree of confidence.

Over the study period, increasing the VaR Floor percentage to 10 basis points would have affected, on average, two portfolios per day, and the average daily margin increase to MBSD's Clearing Fund would have been approximately \$6 million per day (0.12% of the average daily VaR Charge of \$5 billion). The largest daily increase for the total VaR Charge over the study period would have been \$37 million for all Clearing Members, 1% of the total VaR Charge of \$ 3.7 billion on that day.

Although for the twelve months ended February 28, 2019, 21 portfolios would have been impacted by the increase to the VaR Floor percentage over the study period, for each portfolio the increase was less than 1% of the Clearing Member's Excess Capital<sup>23</sup> and 4 portfolios accounted for over 50% of the instances of margin increase. The impact study showed the largest daily increase of an individual portfolio was \$25.5 million. Given the VaR model amount for this portfolio was also below the current 5 basis point VaR Floor, an increase to a 10 basis point VaR Floor would have doubled that portfolio's VaR Charge for that day.

#### 2. Statutory Basis

FICC believes that this proposal is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a registered clearing agency. Specifically, FICC believes that this proposal is consistent with Section 17A(b)(3)(F) of the Act<sup>24</sup> and Rules 17Ad-22(e)(4)(i), (e)(6)(i) and

<sup>23</sup> The term "Excess Capital" means Excess Net Capital, net assets, or equity capital as applicable to a Clearing Member based on its type of regulation. MBSD Rule 1, *supra* note 3.

<sup>24</sup> 15 U.S.C. 78q-1(b)(3)(F).

(e)(23)(ii), each promulgated under the Act,<sup>25</sup> for the reasons described below.

Section 17A(b)(3)(F) of the Act requires, in part, that the MBS Rules be designed to (i) promote the prompt and accurate clearance and settlement of securities transactions and (ii) assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible.<sup>26</sup>

The proposed changes described in Item II(A)1(i) above would allow FICC, subject to the governance process in the Framework, to adjust the VaR Floor percentage within a proposed range when FICC's review of the VaR Floor percentage indicates that the VaR Floor percentage is not sufficient to cover FICC's credit exposure to each Clearing Member fully with a high degree of confidence. FICC believes these proposed changes would assure the safeguarding of securities and funds which are in the custody or control of FICC or for which it is responsible. Specifically, the proposed changes would provide FICC with discretion to adjust the VaR Floor percentage, subject to governance, to cover FICC's credit exposure to each Clearing Member with a high degree of confidence. Covering FICC's exposure to each Clearing Member with a high degree of confidence would help FICC ensure that it maintains an appropriate level of margin to address its risk management needs. Therefore, FICC believes the proposed changes described in Item II(A)1(i) above would safeguard the securities and funds that are in the custody and control of FICC or for which it is responsible, consistent with Section 17A(b)(3)(F) of the Act.<sup>27</sup>

FICC believes that the proposed changes described in Item II(A)1(ii) above to state that Clearing Members would be notified in advance of any adjustment to the VaR Floor percentage would promote the prompt and accurate clearance and settlement of securities transactions. Specifically, FICC believes that providing notice in advance of the implementation of any adjustment would provide Clearing Members with time to adjust to any new VaR Charge amounts that result from any adjustments to the VaR Floor percentage. FICC believes 10 Business Days' prior notice would provide Clearing Members with sufficient time to prepare for any new VaR Charge amounts and thereby ensure that the Clearing Members have the funds to

satisfy their new VaR Charge amounts. This in turn would help FICC ensure that FICC has an adequate margin to address its risk management needs. Therefore, FICC believes the proposed changes described in Item II(A)1(ii) above would promote the prompt and accurate clearance and settlement of securities transactions, consistent with Section 17A(b)(3)(F) of the Act.<sup>28</sup>

In addition, FICC believes that the proposed changes described in Item II(A)1(iii) above to the QRM Methodology to state that the VaR Floor percentage would be subject to at least monthly performance monitoring would assure the safeguarding of securities and funds which are in the custody and control of FICC or for which it is responsible, consistent with Section 17A(b)(3)(F) of the Act.<sup>29</sup> Specifically, this would require FICC to monitor the VaR Floor percentage frequently. This would help FICC ensure that there is an appropriate level of margin as FICC would be monitoring the VaR Floor percentage at least monthly. This change would also alert FICC of the need to make any adjustments to the VaR Floor percentage. As such, FICC believes the proposed changes described in Item II(A)1(iii) above would safeguard the securities and funds that are in the custody and control of FICC or for which it is responsible, consistent with Section 17A(b)(3)(F) of the Act.<sup>30</sup>

FICC believes that the proposed technical changes to the MBS Rules described in Item II(A)1(iv) above would promote the prompt and accurate clearance and settlement of securities transactions by ensuring that the MBS Rules remain clear and accurate to Clearing Members. Having clear and accurate MBS Rules would facilitate Clearing Members' understanding of those rules and provide Clearing Members with increased predictability and certainty regarding their obligations. FICC also believes that proposed technical changes to the QRM Methodology described in Item II(A)1(iv) above would enhance the clarity of the QRM Methodology for FICC. As the QRM Methodology is used by FICC Risk Management personnel regarding the frequency of model validation of the VaR Floor percentage, FICC believes that enhancing clarity of the description as to how often this review should be conducted would promote the prompt and accurate clearance and settlement of securities

transactions, consistent with Section 17A(b)(3)(F) of the Act.<sup>31</sup>

Rule 17Ad-22(e)(4)(i) under the Act<sup>32</sup> requires a covered clearing agency to establish, implement, maintain and enforce written policies and procedures reasonably designed to effectively identify, measure, monitor, and manage its credit exposures to participants and those exposures arising from its payment, clearing, and settlement processes by maintaining sufficient financial resources to cover its credit exposure to each participant fully with a high degree of confidence. The proposed changes described in Item II(A)1(i) would allow adjustment of the VaR Floor percentage (subject to FICC's governance). This change would allow FICC to limit its credit exposures to Clearing Members in the event that the VaR model yields too low a VaR Charge for such portfolios. Under the proposed rule changes, the VaR Floor percentage would be subject to at least monthly model performance monitoring and continue to be subject to at least annual model validations by FICC. In the event the review reveals that the VaR Floor percentage is not resulting in coverage with a high degree of confidence, FICC would adjust the VaR Floor percentage within the proposed range after going through its required governance (and providing Clearing Members with the 10 Business Days' notice as described above). Therefore, FICC believes the proposed changes are consistent with the requirements of Rule 17Ad-22(e)(4)(i) under the Act.<sup>33</sup>

Rule 17Ad-22(e)(6)(i) under the Act<sup>34</sup> requires a covered clearing agency to establish, implement, maintain and enforce written policies and procedures reasonably designed to cover, if the covered clearing agency provides central counterparty services, its credit exposures to its participants by establishing a risk-based margin system that, at a minimum, considers, and produces margin levels commensurate with, the risks and particular attributes of each relevant product, portfolio, and market. FICC, which provides central counterparty services, believes that the proposed changes to allow FICC, subject to its governance, to adjust the VaR Floor percentage within a proposed range (as described in Item II(A)1(i) above) are consistent with the requirements of Rule 17Ad-22(e)(6)(i) cited above. Specifically, FICC believes the proposed changes would provide FICC with the discretion (subject to its

<sup>25</sup> 17 CFR 240.17Ad-22(e)(4)(i), (e)(6)(i) and (e)(23)(ii).

<sup>26</sup> 15 U.S.C. 78q-1(b)(3)(F).

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> 17 CFR 240.17Ad-22(e)(4)(i).

<sup>33</sup> *Id.*

<sup>34</sup> 17 CFR 240.17Ad-22(e)(6)(i).

governance) to appropriately limit FICC's credit exposure to Clearing Members in the event that the VaR model yields too low a VaR Charge. The proposed changes would therefore allow FICC to continue to produce margin levels commensurate with the risks and particular attributes of each relevant product, portfolio, and market. As such, FICC believes that the proposed changes are consistent with the requirements of Rule 17Ad-22(e)(6)(i) under the Act.<sup>35</sup>

The proposed technical changes to the MBS Rules described in Item II(A)1(iv) above are designed to be consistent with Rule 17Ad-22(e)(23)(ii) under the Act.<sup>36</sup> Rule 17Ad-22(e)(23)(ii) under the Act requires a covered clearing agency to establish, implement, maintain and enforce written policies and procedures reasonably designed to provide sufficient information to enable participants to identify and evaluate the risks, fees, and other material costs they incur by participating in the covered clearing agency.<sup>37</sup> The proposed technical changes to the MBS Rules would provide more details as to how the VaR Floor is calculated than is currently set forth in the MBS Rules. As such, FICC believes the proposed changes would enable Clearing Members to have a better understanding of the operation of the VaR Floor because there would be more clarity as to how the VaR Floor to which they are subject is calculated. FICC believes the additional details would provide Clearing Members with sufficient information to enable them to evaluate the costs they incur by participating in FICC. As such, FICC believes that the proposed technical changes to the MBS Rules described in Item II(A)1(iv) above are consistent with Rule 17Ad-22(e)(23)(ii) under the Act.<sup>38</sup>

#### *(B) Clearing Agency's Statement on Burden on Competition*

FICC believes the proposed rule changes described in Item II(A)1(i) above to allow FICC, subject to its governance, to adjust the VaR Floor percentage within a proposed range in the circumstances described above could both promote competition and could impose a burden on competition. In circumstances where FICC exercises its authority to decrease the VaR Floor percentage within the proposed range, Clearing Members would experience decreases in their VaR Charge. FICC believes this may promote competition because Clearing Members would have

a lower VaR Charge, and therefore could use their funds for other purposes.

However, FICC also believes that the proposed changes described in Item II(A)1(i) above could impose a burden on competition. Specifically, in circumstances where FICC exercises its authority to increase the VaR Floor percentage within the proposed range, Clearing Members who are affected by the VaR Floor would experience increases in their VaR Charge. Such increases could burden Clearing Members that have lower operating margins or higher costs of capital than other Clearing Members. It is not clear whether the burden on competition would necessarily be significant because it would depend on whether the affected Clearing Members were similarly situated in terms of business type and size. Regardless of whether the burden on competition is significant, FICC believes that any burden on competition that derives from the proposed rule changes described in Item II(A)1(i) above would be necessary and appropriate in furtherance of the purposes of the Act.<sup>39</sup>

Specifically, FICC believes that the proposed rule changes described in Item II(A)1(i) above would be necessary in furtherance of the purposes of the Act because they would allow FICC to make adjustments to the VaR Floor percentage within a proposed range when FICC's review of the VaR Floor percentage indicates that the VaR Floor percentage is not sufficient to cover FICC's credit exposure to each Clearing Member with a high degree of confidence. The proposed rule changes would provide FICC with the discretion (subject to its governance) to limit its exposure to Clearing Members by ensuring that each Clearing Member has an appropriate minimum VaR Charge in the event that the VaR model yields too low a VaR Charge for such portfolios. Maintaining an appropriate minimum VaR Charge for each Clearing Member would be necessary in furtherance of the Act because it would allow FICC to maintain sufficient financial resources to cover its credit exposure to each Clearing Member. FICC also believes that any burden on competition that derives from the proposed rule change would be appropriate in furtherance of the purposes of the Act because FICC's discretion would be limited by its governance and also the proposed range for the VaR Floor percentage. Making any proposed adjustments to the VaR Floor percentage subject to a required governance process would be appropriate in furtherance of the Act

because it would ensure that the final decision as to whether the adjustment ought to be made falls on a clear and transparent decision-making process. Making any proposed adjustments to the VaR Floor percentage subject to the proposed range would be appropriate in furtherance of the Act because as described above, the proposed range would effectively set a floor on the VaR Charge at a level that has historically impacted only a small number of Clearing Members while at the same time ensuring that FICC can make adjustments to the VaR Floor percentage to minimize FICC's credit exposure to Clearing Members. Therefore, FICC does not believe that the proposed changes described in Item II(A)1(i) above would impose any burden on competition that is not necessary or appropriate in furtherance of the Act.<sup>40</sup>

FICC does not believe that the proposed changes described in Item II(A)1(ii) above to provide Clearing Members with 10 Business Days' notice prior to the implementation of any adjustment to the VaR Floor percentage would impact competition. FICC believes that the proposed change to provide notification of adjustments to the VaR Floor percentage would enhance Clearing Members' information regarding their margin requirements; FICC believes that the proposed 10 Business Days' notice would provide Clearing Members with adequate opportunity to adjust their portfolios if they wish to do so and adequate time to prepare for the increase in their VaR Charge.

FICC does not believe the proposed changes described in Item II(A)1(iii) above to state that the VaR Floor percentage would be subject to monthly performance monitoring would impact competition. The proposed rule changes regarding at least monthly model performance review would not alter Clearing Members' rights and obligations. Rather, they would enable FICC to identify any issues with the VaR Floor percentage on a more frequent basis than the current annual model validation. Moreover, the proposed change regarding at least monthly model performance reviews would be consistent with the Framework.

FICC does not believe that the proposed rule changes described in Item II(A)1(iv) above to make technical changes to the MBS Rules to restate the calculation of the VaR Floor to provide more detail than the current provision and to use defined terms would impact competition. The proposed technical changes would

<sup>35</sup> *Id.*

<sup>36</sup> 17 CFR 240.17Ad-22(e)(23)(ii).

<sup>37</sup> *Id.*

<sup>38</sup> *Id.*

<sup>39</sup> 15 U.S.C. 78q-1(b)(3)(I).

<sup>40</sup> *Id.*

ensure that the MBSD Rules remain clear by replacing the current language with language that sets out in words the calculation of the VaR Floor amount. By doing so, Clearing Members can better understand how the VaR Floor is calculated and understand whether they would be subject to it. FICC believes that the technical changes would not affect Clearing Members' rights and obligations. As such, FICC believes that these proposed rule changes would not have any impact on competition.

FICC does not believe that the proposed technical changes described in Item II(A)1(iv) to the QRM Methodology to reflect at least annual model validation of the VaR Floor percentage would have any impact on competition. This change would reflect current practice and would not alter Clearing Members' rights or obligations. Therefore, FICC does not believe that these proposed changes to clarify the language in the QRM Methodology would have any impact on competition.

*(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

Written comments relating to the proposed rule changes have not been solicited or received. 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

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](mailto:rule-comments@sec.gov). Please include File Number SR-FICC-2019-003 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-2019-003. 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-2019-003 and should be submitted on or before August 29, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>41</sup>

**Jill M. Peterson,**

*Assistant Secretary.*

[FR Doc. 2019-16938 Filed 8-7-19; 8:45 am]

**BILLING CODE 8011-01-P**

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-86563; File No. SR-CboeBZX-2019-047]

### Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Adopt BZX Rule 14.11(k) To Permit the Listing and Trading of Managed Portfolio Shares

August 2, 2019.

On June 6, 2019, Cboe BZX Exchange, Inc. filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> a proposed rule change to adopt new Rule 14.11(k) to permit it to list and trade Managed Portfolio Shares. The proposed rule change was published for comment in the **Federal Register** on June 25, 2019.<sup>3</sup> The Commission has received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act<sup>4</sup> 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 August 9, 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,<sup>5</sup> designates September 23, 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-CboeBZX-2019-047).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> See Securities Exchange Act Release No. 86157 (June 19, 2019), 84 FR 29892.

<sup>4</sup> 15 U.S.C. 78s(b)(2).

<sup>5</sup> *Id.*

<sup>41</sup> 17 CFR 200.30-3(a)(12).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>6</sup>

**Jill M. Peterson,**

*Assistant Secretary.*

[FR Doc. 2019-16943 Filed 8-7-19; 8:45 am]

BILLING CODE 8011-01-P

## DEPARTMENT OF STATE

[Public Notice: 10780]

### Bureau of Oceans and International Environmental and Scientific Affairs

**ACTION:** Notice of annual certification of shrimp-harvesting nations.

**SUMMARY:** On April 23, 2019, the acting Under Secretary of State for Economic Growth, Energy, and the Environment declared that wild-caught shrimp harvested in the following nations, particular fisheries of certain nations, and Hong Kong are eligible to enter the United States: Argentina, Australia (Northern Prawn Fishery, the Queensland East Coast Trawl Fishery, the Spencer Gulf, and the Torres Strait Prawn Fishery), the Bahamas, Belgium, Belize, Canada, Chile, China, Colombia, Costa Rica, Denmark, the Dominican Republic, Ecuador, El Salvador, Fiji, Finland, France (French Guiana), Gabon, Germany, Guatemala, Guyana, Honduras, Iceland, Ireland, Jamaica, Japan (shrimp baskets in Hokkaido), Republic of Korea (mosquito nets), Malaysia (East Coast of the peninsula), Mexico, Netherlands, New Zealand, Nicaragua, Nigeria, Norway, Oman, Panama, Peru, Russia, Spain (Mediterranean red shrimp), Sri Lanka, Suriname, Sweden, the United Kingdom, Uruguay, and Venezuela. For nations, economies, and fisheries not listed above, only shrimp harvested from aquaculture is eligible to enter the United States. All shrimp imports into the United States must be accompanied by the DS-2031 Shrimp Exporter's/Importer's Declaration.

**DATES:** This notice is applicable on August 8, 2019.

**FOR FURTHER INFORMATION CONTACT:** Joseph Fette, Section 609 Program Manager, Office of Marine Conservation, Bureau of Oceans and International Environmental and Scientific Affairs, Department of State, 2201 C Street NW, Washington, DC 20520-2758; telephone: (202) 647-2335; email: [DS2031@state.gov](mailto:DS2031@state.gov).

**SUPPLEMENTARY INFORMATION:** Section 609 of Public Law 101-162 ("Sec. 609") prohibits imports of wild-caught shrimp

or products from shrimp harvested with commercial fishing technology unless the President certifies to the Congress by May 1, 1991, and annually thereafter, that either: (1) The harvesting nation has adopted a regulatory program governing the incidental taking of relevant species of sea turtles in the course of commercial shrimp harvesting that is comparable to that of the United States and that the average rate of that incidental taking by the vessels of the harvesting nation is comparable to the average rate of incidental taking of sea turtles by United States vessels in the course of such harvesting; or (2) the particular fishing environment of the harvesting nation does not pose a threat of the incidental taking of sea turtles in the course of shrimp harvesting. The President has delegated the authority to make this certification to the Secretary of State ("Secretary") who further delegated the authority to the Under Secretary of State for Economic Growth, Energy, and the Environment ("Under Secretary"). The Department of State's Revised Guidelines for the Implementation of Section 609 were published in the **Federal Register** on July 8, 1999, at 64 FR 36946.

On April 23, 2019, the acting Under Secretary certified 13 nations on the basis that their sea turtle protection programs are comparable to that of the United States: Colombia, Costa Rica, Ecuador, El Salvador, Gabon, Guatemala, Guyana, Honduras, Mexico, Nicaragua, Nigeria, Panama, and Suriname. The acting Under Secretary also certified 26 shrimp-harvesting nations and one economy as having fishing environments that do not pose a danger to sea turtles. Sixteen nations have shrimping grounds only in cold waters where the risk of taking sea turtles is negligible: Argentina, Belgium, Canada, Chile, Denmark, Finland, Germany, Iceland, Ireland, the Netherlands, New Zealand, Norway, Russia, Sweden, the United Kingdom, and Uruguay. Ten nations and Hong Kong only harvest shrimp using small boats with crews of less than five that use manual rather than mechanical means to retrieve nets or catch shrimp using other methods that do not threaten sea turtles. Use of such small-scale technology does not adversely affect sea turtles. The 10 nations are the Bahamas, Belize, China, the Dominican Republic, Fiji, Jamaica, Oman, Peru, Sri Lanka, and Venezuela.

A completed DS-2031 Shrimp Exporter's/Importer's Declaration ("DS-2031") must accompany all imports of shrimp and products from shrimp into the United States. Importers of shrimp and products from shrimp harvested in

the 39 certified nations and one economy listed above must either provide the DS-2031 form to Customs and Border Protection at the port of entry or provide the information required by the DS-2031 through the Automated Commercial Environment. DS-2031 forms accompanying all imports of shrimp and products from shrimp harvested in uncertified nations and economies must be originals with Box 7(A)(1), 7(A)(2), or 7(A)(4) checked, consistent with the form's instructions with regard to the method of harvest of the shrimp and based on any relevant prior determinations by the acting Under Secretary, and signed by a responsible government official of the harvesting nation. The acting Under Secretary did not determine that shrimp or products from shrimp harvested in a manner as described in 7(A)(3) in any uncertified nation or economy is eligible to enter the United States.

Shrimp and products of shrimp harvested with turtle excluder devices ("TEDs") in an uncertified nation may, under specific circumstances, be eligible for importation into the United States under the DS-2031 Box 7(A)(2) provision for "shrimp harvested by commercial shrimp trawl vessels using TEDs comparable in effectiveness to those required in the United States." Use of this provision requires that the Secretary or his or her delegate determine in advance that the government of the harvesting nation has put in place adequate procedures to monitor the use of TEDs in the specific fishery in question and to ensure the accurate completion of the DS-2031 forms. At this time, the acting Under Secretary has determined that only shrimp and products from shrimp harvested in the Northern Prawn Fishery, the Queensland East Coast Trawl Fishery, and the Torres Strait Prawn Fishery in Australia, in the French Guiana domestic trawl fishery, and in the East Coast fishery of peninsular Malaysia are eligible for entry under this provision. The importation of TED-caught shrimp from any other uncertified nation will not be allowed. A responsible government official of Australia, France, or Malaysia must sign in Block 8 of the DS-2031 form accompanying these imports into the United States.

In addition, the acting Under Secretary has determined that shrimp and products from shrimp harvested in the Spencer Gulf region in Australia, with shrimp baskets in Hokkaido, Japan, with "mosquito" nets in the Republic of Korea, and Mediterranean red shrimp (*Aristeus antennatus*) and products from that shrimp harvested in the

<sup>6</sup> 17 CFR 200.30-3(a)(31).

Mediterranean Sea by Spain may be imported into the United States under the DS-2031 Box 7(A)(4) provision for "shrimp harvested in a manner or under circumstances determined by the Department of State not to pose a threat of the incidental taking of sea turtles." A responsible government official of Australia, Japan, the Republic of Korea, or Spain must sign in Block 8 of the DS-2031 form accompanying these imports into the United States.

The Department of State has communicated these certifications and determinations under Sec. 609 to the Office of International Trade of U.S. Customs and Border Protection.

**William H. Gibbons-Fly,**

*Acting Deputy Assistant Secretary of State for Oceans and Fisheries, Bureau of Oceans and International Environmental and Scientific Affairs, Department of State.*

[FR Doc. 2019-16590 Filed 8-7-19; 8:45 am]

**BILLING CODE 4710-09-P**

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**DEPARTMENT OF STATE**

[Public Notice: 10842]

**U.S. Advisory Commission on Public Diplomacy; Notice of Meeting**

The U.S. Advisory Commission on Public Diplomacy will hold a public meeting from 10:00 a.m. until 12:00 p.m., Wednesday, September 4, 2019, at the Elliott School of International Affairs at George Washington University in the Lindner Family Commons, Room 602 (1957 E Street NW, Washington, DC 20052). The focus of the meeting will be the creation of the new Global Public Affairs Bureau and the accompanying strategic vision for Public Diplomacy going forward in the Department of State.

This meeting is open to the public, including the media and members and staff of governmental and non-governmental organizations. Any requests for a reasonable accommodation for a disability should be sent by email to Vivian Walker at [WalkerVS@state.gov](mailto:WalkerVS@state.gov) by 5:00 p.m. on Wednesday, August 28, 2019. Attendees should plan to arrive for the meeting by 9:45 a.m. to allow for a prompt start.

The U.S. Advisory Commission on Public Diplomacy appraises U.S. government activities intended to understand, inform, and influence foreign publics. The Advisory Commission may conduct studies, inquiries, and meetings, as it deems necessary. It may assemble and disseminate information and issue reports and other publications, subject

to the approval of the Chairperson, in consultation with the Executive Director. The Advisory Commission may undertake foreign travel in pursuit of its studies and coordinate, sponsor, or oversee projects, studies, events, or other activities that it deems desirable and necessary in fulfilling its functions.

For more information on the U.S. Advisory Commission on Public Diplomacy, please visit <https://www.state.gov/bureaus-offices/under-secretary-for-public-diplomacy-and-public-affairs/united-states-advisory-commission-on-public-diplomacy/>. For more information on the upcoming public meeting, contact the Commission's Executive Director, Vivian S. Walker, at [WalkerVS@state.gov](mailto:WalkerVS@state.gov).

**Vivian S. Walker,**

*Executive Director, Advisory Commission on Public Diplomacy, Department of State.*

[FR Doc. 2019-16981 Filed 8-7-19; 8:45 am]

**BILLING CODE 4710-45-P**

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**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

[Summary Notice No. 50]

**Petition for Exemption; Summary of Petition Received; Amazon Prime Air**

**AGENCY:** Federal Aviation Administration (FAA), Department of Transportation (DOT).

**ACTION:** Notice.

**SUMMARY:** This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

**DATES:** Comments on this petition must identify the petition docket number and must be received on or before August 28, 2019.

**ADDRESSES:** Send comments identified by docket number FAA-2019-0573 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M-30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12-140, West

Building Ground Floor, Washington, DC 20590-0001.

- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590-0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- *Fax:* Fax comments to Docket Operations at (202) 493-2251.

*Privacy:* In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to <http://www.regulations.gov>, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>.

*Docket:* Background documents or comments received may be read at <http://www.regulations.gov> at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590-0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Nia Daniels, (202) 267-7626, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on August 2, 2019.

**Brandon L. Roberts,**

*Deputy Executive Director, Office of Rulemaking.*

**Petition for Exemption**

*Docket No.:* FAA-2019-0573.

*Petitioner:* Amazon Prime Air.

*Sections of 14 CFR Affected:* 61.23; 61.133, 91.113(b) through (f); 91.119(b) and (c); 91.121; 91.151(a); 135.25(a)(1) and (2); 135.63(c) and (d); 135.65(d); 135.93(g); 135.149(a); 135.161(a)(1) through (3); 135.203(a); 135.209(a); 135.243(b)(1) through (3); 135.415(b); and 135.501(a).

*Description of Relief Sought:* Amazon Prime Air petitions for an exemption to allow it to conduct operations under a part 135 air carrier operating certificate with an unmanned aircraft system (UAS), to enable its commercial delivery operations using UAS.

[FR Doc. 2019-17010 Filed 8-7-19; 8:45 am]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF TRANSPORTATION****Federal Aviation Administration**

[Summary Notice No. FAA-2019-45]

**Subject: Heading Correction; Petition for Exemption; Summary of Petition Received: The Boeing Company**

**AGENCY:** Federal Aviation Administration (FAA), Department of Transportation (DOT).

**ACTION:** Notice; correction.

**SUMMARY:** This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

**DATES:** Comments on this petition must identify the petition docket number and must be received on or before August 12, 2019.

**ADDRESSES:** Send comments identified by docket number FAA-2013-0221 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the online instructions for sending your comments electronically.

- *Mail:* Send comments to Docket Operations, M-30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.

- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590-0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- *Fax:* Fax comments to Docket Operations at (202) 493-2251.

*Privacy:* In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to <http://www.regulations.gov>, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>.

*Docket:* Background documents or comments received may be read at <http://www.regulations.gov> at any time. Follow the online instructions for

accessing the docket or go to the Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590-0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Brenda Robeson (202) 267-4712, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

*Background:* When the original notice was published on July 23, 2019, the title incorrectly had NetJet Aviation, Inc. This corrects the title to be The Boeing Company. The comment period remains the same, ending on August 12, 2019.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on August 5, 2019.

**Brandon Roberts,**

*Acting Executive Director, Office of Rulemaking.*

**Petition for Exemption**

*Docket No.:* FAA-2013-0221.

*Petitioner:* The Boeing Company.

*Section(s) of 14 CFR Affected:* §§ 61.75(d)(2) and 61.117.

*Description of Relief Sought:* The Boeing Company (Boeing) requests a renewal to Exemption No. 10871D, which provides relief from the requirements of 14 CFR 61.75(d)(2) and 61.117 for pilots obtaining an FAA Private Pilot certificate based on a foreign license. In addition, Boeing requests revisions to Exemption 10871D to align the exemption with Boeing's operations. Specifically, Boeing is requesting Exemption No. 10871D be modified to (1) Expand the definition of what non-crewmember supernumeraries may be carried on flights, (2) Remove the requirement for a Market Surveys—Experimental Special Airworthiness Certificate, (3) Expand the definition of what types of foreign pilots are eligible to use the exemption, and Enable exempted customer pilots to obtain training credit with their Foreign Civil Aviation Authority for elements of customer sales demonstration flights that meet their training requirements.

[FR Doc. 2019-17011 Filed 8-7-19; 8:45 am]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF TRANSPORTATION****Office of the Secretary**

[Docket No. DOT-OST-2019-0105]

**Senior Executive Service Performance Review Boards Membership**

**AGENCY:** Office of the Secretary, Department of Transportation (DOT).

**ACTION:** Notice of Performance Review Board (PRB) Appointments.

**SUMMARY:** DOT published the names of the persons selected to serve on Departmental PRBs as required by 5 U.S.C. 4314(c)(4).

**FOR FURTHER INFORMATION CONTACT:** Lisa M. Williams, Director, Departmental Office of Human Resource Management (202) 366-4088.

**SUPPLEMENTARY INFORMATION:** The persons named below may be selected to serve on one or more Departmental PRBs.

Issued in Washington, DC, on August 2, 2019.

**Keith E. Washington,**

*Deputy Assistant Secretary for Administration.*

**Department of Transportation***Federal Highway Administration*

ALONZI, ACHILLE  
 ARNOLD, ROBERT E  
 BAKER, SHANA V  
 BEZIO, BRIAN R  
 BIONDI, EMILY CHRISTINE  
 BRIGGS, VALERIE ANNETTE  
 CHRISTIAN, JAMES C  
 COLLINS, BERNETTA L.  
 CRONIN, BRIAN P  
 EVANS, MONIQUE REDWINE  
 EVERETT, THOMAS D  
 FINFROCK, ARLAN E JR  
 FLEURY, NICOLLE M  
 FOUCH, BRIAN J  
 FURST, ANTHONY T  
 GATTI, JONATHAN D  
 GRIFFITH, MICHAEL S  
 HARTMANN, JOSEPH L  
 HESS, TIMOTHY G.  
 HUGHES, CAITLIN GWYNNE  
 KALLA, HARI  
 KEHRLI, MARK R  
 KNOPP, MARTIN C  
 KRISHNAMOORTI, MALATHI  
 LEONARD, KENNETH  
 LEWIS, DAVID A  
 LILLIE, MARK STEVEN  
 LUCERO, AMY C  
 MAMMANO, VINCENT P  
 MARQUIS, RICHARD J  
 OSBORN, PETER W  
 PETTY, KENNETH II  
 RICHARDSON, CHRISTOPHER S  
 RICHTER, CHERYL ALLEN  
 RICO, IRENE

RIDGEWAY, MARY F  
ROHLF, JOHN G  
SCHAFTLEIN, SHARI M  
SCHMIDT, ROBERT T  
SHEPHERD, GLORIA MORGAN  
SIGEL, BETHANY RENEE  
STEPHANOS, PETER J  
SUAREZ, RICARDO  
TURNER, DERRELL E  
WALKER, CHERYL J  
WINTER, DAVID R  
WRIGHT, LESLIE JANICE  
ZIMMERMAN, MARY BETH

*Federal Motor Carrier Safety  
Administration*

COLLINS, ANNE L  
DELORENZO, JOSEPH P  
FROMM, CHARLES J  
HANSON, ALAN ROSS  
HERNANDEZ, SCOTT  
HORAN, CHARLES A III  
JONES, DARIN G  
KEANE, THOMAS P  
MILLER, ROBERT WILLIAM  
MINOR, LARRY W  
MULLEN, JAMES ANTHONY  
REGAL, GERALDINE K  
RIDDLE, KENNETH H.  
RUBAN, DARRELL L  
SCHREIBMAN, JACK L  
VAN STEENBURG, JOHN W

*Federal Railroad Administration*

ALEXY, JOHN KARL  
ALLAHYAR, MARYAM  
HAYWARD-WILLIAMS, CAROLYN  
JORTLAND, BRETT ANDREW  
KENDALL, QUINTIN C  
LESTINGI, MICHAEL W.  
LONG, MICHAEL T  
NISSENBAUM, PAUL  
PENNINGTON, REBECCA A  
RENNERT, JAMIE P.  
REYES-ALICEA, REBECCA  
RIGGS, TAMELA LYNN

*Federal Transit Administration*

AHMAD, MOKHTEE  
ALLEN, REGINALD E  
BRENNAN, JOHN J III  
BROOKINS, KELLEY  
BUCHANAN, HENRIKA J.  
DALTON-KUMINS, SELENE FAE  
GARCIA CREWS, THERESA  
GEHRKE, LINDA M  
GOODMAN, STEPHEN C  
NIFOSI, DANA C.  
PATRICK, ROBERT C  
TAYLOR, YVETTE G  
TELLIS, RAYMOND S  
TERWILLIGER, CINDY E  
TUCCILLO, ROBERT J  
VALDES, VINCENT  
WELBES, MATTHEW J  
WILLIAMS, KIMBERLY JANE

*Maritime Administration*

BALLARD, JOHN R

BALZANO, RICHARD A  
BRAND, LAUREN K  
BROHL, HELEN A  
BUONO, JOACHIM  
BURNETT, DOUGLAS R  
DAVIS, DELIA P  
DUNLAP, SUSAN LYNN  
FISHER, ANTHONY JR  
KUMAR, SHASHI N  
MC MAHON, CHRISTOPHER J  
MOSCHKIN, LYDIA  
PIXA, RAND R.  
TOKARSKI, KEVIN M

*National Highway Traffic Safety  
Administration*

AIZCORBE, CHRISTINA G  
BLINCOE, LAWRENCE J  
DANIELSON, JACK H.  
DOHERTY, JANE H  
DONALDSON, K JOHN  
GIUSEPPE, JEFFREY M  
HATIPOGLU, CEM  
HINES, DAVID M  
JOHNSON, TIM J  
KING, HEIDI R  
KOLLY, JOSEPH M  
KROHMER, JON R  
MARSHALL, JOHN W  
MATHEKE, OTTO G III  
MORRISON, JONATHAN C  
PARKER, CYNTHIA D  
PFISTER, JAMIE DURHAM  
POSTEN, RAYMOND R  
RIDECCA, STEPHEN A  
RITTER, ROBERT G  
RUSHTON, SEAN G  
SPRAGUE, MARY G.  
WOOD, STEPHEN P

*Pipeline and Hazardous Materials  
Safety Administration*

BORENER, SHERRY S  
CURRY, KIM Y  
DAUGHERTY, LINDA  
FARLEY, AUDREY L.  
MAYBERRY, ALAN K  
MCMILLAN, HOWARD W  
PEARCE, DRUE  
PERRIELLO, TAMI L  
QUADE, WILLIAM A III  
ROBERTI, PAUL  
SCHOONOVER, WILLIAM S  
TAHAMTANI, MASSOUD  
TSAGANOS, VASILIKI B

*Saint Lawrence Seaway Development  
Corporation*

LAVIGNE, THOMAS A  
MCINERNEY, MARIANNE  
MIDDLEBROOK, CRAIG H

*Office of the Secretary*

ABRAHAM, JULIE  
ALBRIGHT, JACK G  
AUDET, ANNE H  
AUGUSTINE, JOHN E  
AYLWARD, ANNE D  
BALDWIN, KRISTEN K.

BEDELL, ANTHONY R.  
BOHNERT, ROGER V  
CALLENDER, DUANE A  
CARLSON, TERENCE W  
CHAVEZ, RICHARD M.  
CHULUMOVICH, MADELINE M  
COGGINS, COLLEEN P  
CONNORS, SUSAN M  
CONRAD, JESSICA MARIE  
COTE, GREGORY D  
COTE, RYAN ERNEST  
DEBONO, DAN PATRICK  
FARAJIAN, MORTEZA  
FLEMING, GREGG G  
FULTON, THOMAS FINCH  
FUNK, JENNIFER S  
FURCHTGOTT—ROTH, DIANA EL  
GAUTREAU, CATHY FOSTER  
GEIER, PAUL M  
GENERO, LAURA  
HEDBERG, BRIAN J  
HERLIHY, THOMAS W  
HOLDEN, STEPHEN H.  
HOMAN, TODD M  
HORN, DONALD H  
HU, PATRICIA S.  
HURDLE, LANA T  
INMAN, JAMES TODD  
JACKSON, RONALD A  
JAMES, CHARLES E.  
JEFFERSON, DAPHNE Y  
JOYNER, GREGORY GILBERT  
KALETA, JUDITH S  
KNOUSE, RUTH D.  
KRAMER, JOHN E JR  
LAWRENCE, CHRISTINE A  
LEFEVRE, MARIA S.  
LOHRENZ, MAURA C  
MACECEVIC, LISA J  
MARCHESE, APRIL LYNN  
MARTIN, HAROLD W III  
MCCARTNEY, ERIN P  
MCKENNA, WILLIAM  
MCMASTER, SEAN K B  
MEDINA, YVONNE R.  
MILLER, JANNINE MARIE  
MORGAN, DANIEL S.  
MORRIS, WILLIS A.  
MOSS, JONATHAN P.  
O'BERRY, DONNA  
ORNDORFF, ANDREW R  
OWENS, JAMES C JR  
PAIEWONSKY, LUISA M  
PETROSINOWOOLVERTON, MARI  
POPKIN, STEPHEN M  
POST, ANDREW CHARLES  
REINKE, ANNE CHETTLE  
SCHMITT, ROLF R  
SHORT, DAVID E  
SIMPSON, JOAN  
SMITH, LOREN A. JR  
SMITH, WILLIE H  
SOLOMON, GERALD L  
STURGES, MATHEW MICHAEL  
SZAKAL, KEITH J  
SZATMARY, RONALD ALLEN JR  
TIMOTHY, DARREN P  
WASHINGTON, KEITH E  
WILLIAMS, LISA M

WOMACK, KEVIN C.  
WORKIE, BLANE A  
ZIFF, LAURA M

[FR Doc. 2019-16977 Filed 8-7-19; 8:45 am]

BILLING CODE 4910-9X-P

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## DEPARTMENT OF VETERANS AFFAIRS

### Genomic Medicine Program Advisory Committee

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, that a meeting of the Genomic Medicine Program Advisory Committee (the Committee) will be held on Wednesday, September 18, at the Hilton Garden Inn/Capitol Hill located at 1225 First Street NE, Washington, District of Columbia 20002, USA. The meeting will begin at 9 a.m. EST and adjourn at 4:30 p.m. EDT. The meeting is open to the public.

The purpose of the Committee is to provide advice and make

recommendations to the Secretary of Veterans Affairs on using genetic information to optimize medical care for Veterans and to enhance development of tests and treatments for diseases particularly relevant to Veterans.

On September 18, 2019, the Committee will receive updated briefings on various VA research programs, including the Million Veteran Program (MVP) to ascertain the progress of the program in the areas of participant recruitment, data generation and storage, and data access. The Committee will also receive updates from ongoing MVP endeavors, including cohort building, data generation and usage, and the VA-Department of Energy (DOE) collaborative projects. Additionally, the Committee will discuss and explore potential recommendations to be included in the next annual report.

Public comments will be received at 3:30 p.m. and are limited to 5 minutes each. Individuals who speak are invited

to submit a 1–2 page summary of their comments for inclusion in the official meeting record to Jennifer Moser, Designated Federal Officer, Office of Research and Development (10X2), 810 Vermont Avenue NW, Washington, DC 20420, or via email at [Jennifer.Moser@va.gov](mailto:Jennifer.Moser@va.gov). In the communication, writers must identify themselves and state the organization, association or person(s) they represent. Any member of the public who wishes to attend the meeting should RSVP to Jennifer Moser at (202) 443-5678 no later than close of business, September 8, 2019 at the phone number or email address noted above.

Dated: August 2, 2019.

**LaTonya L. Small,**

*Federal Advisory Committee Management  
Officer.*

[FR Doc. 2019-16931 Filed 8-7-19; 8:45 am]

BILLING CODE P



# FEDERAL REGISTER

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Part II

## Department of Health and Human Services

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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; Final Rule

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Part 412**

[CMS-1710-F]

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:** Final rule.

**SUMMARY:** This final rule updates the prospective payment rates for inpatient rehabilitation facilities (IRFs) for federal fiscal year (FY) 2020. As required by the statute, this final 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. This final rule rebases and revises the IRF market basket to reflect a 2016 base year rather than the current 2012 base year. Additionally, this final rule revises the CMGs and updates the CMG relative weights and average length of stay (LOS) values beginning with FY 2020, based on analysis of 2 years of data (FYs 2017 and 2018). Although we proposed to use a weighted motor score to assign patients to CMGs, we are finalizing based on public comments the use of an unweighted motor score to assign patients to CMGs beginning with FY 2020. Additionally, we are finalizing the removal of one item from the motor score. We are updating the IRF wage index to use the concurrent fiscal year inpatient prospective payment system (IPPS) wage index beginning with FY 2020. We are amending 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 adopting two new measures, modifying an existing measure, and adopting new standardized patient assessment data elements. We are also making updates to reflect our migration to a new data submission system.

**DATES:**

*Effective date:* These regulations are effective on October 1, 2019.

*Applicability dates:* The updated IRF prospective payment rates are applicable for IRF discharges occurring on or after October 1, 2019, and on or before September 30, 2020 (FY 2020). The new and updated quality measures and reporting requirements under the IRF QRP are applicable for IRF discharges occurring on or after October 1, 2020.

**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:**

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period as soon as possible after they have been received at <http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

The IRF PPS Addenda along with other supporting documents and tables referenced in this final 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 final rule updates 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 Social Security Act (the Act). As required by section 1886(j)(5) of the Act, this final rule includes the classification and weighting factors for the IRF PPS's case-mix groups (CMGs) and a description of the methodologies and data used in computing the prospective payment rates for FY 2020. This final rule also rebases and revises the IRF market basket to reflect a 2016 base year, rather than the current 2012 base year. Additionally, this final rule revises the CMGs and updates the CMG relative weights and average LOS values

beginning with FY 2020, based on analysis of 2 years of data (FYs 2017 and 2018). Although we proposed to use a weighted motor score to assign patients to CMGs, we are finalizing based on public comments the use of an unweighted motor score to assign patients to CMGs beginning with FY 2020. Additionally, we are finalizing the removal of one item from the motor score. We are also updating the IRF wage index to use the concurrent FY IPPS wage index for the IRF PPS beginning with FY 2020. We are also amending the regulations at 42 CFR 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 QRP, we are adopting two new measures, modifying an existing measure, and adopting new standardized patient assessment data elements. We also include updates related to the system used for the submission of data and related regulation text. We are not finalizing our proposal requiring that IRFs submit data on measures and standardized patient assessment data for which the source of the data is the IRF-PAI to all patients, regardless of payer, but plan to propose this policy in future rulemaking.

*B. Summary of Major Provisions*

In this final 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 final rule also rebases and revises the IRF market basket to reflect a 2016 base year rather than the current 2012 base year. Additionally, this final rule revises the CMGs and updates the CMG relative weights and average LOS values beginning with FY 2020, based on analysis of 2 years of data (FYs 2017 and 2018). Although we proposed to use a weighted motor score to assign patients to CMGs, we are finalizing based on public comments the use of an unweighted motor score to assign patients to CMGs beginning with FY 2020. Additionally, we are finalizing the removal of one item from the motor score. We are also updating the IRF wage index to use the concurrent FY IPPS wage index for the IRF PPS beginning in FY 2020. We are also amending 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

also 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 final rule is an estimated \$210 million in increased payments from the Federal government to IRFs during FY 2020.
Provision Description	Costs
IRF QRP requirements	The total addition in costs in FY 2020 for IRFs as a result of the quality reporting requirements is estimated to be \$8.2 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 final 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 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 LOS 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 LOS 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 final 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 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 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 LOS values. Any reference to the FY 2011 IRF PPS notice in this final 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 LOS 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 IRF 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 final 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 final 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 (FYs 2017 and 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 FY 2012 and each subsequent fiscal year). The productivity adjustment for FY 2020 is discussed in section VI.D. of this final 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 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 paragraphs (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 paragraph (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 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 August 21, 1996) (HIPAA) compliant electronic claim or, if the Administrative Simplification Compliance Act of 2002 (Pub. L. 107–105, enacted 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. 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. 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 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. We solicited comment on the two proposed rules. We invited 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 the FY 2020 IRF PPS proposed rule, we proposed 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 also proposed 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 LOS values beginning with FY 2020, based on analysis of 2 years of data (FYs 2017 and 2018). We also proposed to use the concurrent FY IPPS wage index for the IRF PPS beginning with FY 2020. We also solicited comments on stakeholder concerns regarding the appropriateness of the wage index used to adjust IRF payments. We proposed 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 (FYs 2017 and 2018) using the Quality Indicator items in the IRF-PAI. This includes proposed revisions to the CMG relative weights and average LOS values for FY 2020, in a budget neutral manner, as discussed in section III. of the FY 2020 IRF PPS proposed rule (84 FR 17244, 17249 through 17260).
- 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 the FY 2020 IRF PPS proposed rule (84 FR 17244, 17261 through 17273).
- 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 the FY 2020 IRF PPS proposed rule (84 FR 17244, 17274 through 17275).

- Describe the proposed update to the IRF wage index to use the concurrent FY IPPS wage index and the FY 2020 proposed labor-related share in a budget-neutral manner, as described in section V. of the FY 2020 IRF PPS proposed rule (84 FR 17244, 17276 through 17279).

- Describe the continued use of FY 2014 facility-level adjustment factors, as discussed in section IV. of the FY 2020 IRF PPS proposed rule (84 FR 17244, 17260 through 17261).

- Describe the calculation of the IRF standard payment conversion factor for FY 2020, as discussed in section V. of the FY 2020 IRF PPS proposed rule (84 FR 17244, 17280 through 17282).

- Update the outlier threshold amount for FY 2020, as discussed in section VI. of the FY 2020 IRF PPS proposed rule (84 FR 17244, 17283 through 17284).

- Update the cost-to-charge ratio (CCR) ceiling and urban/rural average CCRs for FY 2020, as discussed in section VI. of the FY 2020 IRF PPS proposed rule (84 FR 17244 at 17284).

- 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 the FY 2020 IRF PPS proposed rule (84 FR 17244, 17284 through 17285).

- Updates to the requirements for the IRF QRP, as discussed in section VIII. of the FY 2020 IRF PPS proposed rule (84 FR 17244, 17285 through 17330).

## III. Analysis and Response to Public Comments

We received 1,257 timely responses from the public, many of which contained multiple comments on the FY 2020 IRF PPS proposed rule (84 FR 17244). The majority consisted of form letters, in which we received multiple copies of two types of identically-worded letters that had been signed and submitted by different individuals. We received comments from various trade associations, IRFs, individual physicians, therapists, clinicians, health care industry organizations, and health care consulting firms. The following sections, arranged by subject area, include a summary of the public comments that we received, and our responses.

## IV. 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 CMGs 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 CMG 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 IV.B of this final rule, based on further analysis to examine the potential impact of weighting the motor score, we proposed 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 2 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 the FY 2020 IRF PPS proposed rule (84 FR 17244, 17250 through 17260), we proposed to revise the CMGs based on analysis of 2 years of data (FYs 2017 and 2018) beginning with FY 2020. We also proposed to update the relative weights and average LOS 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 believed that a weighted motor score would improve the accuracy of payments to IRFs and proposed 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 proposed 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 would have resulted in either a negative or non-significant coefficient. As such, we did not believe it would be appropriate to include this item in the motor score calculation. 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 suggested 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 proposed to use 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 proposed 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 received several 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. As summarized in more detail below, with the exception of one comment from MedPAC, the commenters overwhelmingly requested that CMS delay implementation of a weighted motor score and use an unweighted motor score to assign patients to CMGs until we can more fully analyze and work with stakeholders on developing a weighted motor score methodology.

In response to public comments, we carefully considered whether to finalize the proposed weighted motor score or go back to using an unweighted motor score to assign patients to CMGs. Although the proposed weighted motor score results in a slight improvement in the ability of the IRF PPS to predict patient costs and thus the accuracy of IRF PPS payments (less than 0.18 difference in accuracy between the weighted and the unweighted motor scores), we acknowledge the unweighted motor score is conceptually

simpler and, as such, believe it will ease providers' transition to the use of the data items located in the Quality Indicators section of the IRF-PAI (also referred to as section GG items). Thus, we are finalizing based on public comments the use of an unweighted motor score to assign patients to CMGs beginning with FY 2020. We appreciate the commenters' suggestions on the weighting methodology and will take them into consideration as we explore possible refinements to the case-mix classification system in the future.

*Comment:* Although several commenters noted appreciation for the fact that we analyzed a weighted motor score in response to their comments on the FY 2019 IRF PPS proposed rule (83 FR 38546), these same commenters expressed concerns with the actual weighted values that CMS proposed for FY 2020, as indicated in Table 1, and stated that we should go back to an unweighted motor score so that we can do further analysis and collaborate with stakeholders to further refine the weighting methodology. Some commenters expressed concern that CMS might be proposing higher weights for the self-care items than for the mobility items, in contrast to the current weighted motor score, which weights mobility items higher than self-care items. Some commenters specifically requested that CMS explain why the weight for the eating item increased from 0.6 under the current weighting methodology to 2.7 under the proposed methodology, and requested we explain what we believe this change will mean for patients with eating deficits.

Commenters were also generally concerned by what they suggested were large differences in the weight value assignments between the current and proposed motor score.

*Response:* We used simple ordinary least squares regression analysis of the data that IRFs submitted to us in FYs 2017 and 2018 to calculate the proposed weight values for the motor score, in response to stakeholder feedback on the FY 2019 IRF PPS proposed rule (83 FR 38546). Commenters are correct that the proposed weights for the motor score items, in comparison with the current weights, shift some of the weight from the mobility to the self-care items. We also note that the proposed weights assigned to the bowel and bladder function items increased compared with the current weights. These changes are all reflective of the data the IRFs submitted to us in FYs 2017 and 2018.

Regarding the proposed increase in the weight for the eating item, it is important to note key differences in the coding guidelines between the FIM™ eating item and the section GG eating item that may have contributed to the change in the relative importance of this item for predicting IRF costs. For item GG0130A, Eating, assistance with tube feedings is not considered when coding this item. If a patient does not eat or drink by mouth but is instead tube fed, item GG0130A must be coded as 88—“Not attempted due to medical condition or safety concerns” or 09—“Not applicable”. Both of these responses would be recoded to a 01—“Dependent” for the purposes of assigning the patient to a CMG. This

differs from the coding instructions for the FIM™ eating item used in the current motor score, which takes into consideration assistance with tube feedings in scoring the item. For example, according to the FIM™ instructions, a patient who could administer the tube feeding completely independently could receive a score of 7-Complete independence on the eating item.

In regards to the suggested differences in the weight value assignments between the current and proposed methodologies, we note that in certain cases the proposed weights were divided among multiple items in the motor score that were found to be highly correlated to avoid overweighting any particular measure of function. For instance, the three items (GG0170I1, GG0170J1, and GG0170K1) that assess walking function were each assigned a proposed weight of 0.8. When summed together, the weight value for walking under the proposed methodology is 2.4, which is slightly higher than the weight value of 1.6 for the single walking item used in the current motor score.

*Comment:* One commenter disagreed with the removal of item GG0170A1 roll left and right from the motor score and noted it is an important functional task in the IRF setting. Some commenters questioned the use of averaging values across pairs of items that were correlated and inquired why the roll left and right item was removed from the motor score while other correlated items were not removed. Commenters also inquired about the use of the item “walk 10 feet” to derive the weights for the “walk 50 feet” and “walk 150 feet” items.

*Response:* We appreciate the commenter’s concerns regarding the removal of item GG0170A1 from the motor score. As described in detail in the technical report, “Analyses to Inform the Use of Standardized Patient Assessment Data Elements in the Inpatient Rehabilitation Facility Prospective Payment System,” the roll left and right item was found to have a high degree of multicollinearity with other standardized patient assessment elements and to be inversely correlated with costs after controlling for each of the other self-care and mobility items. This relationship persisted when this item was paired with the other correlated items. The continued inclusion of this item in the motor score would have resulted in either a negative or non-significant coefficient. As such, we do not believe it is appropriate to include this item in the construction of the motor score. The other item pairs that were found to be correlated did not

generate negative or non-significant coefficients, and were therefore maintained in the calculation of the motor score.

Unlike the FIM™ instrument, the items from the quality indicator section of the IRF-PAI sometimes use more than one item to measure functional areas. As discussed in more detail in the technical report, we noted that a few items were found to be highly correlated. Because of the correlation, we proposed to use an average score for some items so as to avoid introducing bias or inappropriately overweighting any particular functional area. We note this methodology is consistent with the methodology used under the Patient Driven Payment Model (PDPM), as described in more detail in the FY 2019 SNF final rule (83 FR 39204) and the accompanying technical report entitled “Skilled Nursing Facilities Patient-Driven Payment Model Technical Report” available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html>.

Regarding the “walk 10 feet” item, that item was used to derive the weights for the “walk 50 feet” and “walk 150 feet” items as these three items were found to be highly correlated and the “walk 150 feet” item had a high proportion of observations coded on admission with “activity not attempted” codes.

*Comment:* Some commenters requested that CMS apply the current motor score weights associated with the FIM™ items to the revised motor score while other commenters requested that CMS postpone weighting the motor score until additional data can be collected and analyzed. While a few commenters were supportive of using a weighted motor score, other commenters suggested that CMS use a 1-year payment model or phase in the use of a weighted motor score.

*Response:* We do not believe it would be appropriate to apply the weight values associated with the FIM™ items to the components of the revised motor score, as these weights would not accurately reflect how the various components of the revised motor score contribute to predicting patient costs. We used simple ordinary least squares regression analysis of the data that IRF’s submitted to us in FYs 2017 and 2018 to calculate the proposed weight values for the revised motor score. Changes in patient demographics, treatment practices, technology, and other factors that may affect the relative use of resources in an IRF since the motor score weights were originally calculated have likely contributed to changes in

the weight values applied across the self-care and mobility items. We proposed to apply weights to the motor score items because RTI’s analysis indicated that a weighted motor score would improve the classification of patients into CMGs, which in turn would improve the accuracy of payments to IRFs. However, as discussed above, in response to public comments, we carefully considered whether to finalize the proposed weighted motor score or go back to using an unweighted motor score to assign patients to CMGs. Although the proposed weighted motor score results in a slight improvement in the ability of the IRF PPS to predict patient costs and thus the accuracy of IRF PPS payments (less than 0.18 difference in accuracy between the weighted and the unweighted motor scores), we acknowledge the unweighted motor score is conceptually simpler and, as such, believe it will ease providers’ transition to the use of the data items located in the Quality Indicators section of the IRF-PAI (also referred to as section GG items). Thus, we are finalizing based on public comments the use of an unweighted motor score, in which each of the 18 items have a weight of 1, to assign patients to CMGs beginning with FY 2020.

*Comment:* Commenters expressed concern that the analysis performed by RTI did not explicitly follow the analysis conducted by RAND when the motor score weights were developed for FY 2006 (70 FR 47896 through 47900) and that RTI based their analyses on 2 years of data instead of several years of data. Additionally, commenters requested more information on the other weighting methodologies that RTI considered.

*Response:* We disagree with the commenters that the RAND analysis for FY 2006 used more years of data than RTI’s analysis for the FY 2020 proposed rule. As discussed in the FY 2006 IRF PPS final rule (70 FR 47897), RAND performed regression analysis on less than 2 full years of data (calendar year (CY) 2002 and FY 2003) to derive the current motor score weights. In contrast, RTI used 2 full years of data (FYs 2017 and 2018) to perform the analysis for the weighted motor score proposed in the FY 2020 IRF PPS proposed rule. As the FYs 2017 and 2018 data portrays the most recent and complete picture of patients under the IRF PPS, we believe it was sufficient and appropriate to utilize for the analysis for the proposed rule.

While RTI utilized a different weighting methodology than was used by RAND in 2006, the overall model

prediction using the weighted motor score developed by RAND and the weighted motor score developed by RTI is extremely similar. The model using the CMGs based on the standardized patient assessment data elements and comorbidity tiers to predict wage-adjusted costs of care has an r-squared value is 0.3358, while the r-squared value is 0.3169 for the CMGs in the current IRF PPS. This is indicative of similar model performance regardless of model specification. The item weights that the RAND work notes as “optimally weighted” are weights that were constructed separately for each RIC. These were not the weights that were used in the final weights developed by RAND.

RTI also examined weighing methodologies utilizing a general linear model (GLM) and log transformed ordinary least squares (OLS) regression models, as well as the OLS model described in more detail in the technical report. All three models had comparable model fit and generated similar item weights. Based on the greater simplicity achieved through the use of the OLS regression model we believe using the OLS regression was appropriate to maintain simplicity and transparency in the payment system.

*Comment:* Commenters disagreed with the omission of the wheelchair mobility items from the items used to construct the motor score.

*Response:* We appreciate the commenters’ concerns about wheelchair-dependent patients. As most recently discussed in the FY 2019 IRF PPS final rule (83 FR 38546) in response to similar stakeholder comments, we explained our rationale for not including the wheelchair mobility items in the construction of the finalized motor score. We continue to believe that the higher resource needs of wheelchair dependent patients in IRFs will be better accounted for by not including a wheelchair item in the motor score at this time. Patients that are considered wheelchair dependent or unable to walk will be accounted for through the “not attempted” response codes captured through other items, especially some of the walking items, that are included in the motor score. In this way, we ensure that IRFs will be appropriately compensated for the higher costs they incur in treating wheelchair-dependent patients. We refer readers to the FY 2019 IRF PPS final rule (83 FR 38546) and the technical report entitled “Analyses to Inform the Use of Standardized Patient Assessment Data Elements in the Inpatient Rehabilitation Facility Prospective Payment System” for more information on the rationale as

to why this item was not included in the calculation of the motor score.

*Comment:* Commenters expressed concern with the weighted motor score and questioned the reliability and validity of the weighted motor score. Some commenters stated that they believe the weighted and unweighted motor scores have shown little to no correlation with the weighted motor score currently in use, and therefore, questioned if the weighted motor score could accurately measure patient severity.

*Response:* We disagree with the commenters’ suggestion that unweighted and weighted motor scores have shown little to no correlation with the weighted motor score currently in use as our analysis shows a strong correlation between the scores. In addition, each of the proposed Quality Indicators data items that were included in the motor score were found to have statistically significant correlation with IRF costs. As discussed in the technical report “Analyses to Inform the Use of Standardized Patient Assessment Data Elements in the Inpatient Rehabilitation Facility Prospective Payment System” the use of a weighted motor score was found to increase the predictive ability of the payment model.

*Comment:* Commenters requested that CMS make available the data utilized in the analyses including patient assessment data, matching claims data, and additional facility and cost report data to enable stakeholders to replicate the analyses.

*Response:* We appreciate the commenters’ feedback regarding the types of information that would be most useful to them in replicating our analyses. We are unable to make patient assessment and claims data publicly available on the CMS website because these data contain personally identifiable information. However, we believe that we released sufficient information in the proposed rule, the accompanying data files, and the technical report entitled “Analyses to Inform the Use of Standardized Patient Assessment Data Elements in the Inpatient Rehabilitation Facility Prospective Payment System,” to enable stakeholders to submit meaningful comments on the underlying analyses and methodologies used to revise the IRF case-mix classification system, to pose alternative approaches, and to assess the impacts of the proposed revisions.

*Comment:* A few commenters noted that they did not believe that CMS has performed the thorough data analyses and engagement with the provider community that are necessary prior to

making significant changes to the existing IRF PPS. These commenters requested that we solicit additional feedback from the stakeholder community, including convening technical advisory panels (TEPs), to provide additional transparency into the underlying analyses and to delay implementation of a weighted motor score until we conduct additional engagements with stakeholders.

*Response:* We value transparency in our processes and will continue to engage stakeholders in future development of payment policies. We appreciate the offers from stakeholders to assist in the development of future revisions to payment policies and we recognize the value from these partnerships. However, for something as analytically simple as running a regression analysis to determine the weights for the motor score items that best reflect patients’ resource needs in the IRF, we do not believe that a TEP is necessary.

As noted above, although the proposed weighted motor score results in a slight improvement in the ability of the IRF PPS to predict patient costs and thus the accuracy of IRF PPS payments (less than 0.18 difference in accuracy between the weighted and the unweighted motor scores), we acknowledge the unweighted motor score is conceptually simpler and, as such, believe it will ease providers’ transition to the use of the data items located in the Quality Indicators section of the IRF-PAI (also referred to as section GG items). Thus, we are finalizing based on public comments the use of an unweighted motor score to assign patients to CMGs beginning with FY 2020. We appreciate the stakeholders’ comments on this topic and will take them into consideration for future analysis.

*Comment:* A few commenters requested that CMS provide additional information regarding the provider specific impact analysis file that accompanied the rule, such as a data dictionary describing the data used to calculate the impacts.

*Response:* In conjunction with the release of the FY 2020 IRF PPS proposed rule, we posted a provider-specific impact analysis file that compared estimated payments to providers for FY 2020 without the proposed revisions to the CMGs with estimated payments to providers for FY 2020 with the proposed revisions to the CMGs. We believe that this file gives IRFs added information to enable them to see how their individual payments would be affected by the proposed changes to the CMGs. We updated this

provider specific impact analysis file shortly after it was initially posted to include additional information regarding the underlying data used to calculate the provider specific impacts, and we believe that this additional information is responsive to commenters' requests. The file can be downloaded from the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRF-Rules-and-Related-Files.html>. We appreciate the commenters' suggestions regarding the additional types of information that would be most useful to them to further facilitate understanding of our analyses.

As previously discussed, we proposed a weighted motor score as it was found to slightly improve the predicative ability of the case-mix system and thus the accuracy of IRF PPS payments. However, nearly all of the comments we received requested that we revert to an unweighted motor score for the various reasons discussed above. While we continue to believe that a weighted motor score is slightly more accurate, the difference is small, and in light of the conceptual simplicity achieved through the use of an unweighted motor score, which we believe will ease providers' transition to the use of the data items located in the Quality

Indicators section of the IRF-PAI, we are finalizing the use of an unweighted motor score, in which each of the 18 items used in the score have an equal weight of 1, to assign patients to CMGs beginning with FY 2020. Additionally, we are finalizing the proposed removal of one item (GG0170A1 Roll left to right) from the motor score beginning with FY 2020. Effective for all discharges beginning on or after October 1, 2019, we will use an unweighted motor score as indicated in Table 2 to determine a beneficiary's CMG placement.

**TABLE 2: Final Motor Score Weight Index for FY 2020**

Item	Weight
GG0130A1 - Eating	1
GG0130B1 - Oral hygiene	1
GG0130C1 - Toileting hygiene	1
GG0130E1 - Shower bathe self	1
GG0130F1 - Upper-body dressing	1
GG0130G1 - Lower-body dressing	1
GG0130H1 - Putting on/taking off footwear	1
GG0170B1 - Sit to lying	1
GG0170C1 - Lying to sitting on side of bed	1
GG0170D1 - Sit to stand	1
GG0170E1 - Chair/bed-to-chair transfer	1
GG0170F1 - Toilet transfer	1
GG0170I1 - Walk 10 feet	1
GG0170J1 - Walk 50 feet with two turns	1
GG0170K1 - Walk 150 feet	1
GG0170M1 - One-step curb	1
H0350 - Bladder Continence	1
H0400 - Bowel Continence	1

*C. Revisions to the CMGs and 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 2 years of data (FYs 2017 and 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 LOS values associated with any revised CMG definitions in future rulemaking.

As noted in the FY 2020 IRF PPS proposed rule (84 FR 17251), we 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 (FYs 2017 and 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 used this analysis to revise the CMGs utilizing FYs 2017 and 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 the FY 2020 IRF PPS proposed rule. However, as discussed in section IV.B of this final rule, we are finalizing based on public comments the use of an unweighted motor score to assign patients to a CMGs beginning in with FY 2020.

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>. Additionally, we refer readers to the FY 2020 IRF PPS proposed rule (84 FR 17250 through 17260) for more information on the proposed revisions to the CMGs.

As noted above, we are finalizing the use of an unweighted motor score beginning with FY 2020. As the motor score is a key input in the CART analysis used to revise the CMGs, the use of the unweighted motor score required that the CART analysis be rerun utilizing the unweighted motor score. RTI utilized the same methodology described in the FY 2020 IRF PPS proposed rule (84 FR 17250 through 17260) to support us in developing revisions to the CMGs, incorporating the unweighted motor score, as described in section IV.B of this final rule. The revised CMGs can be found in Table 3.

After developing the revised CMGs, RTI then calculated the relative weights and average LOS values for each revised CMG using the same methodologies that we have used to update the CMG relative weights and average LOS 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 proposed to use the FYs 2017 and 2018 IRF claims and FY 2017 IRF cost report data to update the CMG relative weights and average LOS 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 LOS 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 LOS values can be 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](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 proposed 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 used 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 final 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.

We note that, as we typically do, we updated our data between the FY 2020 IRF PPS proposed and final rules to ensure that we use the most recent available data in calculating IRF PPS payments. Additionally, we are finalizing the use of unweighted motor score beginning in with FY 2020 which generated revisions to the CMGs and relative weights. Based on our analysis using this updated data and an unweighted motor score, we now estimate a budget neutrality factor of (1.0010) to maintain the same total estimated aggregate payments in FY 2020 with and without the changes to the CMGs and the associated CMG relative weights. For FY 2020 we will apply the budget neutrality factor (1.0010) to the FY 2019 IRF PPS standard payment amount after the application of the budget-neutral wage adjustment factor.

The relative weights and average LOS values for those revised CMGs (found in Table 3) were calculated using the same methodology described in the FY 2020 IRF PPS proposed rule, which is the same methodology that we have used to update the CMG relative weights and average LOS values each fiscal year since we implemented an update to the

methodology in FY 2009. The revised CMGs (reflecting the unweighted motor score) and their respective descriptions, as well as the comorbidity tiers, corresponding relative weights and the average LOS values for each CMG and tier for FY 2020 are shown in Table 3. The average LOS 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. In section V.H. of this final rule, we discuss the proposed use of the existing methodology to calculate the standard payment conversion factor for FY 2020.

We received a number of comments 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 LOS values associated with the revised CMGs beginning with FY 2020, that is, for all discharges beginning on or after October 1, 2019, which are summarized below.

*Comment:* A number of commenters were appreciative of the use of 2 years of data to revise the CMGs; however, commenters expressed concern with the proposed CMG revisions and suggested that these changes could result in payment rate compression or a misalignment between payments and the costs of caring for patients. Commenters suggested payment compression would result in reduced payments for higher acuity patients and increased payments for lower acuity patients which could compromise access to care for patients with certain impairments. Additionally, some commenters questioned why there would be fewer CMGs within some RICs and suggested having fewer CMGs would also contribute to payment rate compression.

*Response:* We disagree with the commenters that revisions to CMGs will lead to payment rate compression or could compromise access to care for any particular group of patients. As the revised CMGs are reflective of the data that IRFs submitted to us in FYs 2017 and 2018, we believe the revised CMGs reflect the distinct resource needs of the current Medicare IRF population. We believe the revised CMGs more accurately predict resource use in IRFs and better align payments with the expected costs of treating patients in the IRF setting. As such, we believe that the revised CMGs may in fact improve access to and quality of care for IRF patients by increasing the accuracy of IRF payments to providers.

Regarding why some RICs would have fewer CMGs, we refer the commenters to the Technical Report entitled “Analyses

to Inform the Use of Standardized Patient Assessment Data Elements in the Inpatient Rehabilitation Facility Prospective Payment System” that describes in detail the analysis used to derive the CMGs and the criteria required to generate additional payment groups. As noted in the FY 2020 IRF PPS proposed rule (84 FR 17250 through 17252), RTI imposed some typically-used constraints in their analysis to identify the proposed set of payment groups. These constraints consisted of a minimum number of stays within a node, a 0.5 percentage point increase of explanatory power, and monotonicity across the CMGs within each RIC. We do not believe it would be appropriate to generate additional CMGs that did not improve the predicative ability of the model beyond what was produced through the CART analysis utilizing the constraints above. We note that while the CART analysis generated fewer CMGs within some RICs, it generated a greater number of CMGs within other RICs and that the overall number of CMGs increases through these revisions to the case-mix classification system. We do not believe having fewer CMGs within any RIC will contribute to payment rate compression as we believe these revisions better align payments with the expected costs of treating patients in IRFs.

Additionally, we disagree with the commenters’ statements that the CMG revisions will result in higher payments for lower acuity patients and reduced payments for higher acuity patients. Our analysis has found that higher function is associated with a slight reduction in payment under the revised CMGs and that lower function is associated with a slight increase in payments. The purpose of the proposed revisions to the CMGs is to align payments more appropriately with the costs of caring for all types of patients in IRFs. As such, we do not believe that the revisions will result in higher payments for lower acuity patients. We appreciate the commenters’ concerns and will continue to monitor the IRF data closely to ensure that IRF payments are appropriately aligned with costs of care and that Medicare patients continue to have appropriate access to IRF services.

*Comment:* Several commenters expressed concerns that the proposed CMG revisions could cause a significant redistribution of payments among IRF providers. These commenters indicated that they believe the section GG items make patients appear to be less severe and requested additional information on how patients would be redistributed among the revised CMGs. Additionally, commenters encouraged CMS to

monitor the data based on these changes and to update the model if necessary in the future.

*Response:* We agree with the commenters that the revisions to the CMGs may result in some redistribution of payments among providers. As noted in the FY 2019 IRF PPS final rule (83 FR 38547), the scales and coding instructions are slightly different between the item sets used to derive the existing CMGs and those used to derive the revised CMGs. As such, these differences may result in some patients grouping into different CMGs that more accurately account for the expected resource needs of the patient. While we cannot make individual Medicare beneficiary data publically available, we believe we released adequate information for stakeholders to determine how beneficiaries could be distributed across the revised CMGs. We appreciate the commenters’ suggestions to conduct monitoring activities and make future updates to the case-mix classification system and will take this into consideration in the future.

*Comment:* Commenters expressed concern with the use of section GG items to assign a patient to a CMG and suggested that these items are not sensitive enough and do not capture patients’ true burden of care. Commenters also expressed concern with the reliability of the data collected through these items and suggested that the data is not accurate or valid.

*Response:* As discussed in detail in the FY 2019 IRF PPS final rule (83 FR 38541), we believe that the data items located in the Quality Indicators section of the IRF–PAI are sensitive and accurately capture the functional and cognitive status of patients and can also be used to accurately assess changes in patients’ functional status. As noted above, RTI found that the model predicting costs using the CMGs derived from the items located in the Quality Indicators section of the IRF–PAI had a slightly higher R-squared value than models using the current CMGs which are derived from items in the FIM™ instrument, indicating that the revised CMGs more accurately predict resource use in IRFs than the CMGs that are currently utilized. As the data collected in the Quality Indicators section of the IRF–PAI have been collected nationally for all IRFs since October 1, 2016, we believe the data to be accurate and valid at this time. We also believe it is the responsibility of the IRF to submit accurate and valid data that adheres to the coding guidelines detailed in the IRF–PAI training manual.

*Comment:* Commenters expressed concern with the cognition items

collected on the IRF–PAI and their omission from the revised CMGs. A few commenters noted the importance of cognitive impairment in the IRF setting and encouraged CMS to conduct further analysis of the relationship between cognitive function and resource use in the IRF setting and to improve the items that are used to measure cognitive function.

*Response:* We appreciate the commenters’ concerns with the cognitive items that are collected on the IRF–PAI. As we discussed in the FY 2019 IRF PPS final rule (83 FR 38546), the cognitive items that we used for this analysis are the best ones that we have for use at the present time. Unfortunately, we found that including these cognitive items in generating the CMGs would have resulted in lower payments for patients with higher cognitive deficits. This result does not make sense from a clinical perspective, and could have the unintended consequence of reducing access to IRF care for more cognitively impaired beneficiaries. Thus, we determined that it would be better at this time to remove the CMG splits that were generated by the cognitive items. We appreciate the commenters’ suggestion to incorporate improved cognition measures into the IRF–PAI and will take this into consideration in the future.

*Comment:* Commenters suggested that CMS has not provided sufficient education, training materials, or supporting documentation regarding the functional items to support their use in developing a payment model. Some commenters suggested revisions to the existing training materials while other commenters requested that CMS provide additional training, monitor the data, and modify the case mix groupings as needed.

*Response:* We disagree with the commenters that we have provided insufficient training or guidance on proper coding of this data. We believe we have provided adequate training opportunities for IRFs on coding the Quality Indicator data items, including multiple in-person training opportunities, webinars, on-line training and on-going help desk guidance. We are committed to providing information and support that will allow providers to accurately interpret and complete quality reporting items and we will continue to provide these types of opportunities to the IRF community. We thank the commenters for their suggestions to improve the training materials and we appreciate the commenters’ suggestions to continue to monitor the data and make updates to

the case-mix classification system when necessary.

After careful consideration of the comments received, we are finalizing revisions to the CMGs based on analysis of 2 years of data (FYs 2017 and 2018) and the incorporation of the unweighted motor score described in section IV.B of this final rule. The revised CMGs that

will be effective October 1, 2019 are presented below in Table 3. We refer readers to Table 20 in section XIII.C of this final rule for more information on the distributional effects of revisions to the CMGs. For a provider specific impact analysis for this change, we refer readers to the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee->

*for-Service-Payment/InpatientRehab-FacPPS/IRF-Rules-and-Related-Files.html*. We are also updating the relative weights and average LOS values associated with the revised CMGs (reflecting an unweighted motor score) beginning with FY 2020.

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**TABLE 3: Relative Weights and Average Length of Stay Values  
for the Revised 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 >=72.50	1.0351	0.8965	0.8300	0.7906	11	11	10	9
0102	Stroke M >=63.50 and M <72.50	1.3150	1.1389	1.0545	1.0045	13	13	12	12
0103	Stroke M >=50.50 and M <63.50	1.6790	1.4541	1.3464	1.2825	15	16	15	15
0104	Stroke M >=41.50 and M <50.50	2.1958	1.9017	1.7608	1.6772	19	20	19	19
0105	Stroke M <41.50 and A >=84.50	2.4300	2.1046	1.9487	1.8562	22	22	21	20
0106	Stroke M <41.50 and A <84.50	2.8360	2.4562	2.2742	2.1663	27	26	24	24
0201	Traumatic brain injury M >=73.50	1.1593	0.9500	0.8568	0.7992	11	11	10	10
0202	Traumatic brain injury M >=61.50 and M <73.50	1.4366	1.1772	1.0618	0.9903	13	13	12	12
0203	Traumatic brain injury M >=49.50 and M <61.50	1.7487	1.4330	1.2924	1.2055	15	16	14	14
0204	Traumatic brain injury M >=35.50 and M <49.50	2.1339	1.7487	1.5772	1.4710	21	19	17	16
0205	Traumatic brain injury M <35.50	2.6631	2.1823	1.9683	1.8358	31	24	21	19
0301	Non-traumatic brain injury M >=65.50	1.2280	0.9995	0.9218	0.8618	11	11	10	10
0302	Non-traumatic brain injury M >=52.50 and M <65.50	1.5603	1.2700	1.1712	1.0950	14	14	13	13
0303	Non-traumatic brain injury M >=42.50 and M <52.50	1.8814	1.5313	1.4123	1.3203	17	16	15	15
0304	Non-traumatic brain injury M <42.50 and A >=78.50	2.1097	1.7171	1.5836	1.4805	20	18	17	16
0305	Non-traumatic brain injury M <42.50 and A <78.50	2.2889	1.8630	1.7182	1.6063	21	20	18	17
0401	Traumatic spinal cord injury M >=56.50	1.3702	1.1748	1.0753	0.9860	14	13	12	12
0402	Traumatic spinal cord injury M >=47.50 and M <56.50	1.7987	1.5423	1.4117	1.2944	15	18	16	15
0403	Traumatic spinal cord injury M >=41.50 and M <47.50	2.1749	1.8649	1.7070	1.5652	20	20	19	18
0404	Traumatic spinal cord injury M <31.50 and A <61.50	3.1944	2.7390	2.5070	2.2988	36	31	27	23
0405	Traumatic spinal cord injury M >=31.50 and M <41.50	2.7206	2.3328	2.1352	1.9578	27	27	23	21
0406	Traumatic spinal cord injury M >=24.50 and M <31.50 and A >=61.50	3.3266	2.8523	2.6108	2.3939	39	32	27	26
0407	Traumatic spinal cord injury M <24.50 and A >=61.50	4.1203	3.5330	3.2337	2.9651	49	37	32	36
0501	Non-traumatic spinal cord injury M >=60.50	1.2696	1.0371	0.9614	0.8798	13	12	11	10
0502	Non-traumatic spinal cord injury M >=53.50 and M <60.50	1.5859	1.2954	1.2009	1.0990	15	14	13	13
0503	Non-traumatic spinal cord injury M >=48.50 and M <53.50	1.8273	1.4926	1.3837	1.2663	17	15	15	14
0504	Non-traumatic spinal cord injury M >=39.50 and M <48.50	2.2209	1.8141	1.6817	1.5390	20	19	18	17
0505	Non-traumatic spinal cord injury M <39.50	2.8362	2.3166	2.1477	1.9654	30	24	23	21
0601	Neurological M >=64.50	1.3431	1.0441	0.9748	0.8864	12	11	11	10
0602	Neurological M >=52.50 and M <64.50	1.6641	1.2937	1.2078	1.0983	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 >=43.50 and M <52.50	1.9606	1.5242	1.4230	1.2940	16	16	15	14
0604	Neurological M <43.50	2.2535	1.7519	1.6356	1.4873	20	18	17	16
0701	Fracture of lower extremity M >=61.50	1.2511	1.0096	0.9644	0.8771	12	12	11	10
0702	Fracture of lower extremity M >=52.50 and M <61.50	1.5660	1.2636	1.2072	1.0978	14	14	13	13
0703	Fracture of lower extremity M >=41.50 and M <52.50	1.8960	1.5299	1.4615	1.3291	17	17	16	15
0704	Fracture of lower extremity M <41.50	2.1443	1.7303	1.6529	1.5032	18	18	18	17
0801	Replacement of lower-extremity joint M >=63.50	1.0611	0.8826	0.7992	0.7434	10	10	9	9
0802	Replacement of lower-extremity joint M >=57.50 and M <63.50	1.2506	1.0402	0.9419	0.8762	11	12	11	10
0803	Replacement of lower-extremity joint M >=51.50 and M <57.50	1.4028	1.1669	1.0566	0.9829	13	13	12	11
0804	Replacement of lower-extremity joint M >=42.50 and M <51.50	1.6133	1.3419	1.2151	1.1304	15	15	13	13
0805	Replacement of lower-extremity joint M <42.50	1.9202	1.5973	1.4463	1.3454	16	17	15	15
0901	Other orthopedic M >=63.50	1.2066	0.9641	0.8950	0.8243	11	11	10	10
0902	Other orthopedic M >=51.50 and M <63.50	1.5262	1.2196	1.1321	1.0427	13	14	13	12
0903	Other orthopedic M >=44.50 and M <51.50	1.7937	1.4333	1.3305	1.2254	15	15	14	14
0904	Other orthopedic M <44.5	2.0358	1.6268	1.5101	1.3908	18	17	16	15
1001	Amputation lower extremity M >=64.50	1.2854	1.0952	0.9915	0.9110	12	13	11	11
1002	Amputation lower extremity M >=55.50 and M <64.50	1.6019	1.3648	1.2357	1.1353	15	15	13	13
1003	Amputation lower extremity M >=47.50 and M <55.50	1.8483	1.5748	1.4258	1.3100	16	17	16	15
1004	Amputation lower extremity M <47.50	2.1480	1.8301	1.6570	1.5224	18	19	18	16
1101	Amputation non-lower extremity M >=58.50	1.4202	1.1802	1.0683	0.8943	13	13	12	10
1102	Amputation non-lower extremity M >=52.50 and M <58.50	1.7633	1.4653	1.3264	1.1103	15	14	14	13
1103	Amputation non-lower extremity M <52.50	2.0223	1.6806	1.5212	1.2734	17	19	15	14
1201	Osteoarthritis M >=61.50	1.2378	0.9532	0.9256	0.8600	11	11	10	10
1202	Osteoarthritis M >=49.50 and M <61.50	1.5753	1.2131	1.1780	1.0944	14	14	13	13
1203	Osteoarthritis M <49.50 and A >=74.50	1.7998	1.3860	1.3459	1.2505	15	16	15	14
1204	Osteoarthritis M <49.50 and A <74.50	1.9148	1.4746	1.4318	1.3303	15	15	16	15
1301	Rheumatoid other arthritis M >=62.50	1.1667	0.9831	0.9315	0.8579	11	11	10	10
1302	Rheumatoid other arthritis M >=51.50 and M <62.50	1.4269	1.2023	1.1392	1.0492	12	14	12	12
1303	Rheumatoid other arthritis M >=44.50 and M <51.50 and A >=64.50	1.6816	1.4169	1.3425	1.2365	13	15	14	14
1304	Rheumatoid other arthritis M <44.50 and A >=64.50	1.9036	1.6040	1.5198	1.3997	16	17	16	15
1305	Rheumatoid other arthritis M <51.50 and A <64.50	1.8768	1.5814	1.4984	1.3800	14	17	16	14
1401	Cardiac M >=68.50	1.1425	0.9303	0.8576	0.7707	11	11	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
1402	Cardiac M >=55.50 and M <68.50	1.4376	1.1706	1.0792	0.9698	13	13	12	11
1403	Cardiac M >=45.50 and M <55.50	1.7346	1.4125	1.3021	1.1702	15	15	14	13
1404	Cardiac M <45.50	2.0201	1.6450	1.5165	1.3628	18	17	16	15
1501	Pulmonary M >=68.50	1.2446	1.0612	0.9769	0.9280	11	11	10	10
1502	Pulmonary M >=56.50 and M <68.50	1.5082	1.2859	1.1838	1.1245	13	13	12	12
1503	Pulmonary M >=45.50 and M <56.50	1.7761	1.5143	1.3940	1.3242	15	14	14	13
1504	Pulmonary M <45.50	2.0391	1.7385	1.6005	1.5203	20	17	15	15
1601	Pain syndrome M >=65.50	1.1312	0.8992	0.8492	0.7836	10	11	10	9
1602	Pain syndrome M >=58.50 and M <65.50	1.3963	1.1099	1.0482	0.9672	11	11	12	11
1603	Pain syndrome M >=43.50 and M <58.50	1.6234	1.2904	1.2187	1.1245	13	14	13	13
1604	Pain syndrome M <43.50	1.8910	1.5031	1.4196	1.3098	14	15	15	14
1701	Major multiple trauma without brain or spinal cord injury M >=57.50	1.4098	1.1015	1.0310	0.9404	12	12	12	11
1702	Major multiple trauma without brain or spinal cord injury M >=50.50 and M <57.50	1.7293	1.3512	1.2647	1.1536	15	14	14	13
1703	Major multiple trauma without brain or spinal cord injury M >=41.50 and M <50.50	2.0092	1.5699	1.4694	1.3403	17	17	16	15
1704	Major multiple trauma without brain or spinal cord injury M >=36.50 and M <41.50	2.2231	1.7369	1.6258	1.4829	20	18	17	17
1705	Major multiple trauma without brain or spinal cord injury M <36.50	2.4140	1.8861	1.7654	1.6103	21	20	19	17
1801	Major multiple trauma with brain or spinal cord injury M >=67.50	1.1788	0.9975	0.8908	0.8151	13	11	10	10
1802	Major multiple trauma with brain or spinal cord injury M >=55.50 and M <67.50	1.5258	1.2911	1.1530	1.0551	15	15	13	12
1803	Major multiple trauma with brain or spinal cord injury M >=45.50 and M <55.50	1.8891	1.5984	1.4275	1.3063	19	18	15	15
1804	Major multiple trauma with brain or spinal cord injury M >=40.50 and M <45.50	2.1888	1.8521	1.6541	1.5136	26	21	18	16
1805	Major multiple trauma with brain or spinal cord injury M >=30.50 and M <40.50	2.5760	2.1797	1.9467	1.7813	27	22	20	20
1806	Major multiple trauma with brain or spinal cord injury M <30.50	3.4401	2.9109	2.5996	2.3788	40	31	28	25
1901	Guillain-Barré M >=66.50	1.2297	0.9638	0.9258	0.9026	13	11	11	11
1902	Guillain-Barré M >=51.50 and M <66.50	1.7299	1.3558	1.3024	1.2697	17	17	14	15
1903	Guillain-Barré M >=38.50 and M <51.50	2.6270	2.0589	1.9778	1.9282	26	23	22	21
1904	Guillain-Barré M <38.50	3.7274	2.9213	2.8063	2.7359	44	30	29	30
2001	Miscellaneous M >=66.50	1.2127	0.9812	0.9107	0.8268	11	11	10	10
2002	Miscellaneous M >=55.50 and M <66.50	1.4948	1.2094	1.1225	1.0192	13	13	12	12
2003	Miscellaneous M >=46.50 and M	1.7515	1.4171	1.3152	1.1942	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
	<55.50								
2004	Miscellaneous M <46.50 and A >=77.50	1.9679	1.5922	1.4778	1.3417	18	17	16	15
2005	Miscellaneous M <46.50 and A <77.50	2.1020	1.7007	1.5785	1.4332	19	18	16	16
2101	Burns M >=52.50	1.5423	1.2723	1.1809	1.0614	15	13	13	12
2102	Burns M <52.50	2.2036	1.8179	1.6873	1.5165	22	19	16	17
5001	Short-stay cases, length of stay is 3 days or fewer				0.1816				3
5101	Expired, orthopedic, length of stay is 13 days or fewer				0.5703				6
5102	Expired, orthopedic, length of stay is 14 days or more				1.7939				18
5103	Expired, not orthopedic, length of stay is 15 days or fewer				0.6740				7
5104	Expired, not orthopedic, length of stay is 16 days or more				2.1956				22

**BILLING CODE 4120-01-C****V. 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.

**VI. 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, in the FY 2020 IRF proposed rule, we proposed 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 (84 FR 17261).

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 (MCR) data for both freestanding and hospital-based IRFs (80 FR 47049 through 47068). Beginning with FY 2020, we proposed 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 2016-Based IRF Market Basket**

The 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 (for the proposed IRF market basket, 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 to furnish inpatient care between base periods.

### *C. Rebasings 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 proposed 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 MCR data as described in section VI.C.a.(6) of this final rule.

#### 1. Development of Cost Categories and Weights for the 2016-Based IRF Market Basket

##### a. Use of Medicare Cost Report Data

We proposed 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 MCR data available for developing the IRF market basket at the time of the proposed rule.

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 proposed to limit the cost reports used to establish the 2016-based IRF market basket to those from facilities that had a Medicare average 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 proposed 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 proposed 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 MCR data to

derive the Home Office Contract Labor cost weight. A more detailed discussion of this methodological change is provided in section VI.C.1.a.(6) of this final 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.

For freestanding IRFs, total Medicare allowable costs would be equal to the total costs as reported on Worksheet B, part I, column 26, lines 30 through 35, 50 through 76 (excluding 52 and 75), 90 through 91, and 93. For hospital-based IRFs, total Medicare allowable costs would be equal to the 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 reported on Worksheet B, part I, column 26, lines 50 through 76 (excluding 52 and 75), 90 through 91, and 93. We proposed 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 proposed 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 proposed 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 proposed to estimate the proportion of overhead salaries that are attributed to Medicare allowable cost 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 proposed 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 proposed 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 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 proposed 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 proposed 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 MCR 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 proposed 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 proposed to use the sum of Worksheet S-3, part II, lines 17, 18, 20, and 22, to derive Employee Benefits costs. This proposed method allows 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 proposed 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 proposed inpatient unit benefit costs be equal to Worksheet S-3, part V, column 2, line 4. We proposed 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 VI.C.3. of this final rule. To derive contract labor costs using Worksheet S-3, part V, data, for freestanding IRFs, we proposed 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 proposed to use the sum of Worksheet S-3, part II, lines 11 and 13, to derive Contract Labor costs.

For hospital-based IRFs, we proposed that Contract Labor costs would be equal to Worksheet S-3, part V, column 1, line 4. As previously noted, for 2016 MCR 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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, part I, columns 1 through 3, line 118. For hospital-based IRFs, we proposed 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, part I, 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.

#### (6) Home Office/Related Organization Contract Labor Costs

For the 2016-based IRF market basket, we proposed to determine the home office/related organization contract labor costs using MCR 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 VI.C.3. of this final rule. For freestanding and hospital-based IRFs, we proposed 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 I, column 26, line 202). We proposed 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 proposed 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 proposed 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 MCR data as previously described, we proposed 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 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 proposed 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 then proposed 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 then proposed 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 proposed to weight these two cost weights together using

the Medicare-allowable costs to derive a Home Office Contract Labor cost weight for the 2016-based IRF market basket.

Finally, we proposed to calculate the residual “All Other” cost weight that reflects all remaining costs that are not captured in the seven cost categories listed.

We received a few comments on our proposed derivation of the Home Office Contract Labor cost weight from the Medicare cost reports, which are summarized below.

*Comment:* Commenters expressed concern with the proposed methodology change to the Home Office Contract Labor cost weight. These commenters stated that CMS had not provided sufficient rationale for this change in methodology nor has CMS provided a discussion of how these data points were reasonably validated and tested. One commenter requested that CMS provide stakeholders with more information on the rationale and the data validation methodologies employed in the final rule.

The commenters expressed concern with the sample of IRFs reporting the home office cost data and found based on their analysis that reporting was between 50 to 65 percent. These commenters suggested that this was due to these cost report line items being an optional category for IRFs under Medicare cost reporting requirements. One of the commenters further expressed concern with the methodology and approach that CMS applied in determining IRF unit Home Office Contract Labor amounts, specifically the assumption that hospital-based IRFs utilize the same proportion of home office expenses as the rest of the acute care hospital in which it is located. The commenter stated that typically IRF units are a very small part of the larger parent acute care hospital and that the larger systems do not spend the same proportional time and resources on these units compared to hospital system as a whole. They stated that this assumption likely overstates the Home Office Contract Labor cost weight.

Based on these concerns, the commenters requested that CMS not finalize its proposed changes to the Home Office Contract Labor cost category and instead finalize use of the previous methodology relating to this category that was used for the 2012-based market basket. One commenter also requested that CMS revisit this potential change with adequate explanation and data in future rulemaking.

*Response:* We appreciate the commenters’ concerns on the proposed

methodological change for the Home Office Contract Labor cost weight. We proposed to revise our methodology and use the 2016 IRF MCR data to calculate the Home Office Contract Labor costs rather than the 2012 Benchmark I–O data because it reflected more up-to-date data and we believe it to be an improvement over the use of the BEA Benchmark I–O data that is not specific to IRFs. The MCR data allows us to calculate Home Office Contract Labor Costs for freestanding and IRF hospital-based facilities.

We disagree with the commenters’ concern that the MCR data completion rates for the Home Office Contract Labor costs are inadequate to obtain a cost weight. When developing the proposed 2016-based IRF market basket, we conducted a thorough analysis of the MCR data and our proposed Home Office Contract Labor cost weight methodology. We found that approximately 90 percent of freestanding IRFs reported having a home office, of which over 50 percent reported home office compensation data on Worksheet S–3, part II. The composition of the providers (by ownership-type and region) that reported both wage index data (including those who do not have a home office) and home office contract labor cost data were similarly representative to all freestanding IRFs. A sensitivity analysis of calculating a reweighted Home Office Contract Labor cost weight based on ownership-type and region produced a Home Office Contract Labor cost weight similar to the proposed 3.7 percent weight.

For additional sensitivity testing, recognizing that some of the freestanding IRFs with home offices may not have completed the applicable fields on the MCR, we calculated a weight using only freestanding IRFs that reported having a home office (Worksheet S–2, part I, line 140). This produced a Home Office Contract Labor cost weight nearly identical to the freestanding IRF 2016 cost weight using our proposed methodology. Based on this analysis, we believe that the sample of providers included in the Home Office Contract Labor cost weight are a technically representative sample of all IRF providers.

Regarding IRF units, we recognize the commenter’s concern that they represent a small proportion of the total facility. We believe that the assumption that IRFs utilize the same proportion of home office expenses as the rest of the acute care hospital is reasonable. The use of total facility data assumes the facility Home Office Contract Labor cost weight is equal to the Home Office

Contract Labor cost weight for the IRF unit. Further analysis of the MCR data shows IRF unit direct patient care costs (as reported on Worksheet B, part I, column 0, line 41) account for about one percent of total facility costs (excluding capital, Administrative and General (A&G), and Employee Benefit department costs). Similarly, A&G costs (Worksheet B, part I, column 0, line 5), where Home Office Contract Labor costs are likely captured, allocated to the IRF unit account for a similar proportion of direct patient care costs with about one percent of total A&G costs. We also found the proportion of allocated A&G costs for other larger, more medically-complex hospital units (such as the intensive care, surgical care, and operating room) were consistent with direct patient care cost proportions and the proportions for these units were higher than the proportion of the A&G expenses allocated to the IRF unit. This supports the commenter’s claim that hospitals allocate less A&G costs to less medically-complex services (as measured by costs). Our proposed calculation would adhere to this assumption as well since the facility level cost weight is applied to the IRF Medicare allowable total costs representing these relatively less medically-complex services. Furthermore, the Benchmark I–O methodology used in the 2012-based IRF market basket also assumes that the IRF relative costs are the same as those of the hospital total facility. We invite the commenters to submit additional data that would help in this area for consideration in future rulemaking.

We disagree with the commenters’ request to use the Benchmark I–O data to calculate the Home Office Contract Labor cost weight rather than the proposed 2016 MCR data. We believe the proposed methodology is a technical improvement over the prior methodology because it represents more recent data that is representative compositionally and geographically of IRFs. It is also the same data used to determine the other major cost weights in the 2016-based market basket and the proportion of the Home Office Contract Labor cost weight that is allocated to the Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost weights. We believe the assumptions made by using the total facility data for the hospital-based IRFs are reasonable and supported by the MCR data on A&G cost allocation. Finally, we note that the methodological change accounts for only 0.2 percentage point of the 2.0 percentage points change in the labor-related share.

After careful consideration of comments, we are finalizing our

methodology for deriving the major cost weights as proposed.

Table 4 presents the cost weights for these major cost categories calculated

from the Medicare cost reports for the 2016-based IRF market basket, as well as for the 2012-based IRF market basket.

**TABLE 4: Major Cost Categories as Derived from Medicare Cost Reports**

Major Cost Categories	Final 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

Note: Total may not sum to 100 due to rounding.

As we did for the 2012-based IRF market basket, we proposed 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 the proposed rule, this rounded percentage is 81 percent; therefore, we proposed 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). We did not receive any specific public comments on our proposed allocation of Contract Labor. Therefore, we are finalizing our method of allocating Contract Labor as proposed.

Table 5 shows the Wages and Salaries and Employee Benefit cost weights after Contract Labor cost weight allocation for both the 2016-based IRF market basket and 2012-based IRF market basket.

**TABLE 5: Wages and Salaries and Employee Benefits Cost Weights After Contract Labor Allocation**

Major Cost Categories	Final 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 MCR data into more detailed cost categories, we proposed to use the 2012 Benchmark I–O “Use Tables/Before Redefinitions/Purchaser Value” for NAICS 622000, Hospitals, published by the 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.<sup>1</sup> 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 proposed 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

<sup>1</sup> [http://www.bea.gov/papers/pdf/IOmanual\\_092906.pdf](http://www.bea.gov/papers/pdf/IOmanual_092906.pdf).

repeat this practice for each year. We then proposed 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 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 2016-based IRF market basket (0.05 \* 22.2 percent = 1.1 percent).

Using this methodology, we proposed to derive seventeen detailed IRF market

basket cost category weights from the 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 2016-based IRF market basket, we proposed 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 proposed to use the MCR 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.

We did not receive any specific comments on the derivation of the detailed operating cost weights. In this final rule, we are finalizing our methodology for deriving the detailed operating cost weights as proposed.

#### d. Derivation of the Detailed Capital Cost Weights

As described in section VI.C.1.a.(6) of this final rule, we proposed 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 proposed to then separate this total Capital-Related cost weight into more detailed cost categories.

Using 2016 Medicare cost reports, we were able to group Capital-Related costs into the following categories: Depreciation, Interest, Lease, and Other Capital-Related costs. For each of these categories, we proposed to determine separately for hospital-based IRFs and freestanding IRFs what proportion of total capital-related costs the category represents.

For freestanding IRFs, we proposed 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 were not reported separately for the hospital-based IRF; therefore, we proposed to derive these proportions using data reported on Worksheet A-7 for the total facility. We assumed 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 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 2016-based IRF market basket, we proposed 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 2016-based IRF market basket. Rather, we proposed 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 proposed 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 proposed 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 resulted in three primary capital-related

cost categories in the 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 proposed to further divide the Depreciation and Interest cost categories. We proposed to separate Depreciation into the following two categories: (1) Building and Fixed Equipment; and (2) Movable Equipment. We proposed 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 are attributable to Building and Fixed Equipment, which we hereafter refer to as the "fixed percentage." For the 2016-based IRF market basket, we proposed to use slightly different methods to obtain the fixed percentages for hospital-based IRFs compared to freestanding IRFs.

For freestanding IRFs, we proposed 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 proposed 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 proposed to weight these two fixed percentages (inpatient and ancillary) using the proportion that each capital cost type represents of total capital costs in the 2016-based IRF market basket. We proposed 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 proposed to use interest costs data from Worksheet A-7 of the 2016 Medicare cost reports for both freestanding and hospital-based IRFs. We proposed 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 proposed to weight the nonprofit percentages for hospital-based and freestanding IRFs together using the proportion of total capital costs that each provider type represents.

We did not receive any specific public comments on the derivation of the detailed capital cost weights. In this final rule, we are finalizing our

methodology for deriving the detailed capital cost weights as proposed. Table 6 provides the 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 VI.C.1.a.(6) of this final rule.

**TABLE 6: Capital Cost Share Composition for the 2016-based IRF Market Basket**

	Capital Cost Share Composition before Lease Expense Allocation	Capital Cost Share Composition after Lease Expense Allocation
<b>Depreciation</b>	<b>59%</b>	<b>73%</b>
Building and Fixed Equipment	37%	45%
Movable Equipment	22%	28%
<b>Interest</b>	<b>13%</b>	<b>16%</b>
Government/Nonprofit	8%	9%
For Profit	5%	7%
Lease	21%	-
<b>Other</b>	<b>7%</b>	<b>11%</b>

Note: Detail may not add to total due to rounding.

e. 2016-Based IRF Market Basket Cost Categories and Weights

Table 7 compares the cost categories and weights for the final 2016-based IRF

market basket compared to the 2012-based IRF market basket.

**TABLE 7: 2016-based IRF Market Basket Cost Weights Compared to 2012-based IRF Market Basket Cost Weights**

Cost Category	Final 2016-based IRF Market Basket Cost Weight	2012-based IRF Market Basket Cost Weight
<b>Total</b>	<b>100.0</b>	<b>100.0</b>
<b>Compensation</b>	<b>59.4</b>	<b>59.2</b>
Wages and Salaries	47.9	47.9
Employee Benefits	11.4	11.3
<b>Utilities</b>	<b>1.4</b>	<b>2.1</b>
Electricity	1.0	1.0
Fuel, Oil, and Gasoline	0.4	1.1
Water & Sewerage	n/a	0.1
<b>Professional Liability Insurance</b>	<b>0.7</b>	<b>0.9</b>
<b>All Other Products and Services</b>	<b>29.5</b>	<b>29.1</b>
<b>All Other Products</b>	<b>12.5</b>	<b>13.3</b>
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
<b>All Other Services</b>	<b>17.0</b>	<b>15.8</b>
<b>Labor-Related Services</b>	<b>9.2</b>	<b>8.0</b>
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
<b>Nonlabor-Related Services</b>	<b>7.9</b>	<b>7.8</b>
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
<b>Capital-Related Costs</b>	<b>9.0</b>	<b>8.6</b>
<b>Depreciation</b>	<b>6.5</b>	<b>6.4</b>
Fixed Assets	4.1	4.1
Movable Equipment	2.5	2.3
<b>Interest Costs</b>	<b>1.5</b>	<b>1.4</b>
Government/Nonprofit	0.9	0.9
For Profit	0.6	0.5
<b>Other Capital-Related Costs</b>	<b>1.0</b>	<b>0.8</b>

Note: Detail may not add to total due to rounding.

## 2. Selection of Price Proxies

After developing the cost weights for the 2016-based IRF market basket, we selected 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 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 10 lists all price proxies that we proposed to use for the 2016-based IRF market basket. Below is a detailed

explanation of the price proxies we proposed for each cost category weight. We did not receive any specific comments on our proposed price proxies for the 2016-based IRF market basket. Therefore, in this final rule, we are finalizing the price proxies as proposed.

#### a. Price Proxies for the Operating Portion of the 2016-Based IRF Market Basket

##### (1) Wages and Salaries

We proposed to continue to use the ECI for Wages and Salaries for All Civilian workers in Hospitals (BLS series code CIU1026220000000I) 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 proposed 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 CIU1016220000000I) 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 proposed 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 proposed 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 proposed 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 2016-based IRF market basket.

##### (5) Professional Liability Insurance

We proposed 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 proposed 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 proposed 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 proposed 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 proposed to use a four part blended PPI as the proxy for the chemical cost category in the 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 2016-based IRF market basket, we proposed 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 8 shows the weights for each of the four PPIs used to create the proposed blended Chemical proxy for the 2016 IRF market basket compared to the 2012-based blended Chemical proxy.

**TABLE 8: Blended Chemical PPI Weights**

Name	Final 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 2016-Based IRF Market Basket

(1) Capital Price Proxies Prior to Vintage Weighting

We proposed to continue to use the same price proxies for the capital-related cost categories in the 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 proposed 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 proposed 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 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 proposed 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 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 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 proposed to use data from the AHA Panel Survey and the AHA Annual Survey to obtain a time series of total expenses for hospitals. We then proposed 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 proposed 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 2016-based IRF market basket. We proposed to calculate

the expected lives using MCR 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 proposed 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 proposed to apply a similar method for movable equipment. Using these 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 proposed 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 final rule. For the interest vintage weights, we proposed 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 proposed 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 32, 22-year periods of capital-related purchases for building and fixed

equipment and interest, and 43, 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.

We did not receive any specific public comments on our proposed calculation of the vintage weights for the 2016-based IRF market basket. Therefore, in this final rule, we are finalizing the vintage weights as proposed. The vintage weights for the capital-related portion of the 2016-based IRF market basket and the 2012-based IRF market basket are presented in Table 9.

**TABLE 9: Final 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.

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 2016-Based IRF Market Basket

Table 10 shows both the operating and capital price proxies for the 2016-based IRF market basket.

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**TABLE 10: Price Proxies and Cost Share Weights for Use in the Final 2016-based IRF Market Basket**

<b>Cost Description</b>	<b>Price Proxies</b>	<b>Weight</b>
<b>Total</b>		<b>100.0%</b>
<b>Compensation</b>		<b>59.4%</b>
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%
<b>Utilities</b>		<b>1.4%</b>
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%
<b>Professional Liability Insurance</b>		<b>0.7%</b>
Malpractice	CMS Hospital Professional Liability Insurance Premium Index	0.7%
<b>All Other Products and Services</b>		<b>29.5%</b>
<b>All Other Products</b>		<b>12.5%</b>
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%
<b>All Other Services</b>		<b>17.0%</b>
<b>Labor-Related Services</b>		<b>9.2%</b>
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%
<b>Nonlabor-Related Services</b>		<b>7.9%</b>
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%
<b>Capital-Related Costs</b>		<b>9.0%</b>
<b>Depreciation</b>		<b>6.5%</b>
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%
<b>Interest Costs</b>		<b>1.5%</b>
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%
<b>Other Capital-Related Costs</b>	CPI-U for Rent of primary residence	<b>1.0%</b>

Note: Totals may not sum to 100.0 percent due to rounding.

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*D. FY 2020 Market Basket Update and Productivity Adjustment*

## 1. FY 2020 Market Basket Update

For FY 2020 (that is, beginning October 1, 2019 and ending September 30, 2020), we proposed to use the 2016-based IRF market basket increase factor described in section V.C. of the proposed rule to update the IRF PPS base payment rate. Consistent with historical practice, we proposed 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 MFP. In the FY 2020 IRF PPS proposed rule (84 FR 17274), we proposed a market basket increase factor of 3.0 percent for FY 2020, which was based on IGI's first quarter 2019 forecast with historical data through fourth quarter 2018.

In the FY 2020 IRF PPS proposed rule, we also proposed that if more recent data were 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 update in the final rule. Incorporating more recent data, the projected 2016-based IRF market basket increase factor for FY 2020 is 2.9 percent, which is based on IGI's second quarter 2019 forecast with historical data through first quarter 2019.

We received several comments on our proposed market basket update and productivity adjustment, which are summarized below.

*Comment:* Commenters supported the proposal to update the market basket and MFP adjustment using the latest available data, and encouraged CMS to update these factors using the latest available data as part of the release of the FY 2020 IRF PPS final rule.

*Response:* We appreciate the commenters' support for updating the market basket and MFP adjustments using the latest available data.

*Comment:* A few commenters expressed concern about the lack of

transparency of the market basket and MFP payment updates. The commenters stated that the IGI forecast appears to be procured specifically for the purpose of CMS updating the IRF market basket and productivity adjustment. The commenters also noted that it is concerning that CMS does not provide IGI's analyses or report to the public given the key role the market basket and productivity adjustment play in updating the payment system each year and that without such information stakeholders are unable to evaluate the accuracy of the update. The commenters also mentioned that the same comment was submitted in the FY 2019 rulemaking process but they do not believe that the response was adequate since the actual analysis or report used to create the forecasts was not provided (83 FR 38525). The commenters requested that CMS release an IGI report and analysis used to update the IRF market basket and standard payment conversion factor.

*Response:* IGI regularly produces and publishes a wide variety of forecasted series on a monthly or quarterly basis. These forecasts are derived using a framework of proprietary economic models that are created and updated regularly by IGI. IGI provides these forecasts to a wide array of clients in addition to CMS. We use a contractor for the price forecasts so that the forecasts are independent and reflect a complete economic forecasting model, a capability that we do not have. IGI has received multiple awards for their macroeconomic forecast accuracy of major economic indicators. We use IGI's price forecasts in all of the FFS market baskets used for payment updates and has used the forecasts produced by this company for many years.

We select approximately 30 individual price proxies as inputs to the IRF market basket calculation. The price series are discussed in detail as part of the rulemaking process. In order to derive a forecast of the IRF market basket index, we contract with IGI to procure the forecasts of these individual price proxies on a quarterly basis. We then combine these price proxies with the market basket base year cost weights

to derive the levels of the IRF market basket. The data sources and methods used to derive these cost weights are discussed in detail as part of the rulemaking process.

As provided in our previous response to this comment in the FY 2019 IRF PPS final rule (83 FR 38525), the market basket update is derived using: (1) The market basket base year cost weights as finalized by CMS through rulemaking; and (2) the most up-to-date forecast of the price proxies used in the market basket as forecasted by IGI. Specifically, for each cost category in the market basket (for example, Wages and Salaries, Pharmaceuticals), the level of each of these price proxies are multiplied by the cost weight for that cost category. The sum of these products (that is, weights multiplied by proxied index levels) for all cost categories yields the composite index level in the market basket in a given year.

As acknowledged by the commenters, we provided a link from the CMS website to the top-line market basket updates. We also indicated that more detailed forecasts of the IRF market basket calculations are readily available by request by sending an email to [CMSDNHS@cms.hhs.gov](mailto:CMSDNHS@cms.hhs.gov) to request this information (83 FR 38525). Using these detailed data, the commenter would be able to replicate the levels of the IRF market basket update in the history and the forecast period. We encourage stakeholders to utilize these data, which we believe will address the commenters' concerns.

Incorporating more recent data, the projected 2016-based IRF market basket update for FY 2020 is 2.9 percent. After careful consideration of the comments, consistent with our historical practice of estimating market basket increases based on the best available data, we are finalizing a market basket increase factor of 2.9 percent for FY 2020. For comparison, the current 2012-based IRF market basket is also projected to increase by 2.9 percent in FY 2020 based on IGI's second quarter 2019 forecast.

Table 11 compares the 2016-based IRF market basket and the 2012-based IRF market basket percent changes.

**TABLE 11: Final 2016-Based IRF Market Basket and 2012-Based IRF Market Basket Percent Changes, FY 2015 through FY 2022**

	Fiscal Year (FY)	Final 2016-Based IRF Market Basket Index Percent Change	2012-Based IRF Market Basket Index Percent Change
<b>Historical data</b>	FY 2015	1.7	1.6
	FY 2016	1.8	1.8
	FY 2017	2.4	2.5
	FY 2018	2.3	2.4
	<b>Average 2015-2018</b>	<b>2.1</b>	<b>2.1</b>
<b>Forecast</b>	FY 2019	2.5	2.6
	FY 2020	2.9	2.9
	FY 2021	3.1	3.2
	FY 2022	3.1	3.1
	<b>Average 2019-2022</b>	<b>2.9</b>	<b>3.0</b>

Note that these market basket percent changes do not include any further adjustments as may be statutorily required.

Source: IHS Global Inc. 2nd quarter 2019 forecast.

## 2. 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 VI.C and VI.D.1. of this final rule, we are finalizing an estimate of the IRF PPS increase factor for FY 2020 based on the 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 proposed MFP adjustment for FY 2020 (the 10-year moving average of MFP for the period ending FY 2020) was 0.5 percent (84 FR 17274). Thus, in accordance with section 1886(j)(3)(C) of the Act, we proposed 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 2016-based IRF market basket. We proposed to then reduce this percentage increase by the current estimate of the proposed 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 proposed FY 2020 IRF update was 2.5 percent (3.0 percent market basket update, less 0.5 percentage point MFP adjustment). Furthermore, we proposed 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.

We received a few comments on the application of the productivity adjustment, which are summarized below.

*Comment:* Commenters continue to be concerned about the application of the productivity adjustment to IRFs. One of the commenters stated that they understood CMS is bound by statute to reduce the market basket update by a productivity adjustment factor in accordance with the PPACA, but they

believe that IRFs are unable to generate additional productivity gains at a pace matching the productivity of the economy at large on an ongoing, consistent basis. The commenter noted that the services provided in IRFs are labor-intensive and the services do not lend themselves to continuous productivity improvements. The commenter also noted that IRFs are bound by unchanging labor-intensive standards such as the 3-hour therapy rule and other regulatory requirements that reduce flexibility and restrict the pursuit of certain efficiencies. The commenter noted that continued application of a productivity adjustment to payments could result in decreased beneficiary access to IRF services. The commenter requested that CMS continue to monitor the impact that the multi-factor productivity adjustments have on the IRF sector, provide feedback to Congress as appropriate, and reduce the productivity adjustment. One commenter requested that, in addition to monitoring its effects on overall payments, CMS should evaluate whether IRFs are able to achieve the same level of productivity improvement as workers across the U.S. economy.

*Response:* We acknowledge the commenters' concerns regarding productivity growth at the economy-wide level and its application to IRFs. As the commenter acknowledges, section 1886(j)(3)(C)(ii)(I) of the Act requires the application of a productivity adjustment to the IRF PPS market basket increase factor.

We will continue to monitor the impact of the payment updates, including the effects of the productivity

adjustment, on IRF finances, as well as beneficiary access to care.

We note that each year, MedPAC makes an annual update recommendation to Congress based on a variety of measures related to payment adequacy, including a detailed margin analysis and analysis of beneficiary access to care for IRF services. For FY 2020, MedPAC recommended that Congress reduce the IRF PPS base rate by 5 percent and found that beneficiary access to care was not a concern. The “March 2019 Report to the Congress: Medicare Payment Policy”, chapter 10 is publicly available at <http://www.medpac.gov/-documents-/reports>.

We would be very interested in better understanding IRF-specific productivity; however, the data elements required to estimate IRF specific multi-factor productivity are not produced at the level of detail that would allow this analysis. We have estimated hospital-sector multi-factor productivity and have published the findings on the CMS website at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/ProductivityMemo2016.pdf>.

After careful consideration of comments, we are incorporating more recent data to determine the market basket update and MFP adjustment for FY 2020. Using IGI's second quarter 2019 forecast, the current estimate of the MFP adjustment for FY 2020 (the 10-year moving average of MFP for the period ending FY 2020) is 0.4 percent. Thus, in accordance with section 1886(j)(3)(C) of the Act, we are finalizing a FY 2020 market basket update of 2.9 percent. We then reduce this percentage increase by the most recent estimate of the MFP adjustment for FY 2020 of 0.4 percentage point (the 10-year moving average of MFP for the period ending FY 2020 based on IGI's second quarter 2019 forecast). Therefore, the final FY 2020 IRF productivity-adjusted market basket update is equal to 2.5 percent (2.9 percent market basket update, less 0.4 percentage point MFP adjustment).

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, we are finalizing an update to IRF PPS payment rates for FY 2020 by a productivity-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.

*Comment:* One commenter (MedPAC) stated that they understand that CMS is required to implement the statutory update of market basket less productivity adjustment, but that their analysis of beneficiary access to rehabilitative services, the supply of providers, and aggregate IRF Medicare margins, which have been above 11 percent since 2012, indicates that the Congress should reduce the IRF payment rate by 5 percent for FY 2020.

*Response:* We appreciate MedPAC's interest in the IRF increase factor. However, we are required to update IRF PPS payments by the market basket reduced by the productivity adjustment, as directed by section 1886(j)(3)(C) of the Act.

#### *E. 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 proposed 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 2016-based IRF market basket, we proposed 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 2016-based IRF market basket.

Similar to the 2012-based IRF market basket (80 FR 47067), the 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 2016-based IRF market basket, we proposed 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 proposed 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 proposed 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 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 proposed 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 proposed 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 proposed 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 Fees: Labor-related and Professional Fees: Nonlabor-related cost categories.

Similar to the 2012-based IRF market basket, we proposed 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 MCR requires a hospital to report information regarding their home office provider. For the 2016-based IRF market basket, we proposed 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 VI.B. of this final rule. For both freestanding and hospital-based providers, we proposed 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 proposed 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 proposed 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 allocated 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.

We received several comments on the proposed labor-related share, which are summarized below.

*Comment:* A few commenters noted that the cost weight for Home Office Contract Labor costs is 3.7 percent of all IRFs' costs and influences changes in other payment areas, such as the total labor-related share. The commenters stated that they believe the proposed changes to the methodology are responsible, at least in large part, to the notable proposed increase of approximately 2 percent of the labor-related share. Some of the commenters also stated that the increase in the labor-related share will adversely impact rural IRFs and IRFs with a wage index below 1.0.

*Response:* The labor-related share for IRFs is derived from the relative importance of the labor-related cost categories. The relative importance for FY 2020 reflects the different rates of price change for each of the individual cost categories between the base year and FY 2020. For the FY 2020 final rule, as proposed, the final labor-related share for FY 2020 is based on a more recent forecast of the 2016-based IRF market basket. Using the more recent forecast, the total difference between the FY 2020 labor-related share using the 2016-based IRF market basket and 2012-based IRF market basket is 2.0 percentage points (72.7 percent using

2016-based IRF market basket and 70.7 percent using 2012-based IRF market basket). This difference can be separated into two primary components: (1) Revision to the base year cost weights (1.4 percentage points); and (2) revision to starting point of calculation of relative importance (base year) from 2012 to 2016 (0.6 percentage point). Of the 1.4-percentage points difference in the base year cost weights, just 0.2 percentage point is attributable to deriving the Home Office Contract Labor cost weight using the MCR data rather than the I-O data; the remainder is due to the increase in Compensation and Capital cost weights (calculated using the MCR data) and the incorporation of the 2012 Benchmark I-O data.

The impact of using the MCR data to calculate the Home Office Contract Labor cost weight is minimal because it also lowers the residual "All Other" cost weight from 25.8 percent (using the I-O data to calculate the Home Office Contract Labor cost weight) to 22.2 percent (using the MCR data to calculate the Home Office Contract labor cost weight). The lower residual "All Other" cost weight then leads to relatively lower cost weights for Administrative and Business Support Services, Installation, Maintenance and Repair Services, and All Other: Labor-related Services (which are calculated using the Benchmark I-O data), each of which is also reflected in the labor-related share.

After careful consideration of comments, in this final rule, we are finalizing the 2016-based IRF market basket labor-related share cost weights as proposed.

As stated previously, we proposed 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 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 2nd quarter 2019 forecast for the 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 are 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 8.6 percent of the 2016-based IRF market basket in FY 2020, we took 46 percent of 8.6 percent to determine the labor-related share of

Capital for FY 2020 of 4.0 percent. Therefore, we are finalizing a total labor-related share for FY 2020 of 72.7 percent (the sum of 68.7 percent for the operating costs and 4.0 percent for the labor-related share of Capital).

Table 12 shows the FY 2020 labor-related share using the final 2016-based IRF market basket relative importance and the FY 2019 labor-related share which was based on the 2012-based IRF market basket relative importance.

**TABLE 12: FY 2020 IRF Labor-Related Share and FY 2019 IRF Labor-Related Share**

	<b>FY 2020 Final Labor-Related Share <sup>1</sup></b>	<b>FY 2019 Final Labor-Related Share <sup>2</sup></b>
Wages and Salaries	48.1	47.7
Employee Benefits	11.4	11.1
Professional Fees: Labor-related <sup>3</sup>	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
<b>Subtotal</b>	<b>68.7</b>	<b>66.7</b>
Labor-related portion of capital (46%)	4.0	3.8
<b>Total Labor-Related Share</b>	<b>72.7</b>	<b>70.5</b>

<sup>1</sup> Based on the final 2016-based IRF Market Basket, IHS Global Insight, Inc. 2nd quarter 2019 forecast.

<sup>2</sup> Based on the 2012-based IRF market basket as published in the **Federal Register** (83 FR 38526).

<sup>3</sup> Includes all contract advertising and marketing costs and a portion of accounting, architectural, engineering, legal, management consulting, and home office contract labor costs.

#### *F. Update to the IRF Wage Index To Use Concurrent 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. Update to the IRF Wage Index To Use Concurrent 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 FY IPPS wage data in the creation of an IRF wage index. We believed that a wage index based on FY 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 FY 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 (PAC) settings. For the IRF PPS, we use a 1-year lag of the pre-floor, pre-reclassified FY 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 IPPS wage index ((83 FR 39172 through 39178) and (83 FR 41731), respectively).

As we look towards a more unified PAC payment system, we believe that standardizing the wage index data across PAC settings is necessary. Therefore, we proposed to change the IRF wage index methodology to align with other PAC settings. Specifically, we proposed changing from our established policy of using the pre-floor, pre-reclassified FY IPPS wage index (that is, for FY 2020 we proposed to use the concurrent FY 2020 pre-floor, pre-reclassified IPPS wage index under the IRF PPS). This proposed change would use the concurrent IPPS pre-floor, pre-reclassified 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 proposed to use the FY 2020 pre-floor, pre-reclassified IPPS wage index, which is based on data submitted for hospital cost reporting periods beginning in FY 2016. We proposed to implement these revisions in a budget neutral manner. For more information

on the distributional impacts of this proposal, we refer readers to the FY 2020 IRF PPS proposed rule (84 FR 17278).

Using the current pre-floor, pre-reclassified FY 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 received 7 comments on this proposal to align the data timeframes with that of the IPPS by using the FY 2020 pre-floor, pre-reclassified FY IPPS wage index as the basis for the FY 2020 IRF wage index, which are summarized below.

*Comment:* All of the commenters supported CMS' proposal to use the FY 2020 pre-floor, pre-reclassified FY IPPS wage index for the FY 2020 IRF wage index. Commenters agreed that the proposed change to use the concurrent FY IPPS wage index data would align the wage index data across PAC settings and move in the direction of unified PAC payment. A few commenters recommended that CMS adopt other wage index policies for IRFs that apply to or have been proposed for IPPS hospitals, such as geographic reclassifications, suggesting that this would increase consistency and alignment across settings.

*Response:* We appreciate the commenter's support for the proposal. We agree that finalizing this proposal is necessary as we move towards a more unified PAC payment system. We plan to monitor the use of the concurrent FY IPPS wage index data before we consider any other potential wage index policy changes.

After careful consideration of the comments we received, we are finalizing our proposal to align the data timeframes with that of the IPPS by using the concurrent pre-floor, pre-reclassified IPPS wage index for the IRF wage index beginning with FY 2020 and continuing for all subsequent years. Thus, we will use the FY 2020 pre-floor, pre-reclassified IPPS wage index as the basis for the FY 2020 IRF wage index (that is, for all IRF discharges beginning on or after October 1, 2019). We will implement these revisions in a budget neutral manner. We refer readers to Table 20 in section XIII.C of this final rule for more information on the distributional effects of this change.

### 3. Wage Adjustment for FY 2020 Using Concurrent IPPS Wage Index Labor Market Area Definitions and the

Due to our proposal to use the concurrent IPPS wage index beginning with FY 2020, for FY 2020, we proposed

using the policy and methodologies described in section VI. of this final rule related to the labor market area definitions and the wage index methodology for areas with wage data. Thus, we proposed using 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 proposed 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 received one comment on this proposal, which is summarized below.

*Comment:* One commenter requested that, until a new wage index system is implemented, CMS should establish a smoothing variable to be applied to the current IRF wage index to reduce the fluctuations IRFs experience annually.

*Response:* Under section 1886(j)(6) of the Act, we adjust IRF PPS rates to account for differences in area wage levels. Any perceived volatility in the wage index is predicated upon volatility in actual wages in that area and reflects real differences in area wage levels. As we believe that the application of a smoothing variable would make the wage index values less reflective of the area wage levels, we do not believe it would be appropriate to implement such a change to the IRF wage index policy.

After careful consideration of the comments we received, we are finalizing our proposal to use the policy and methodologies described in section VI. of this final rule related to the labor market area definitions and the wage index methodology for areas with wage data. Thus, we are finalizing the use of the CBSA labor market area definitions and the FY 2020 pre-reclassification and pre-floor IPPS wage index data. We are finalizing the continued use of 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.

### 4. Core-Based Statistical Areas (CBSAs) for the 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 proposed 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 received 2 comments on this proposal, which are summarized below.

*Comment:* Commenters expressed concern that the IRF wage index values published in the FY 2020 IRF PPS proposed rule were not consistent with the values published in the FY 2020 IPPS proposed rule wage index public use file. These commenters suggested that CMS examine these wage index values and correct them if we find that they are in error prior to finalizing the use of the concurrent IPPS wage index data for the IRF PPS.

*Response:* We identified a slight error in the proposed rule wage index values after the FY 2020 IRF PPS proposed rule was published. A programming error caused the data for all providers in a single county to be included twice, which affected the national average hourly rate, and therefore, affected nearly all wage index values. We have corrected the programming logic so this error cannot occur again. We also standardized our procedures for rounding, to ensure consistency. The correction to the proposed rule wage index data was not completed until after the comment period closed on June 17, 2019. This final rule reflects the corrected and updated wage index data.

We are finalizing and implementing 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.

#### 5. Wage Adjustment

The FY 2020 wage index tables (which, as discussed in section VI.F above, we 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 final 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 (72.7 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 VI.E of this final rule. We would then multiply the labor-related portion by the applicable IRF wage index from the tables in the addendum to this final 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 proposed 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 proposed to use the listed steps to ensure that the FY 2020 IRF standard payment conversion factor reflects the

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 FY 2020 standard payment conversion factor and the 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 FY 2020 budget-neutral wage adjustment factor of 1.0076.

*Step 4.* Apply the 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 standard payment conversion factor.

We note that we have updated our data between the FY 2020 IRF PPS proposed and final rules to ensure that we use the most recent available data in calculating IRF PPS payments. This updated data includes a more complete set of claims for FY 2018 and updated wage index data. Based on our analysis using this updated data, we now estimate a budget-neutral wage adjustment factor of 1.0031 for FY 2020.

We discuss the calculation of the standard payment conversion factor for FY 2020 in section VI.H. of this final rule.

We invited public comments on this proposal. However, we did not receive any comments on the proposed methodology for calculating the budget-neutral wage adjustment factor.

As we did not receive any comments on the proposed methodology for calculating the budget-neutral wage adjustment factor, we are finalizing this policy as proposed 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. Therefore, we solicited public comments in the FY 2020 IRF PPS proposed rule (84 FR 17280) 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.

We appreciate the commenters' responses to this solicitation and will take them into consideration for possible future policy development.

*H. Description of the IRF Standard Payment Conversion Factor and Payment Rates for FY 2020*

To calculate the standard payment conversion factor for FY 2020, as illustrated in Table 13, we begin by applying the 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 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 budget neutrality factor for the FY 2020 wage index and labor-related share of 1.0031, which results in a standard payment amount of \$16,472. We next apply the budget neutrality factor for the revised CMGs and CMG relative weights of 1.0010, which results in the standard payment conversion factor of \$16,489 for FY 2020.

**TABLE 13: Calculations to Determine the 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 (2.9 percent), reduced by 0.4 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 1.0031
Budget Neutrality Factor for the Revisions to the CMGs and CMG Relative Weights	x 1.0010
FY 2020 Standard Payment Conversion Factor	= \$16,489

We received one comment on the proposed FY 2020 standard payment conversion factor, which is summarized below.

*Comment:* One commenter stated that the proposed rate update fails to cover the cost of medical inflation or payment reductions due to sequestration. As a result, this commenter expressed concern that their hospitals' financial viability and their ability to care for their patients will be threatened.

*Response:* We appreciate this commenter's concerns. However, we note that the IRF PPS payment rates are updated annually 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, as required by section 1886(j)(3)(C) of the Act.

After careful consideration of the comment we received, we are finalizing

the IRF standard payment conversion factor of \$16,489 for FY 2020.

After the application of the CMG relative weights described in section IV. of this final rule to the FY 2020 standard payment conversion factor (\$16,489), the resulting unadjusted IRF prospective payment rates for FY 2020 are shown in Table 14.

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TABLE 14: FY 2020 Payment Rates

CMG	Payment Rate Tier 1	Payment Rate Tier 2	Payment Rate Tier 3	Payment Rate No Comorbidity
0101	\$ 17,067.76	\$ 14,782.39	\$ 13,685.87	\$ 13,036.20
0102	\$ 21,683.04	\$ 18,779.32	\$ 17,387.65	\$ 16,563.20
0103	\$ 27,685.03	\$ 23,976.65	\$ 22,200.79	\$ 21,147.14
0104	\$ 36,206.55	\$ 31,357.13	\$ 29,033.83	\$ 27,655.35
0105	\$ 40,068.27	\$ 34,702.75	\$ 32,132.11	\$ 30,606.88
0106	\$ 46,762.80	\$ 40,500.28	\$ 37,499.28	\$ 35,720.12
0201	\$ 19,115.70	\$ 15,664.55	\$ 14,127.78	\$ 13,178.01
0202	\$ 23,688.10	\$ 19,410.85	\$ 17,508.02	\$ 16,329.06
0203	\$ 28,834.31	\$ 23,628.74	\$ 21,310.38	\$ 19,877.49
0204	\$ 35,185.88	\$ 28,834.31	\$ 26,006.45	\$ 24,255.32
0205	\$ 43,911.86	\$ 35,983.94	\$ 32,455.30	\$ 30,270.51
0301	\$ 20,248.49	\$ 16,480.76	\$ 15,199.56	\$ 14,210.22
0302	\$ 25,727.79	\$ 20,941.03	\$ 19,311.92	\$ 18,055.46
0303	\$ 31,022.40	\$ 25,249.61	\$ 23,287.41	\$ 21,770.43
0304	\$ 34,786.84	\$ 28,313.26	\$ 26,111.98	\$ 24,411.96
0305	\$ 37,741.67	\$ 30,719.01	\$ 28,331.40	\$ 26,486.28
0401	\$ 22,593.23	\$ 19,371.28	\$ 17,730.62	\$ 16,258.15
0402	\$ 29,658.76	\$ 25,430.98	\$ 23,277.52	\$ 21,343.36
0403	\$ 35,861.93	\$ 30,750.34	\$ 28,146.72	\$ 25,808.58
0404	\$ 52,672.46	\$ 45,163.37	\$ 41,337.92	\$ 37,904.91
0405	\$ 44,859.97	\$ 38,465.54	\$ 35,207.31	\$ 32,282.16
0406	\$ 54,852.31	\$ 47,031.57	\$ 43,049.48	\$ 39,473.02
0407	\$ 67,939.63	\$ 58,255.64	\$ 53,320.48	\$ 48,891.53
0501	\$ 20,934.43	\$ 17,100.74	\$ 15,852.52	\$ 14,507.02
0502	\$ 26,149.91	\$ 21,359.85	\$ 19,801.64	\$ 18,121.41
0503	\$ 30,130.35	\$ 24,611.48	\$ 22,815.83	\$ 20,880.02
0504	\$ 36,620.42	\$ 29,912.69	\$ 27,729.55	\$ 25,376.57
0505	\$ 46,766.10	\$ 38,198.42	\$ 35,413.43	\$ 32,407.48
0601	\$ 22,146.38	\$ 17,216.16	\$ 16,073.48	\$ 14,615.85
0602	\$ 27,439.34	\$ 21,331.82	\$ 19,915.41	\$ 18,109.87
0603	\$ 32,328.33	\$ 25,132.53	\$ 23,463.85	\$ 21,336.77
0604	\$ 37,157.96	\$ 28,887.08	\$ 26,969.41	\$ 24,524.09
0701	\$ 20,629.39	\$ 16,647.29	\$ 15,901.99	\$ 14,462.50
0702	\$ 25,821.77	\$ 20,835.50	\$ 19,905.52	\$ 18,101.62
0703	\$ 31,263.14	\$ 25,226.52	\$ 24,098.67	\$ 21,915.53
0704	\$ 35,357.36	\$ 28,530.92	\$ 27,254.67	\$ 24,786.26
0801	\$ 17,496.48	\$ 14,553.19	\$ 13,178.01	\$ 12,257.92
0802	\$ 20,621.14	\$ 17,151.86	\$ 15,530.99	\$ 14,447.66
0803	\$ 23,130.77	\$ 19,241.01	\$ 17,422.28	\$ 16,207.04
0804	\$ 26,601.70	\$ 22,126.59	\$ 20,035.78	\$ 18,639.17
0805	\$ 31,662.18	\$ 26,337.88	\$ 23,848.04	\$ 22,184.30
0901	\$ 19,895.63	\$ 15,897.04	\$ 14,757.66	\$ 13,591.88
0902	\$ 25,165.51	\$ 20,109.98	\$ 18,667.20	\$ 17,193.08
0903	\$ 29,576.32	\$ 23,633.68	\$ 21,938.61	\$ 20,205.62
0904	\$ 33,568.31	\$ 26,824.31	\$ 24,900.04	\$ 22,932.90
1001	\$ 21,194.96	\$ 18,058.75	\$ 16,348.84	\$ 15,021.48
1002	\$ 26,413.73	\$ 22,504.19	\$ 20,375.46	\$ 18,719.96
1003	\$ 30,476.62	\$ 25,966.88	\$ 23,510.02	\$ 21,600.59
1004	\$ 35,418.37	\$ 30,176.52	\$ 27,322.27	\$ 25,102.85
1101	\$ 23,417.68	\$ 19,460.32	\$ 17,615.20	\$ 14,746.11
1102	\$ 29,075.05	\$ 24,161.33	\$ 21,871.01	\$ 18,307.74
1103	\$ 33,345.70	\$ 27,711.41	\$ 25,083.07	\$ 20,997.09

CMG	Payment Rate Tier 1	Payment Rate Tier 2	Payment Rate Tier 3	Payment Rate No Comorbidity
1201	\$ 20,410.08	\$ 15,717.31	\$ 15,262.22	\$ 14,180.54
1202	\$ 25,975.12	\$ 20,002.81	\$ 19,424.04	\$ 18,045.56
1203	\$ 29,676.90	\$ 22,853.75	\$ 22,192.55	\$ 20,619.49
1204	\$ 31,573.14	\$ 24,314.68	\$ 23,608.95	\$ 21,935.32
1301	\$ 19,237.72	\$ 16,210.34	\$ 15,359.50	\$ 14,145.91
1302	\$ 23,528.15	\$ 19,824.72	\$ 18,784.27	\$ 17,300.26
1303	\$ 27,727.90	\$ 23,363.26	\$ 22,136.48	\$ 20,388.65
1304	\$ 31,388.46	\$ 26,448.36	\$ 25,059.98	\$ 23,079.65
1305	\$ 30,946.56	\$ 26,075.70	\$ 24,707.12	\$ 22,754.82
1401	\$ 18,838.68	\$ 15,339.72	\$ 14,140.97	\$ 12,708.07
1402	\$ 23,704.59	\$ 19,302.02	\$ 17,794.93	\$ 15,991.03
1403	\$ 28,601.82	\$ 23,290.71	\$ 21,470.33	\$ 19,295.43
1404	\$ 33,309.43	\$ 27,124.41	\$ 25,005.57	\$ 22,471.21
1501	\$ 20,522.21	\$ 17,498.13	\$ 16,108.10	\$ 15,301.79
1502	\$ 24,868.71	\$ 21,203.21	\$ 19,519.68	\$ 18,541.88
1503	\$ 29,286.11	\$ 24,969.29	\$ 22,985.67	\$ 21,834.73
1504	\$ 33,622.72	\$ 28,666.13	\$ 26,390.64	\$ 25,068.23
1601	\$ 18,652.36	\$ 14,826.91	\$ 14,002.46	\$ 12,920.78
1602	\$ 23,023.59	\$ 18,301.14	\$ 17,283.77	\$ 15,948.16
1603	\$ 26,768.24	\$ 21,277.41	\$ 20,095.14	\$ 18,541.88
1604	\$ 31,180.70	\$ 24,784.62	\$ 23,407.78	\$ 21,597.29
1701	\$ 23,246.19	\$ 18,162.63	\$ 17,000.16	\$ 15,506.26
1702	\$ 28,514.43	\$ 22,279.94	\$ 20,853.64	\$ 19,021.71
1703	\$ 33,129.70	\$ 25,886.08	\$ 24,228.94	\$ 22,100.21
1704	\$ 36,656.70	\$ 28,639.74	\$ 26,807.82	\$ 24,451.54
1705	\$ 39,804.45	\$ 31,099.90	\$ 29,109.68	\$ 26,552.24
1801	\$ 19,437.23	\$ 16,447.78	\$ 14,688.40	\$ 13,440.18
1802	\$ 25,158.92	\$ 21,288.95	\$ 19,011.82	\$ 17,397.54
1803	\$ 31,149.37	\$ 26,356.02	\$ 23,538.05	\$ 21,539.58
1804	\$ 36,091.12	\$ 30,539.28	\$ 27,274.45	\$ 24,957.75
1805	\$ 42,475.66	\$ 35,941.07	\$ 32,099.14	\$ 29,371.86
1806	\$ 56,723.81	\$ 47,997.83	\$ 42,864.80	\$ 39,224.03
1901	\$ 20,276.52	\$ 15,892.10	\$ 15,265.52	\$ 14,882.97
1902	\$ 28,524.32	\$ 22,355.79	\$ 21,475.27	\$ 20,936.08
1903	\$ 43,316.60	\$ 33,949.20	\$ 32,611.94	\$ 31,794.09
1904	\$ 61,461.10	\$ 48,169.32	\$ 46,273.08	\$ 45,112.26
2001	\$ 19,996.21	\$ 16,179.01	\$ 15,016.53	\$ 13,633.11
2002	\$ 24,647.76	\$ 19,941.80	\$ 18,508.90	\$ 16,805.59
2003	\$ 28,880.48	\$ 23,366.56	\$ 21,686.33	\$ 19,691.16
2004	\$ 32,448.70	\$ 26,253.79	\$ 24,367.44	\$ 22,123.29
2005	\$ 34,659.88	\$ 28,042.84	\$ 26,027.89	\$ 23,632.03
2101	\$ 25,430.98	\$ 20,978.95	\$ 19,471.86	\$ 17,501.42
2102	\$ 36,335.16	\$ 29,975.35	\$ 27,821.89	\$ 25,005.57
5001				\$ 2,994.40
5101				\$ 9,403.68
5102				\$ 29,579.62
5103				\$ 11,113.59
5104				\$ 36,203.25

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*H. Example of the Methodology for Adjusting the Prospective Payment Rates*

Table 15 illustrates the methodology for adjusting the prospective payments (as described in section VI. of this final

rule). The following examples are based on two hypothetical Medicare beneficiaries, both classified into CMG 0104 (without comorbidities). The unadjusted prospective payment rate for

CMG 0104 (without comorbidities) appears in Table 14.

*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 0.8319, 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 0.8844, and a teaching status adjustment of 0.0784.

To calculate each IRF's labor and non-labor portion of the prospective payment, we begin by taking the unadjusted prospective payment rate for

CMG 0104 (without comorbidities) from Table 14. Then, we multiply the labor-related share for FY 2020 (72.7 percent) described in section VI.E. of this final rule by the unadjusted prospective payment rate. To determine the non-labor portion of the prospective payment rate, we subtract the labor portion of the federal payment from the unadjusted prospective payment.

To compute the wage-adjusted prospective payment, we multiply the labor portion of the 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 wage-adjusted federal

payment by adding the wage-adjusted labor amount to the non-labor portion of the federal payment.

Adjusting the 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 15 illustrates the components of the adjusted payment calculation.

**TABLE 15: 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	\$ 27,655.35	\$27,655.35
2	Labor Share	X 0.727	X 0.727
3	Labor Portion of Payment	= \$20,105.44	= \$20,105.44
4	CBSA-Based Wage Index (shown in the Addendum, Tables A and B)	X 0.8319	X 0.8844
5	Wage-Adjusted Amount	= \$16,725.72	= \$17,781.25
6	Non-Labor Amount	+ \$7,549.91	+ \$7,549.91
7	Wage-Adjusted Payment	= \$24,275.63	= \$25,331.16
8	Rural Adjustment	X 1.149	X 1.000
9	Wage- and Rural-Adjusted Payment	= \$27,892.69	= \$25,331.16
10	LIP Adjustment	X 1.0156	X 1.0454
11	Wage-, Rural- and LIP-Adjusted Payment	= \$28,327.82	= \$26,481.20
12	Wage- and Rural-Adjusted Payment	\$27,892.69	\$25,331.16
13	Teaching Status Adjustment	X 0	X 0.0784
14	Teaching Status Adjustment Amount	= \$0.00	= \$1,985.96
15	Wage-, Rural-, and LIP-Adjusted Payment	+ \$28,327.82	+ \$26,481.20
16	Total Adjusted Payment	= \$28,327.82	= \$28,467.16

Thus, the adjusted payment for Facility A would be \$28,327.82, and the adjusted payment for Facility B would be \$28,467.16.

## VII. Update to Payments for High-Cost Outliers Under the IRF PPS for FY 2020

### A. 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 proposed 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 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 proposed 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 note that, as we typically do, we updated our data between the FY 2020 IRF PPS proposed and final rules to ensure that we use the most recent

available data in calculating IRF PPS payments. This updated data includes a more complete set of claims for FY 2018. Based on our analysis using this updated data, we now estimate that IRF outlier payments as a percentage of total estimated payments are approximately 3.0 percent in FY 2019. Although our analysis shows that we achieved our goal to have estimated outlier payments equal 3.0 percent of total estimated aggregate IRF payments for FY 2019, we still need to adjust the IRF outlier threshold to reflect changes in estimated costs and payments for IRFs in FY 2020. That is, as discussed in section VI. of this final rule, we are finalizing our proposal to increase IRF PPS payment rates by 2.5 percent, in accordance with section 1886(j)(3)(C) of the Act to account for changes over time in the prices of an appropriate mix of goods and services included in the covered IRF services. Similarly, we estimate costs for IRFs in FY 2020 are expected to increase to account for changes over time in the prices of goods and services included in the covered IRF services. Therefore, we will update the outlier threshold amount from \$9,402 for FY 2019 to \$9,300 for FY 2020 to account for the increases in IRF PPS payments and estimated costs and to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2020.

We received three comments on the proposed update to the FY 2020 outlier threshold, which are summarized below.

*Comment:* Commenters suggested that historical outlier reconciliation dollars should be included in the calculation of the fixed loss threshold under the IRF PPS.

*Response:* As we did not propose a change to the methodology used to establish an outlier threshold for IRF PPS payments, these comments are outside the scope of this rule. However, we will continue to monitor our IRF outlier policies to ensure that they continue to compensate IRFs appropriately for treating unusually high-cost patients and do not limit access to care for patients who are likely to require unusually high-cost care.

*Comment:* A few commenters suggested that CMS consider implementing a cap on the amount of outlier payments an individual IRF can receive under the IRF PPS. One commenter was supportive of maintaining estimated payments for outlier payments at approximately 3 percent while other commenters expressed concern with maintaining the

3 percent target and suggested reducing the outlier pool below 3 percent.

*Response:* As we did not propose to implement a cap on the amount of outlier payments an individual IRF can receive under the IRF PPS, these comments are outside the scope of this rule. However, we note that any future consideration given to imposing a limit on outlier payments would have to carefully analyze and take into consideration the effect on access to IRF care for certain high-cost populations.

As most recently discussed in the FY 2019 IRF PPS final rule (83 FR 38532), we analyzed various outlier policies using 3, 4, and 5 percent of the total estimated payments for the FY 2002 IRF PPS final rule, 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. We continue to believe that the outlier policy of 3 percent of total estimated aggregate payments accomplishes this objective. We refer readers to the FY 2002 IRF PPS final rule (66 FR 41316, 41362 through 41363) for more information regarding the rationale for setting the outlier threshold amount for the IRF PPS so that estimated outlier payments would equal 3 percent of total estimated payments.

*Comment:* One commenter requested that CMS update the outlier threshold amount in the final rule using the latest available data.

*Response:* We agree that we should use the most recent data available to calculate the outlier threshold. Therefore, as previously stated, we updated the data used to calculate the outlier threshold between the FY 2020 IRF PPS proposed and final rules.

Having carefully considered the public comments received and also taking into account the most recent available data, we are finalizing the outlier threshold amount of \$9,300 to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2020.

#### *B. 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 proposed to apply a ceiling to IRFs' CCRs. Using the methodology described in that final rule, we proposed 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 proposed 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 proposed 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 final 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. Using updated FY 2017 cost report data for this final rule, we estimate a national average CCR of 0.500 for rural IRFs, and a national average CCR of 0.405 for urban IRFs.

In accordance with past practice, we proposed to set the national CCR ceiling at 3 standard deviations above the mean CCR. Using this method, we proposed 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.

Using the updated FY 2017 cost report data for this final rule, we estimate a national average CCR ceiling of 1.31, using the same methodology.

We did not receive comments on the proposed update to the IRF CCR ceiling and the urban/rural averages for FY 2020.

As we did not receive any comments on the proposed update to the IRF CCR ceiling and the urban/rural averages for FY 2020, we are finalizing the national average urban CCR at 0.405, the national average rural CCR at 0.500, and the national average CCR ceiling at 1.31 for FY 2020.

#### **VIII. 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 proposed 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 (84 FR

17284 through 17285). For clarity, we also proposed to remove this definition from § 412.622(a)(3)(iv) and move it to a new paragraph (§ 412.622(c)). We also proposed 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 received 1,163 comments 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). The majority of these comments consisted of form letters, in which we received multiple copies of two types of identically-worded letters that had been signed and submitted by different individuals. The comments we received on this are summarized below.

*Comment:* Many of the commenters noted appreciation and support for the proposal 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. One commenter stated that while board-certified psychiatrists play a crucial caregiver and leadership role in rehabilitation hospitals, they are not alone in doing so. Physicians representing other specialties can and do also display the leadership and caregiving skills and experience that clearly qualify them as a rehabilitation physician. One commenter indicated that CMS' proposal is consistent with CMS' previously stated position from 2010. Some commenters also stated that clarifying the regulation would reduce the number of claims denials by promoting a shared understanding of the requirements between IRFs and Medicare contractors.

*Response:* We appreciate the commenters' support and agree that this clarification in our regulations supports our longstanding position that the responsibility is, and always has been, on the IRF to ensure that the rehabilitation physician(s) who are making the admission decisions and treating the patients have the necessary training and experience.

*Comment:* Many commenters stated that they do not support CMS' proposal and suggested that CMS not finalize the proposed amendments to § 412.622. These commenters requested that CMS delay any changes to current regulations

until CMS and stakeholders can work together to develop a consensus approach for protecting the quality and integrity of IRF care. These commenters stated that they believe that allowing the IRF to determine whether an individual physician meets the regulatory standards for a rehabilitation physician could increase the risks that some IRFs will hire or contract with unqualified or underqualified physicians, reduce the quality of care that patients receive in IRFs, and reduce the value of physiatrists. These commenters also stated that reducing the value of physiatrists could also deter students from wanting to pursue this specialty in the future. Some commenters also indicated that CMS' proposal, if finalized, would undermine CMS' ability to engage in appropriate program integrity oversight by not reviewing an IRF's decision to hire a particular physician to fill a rehabilitation physician role.

*Response:* While we appreciate and share the commenters' desire to ensure that Medicare beneficiaries in IRFs receive the highest-quality care from trained and qualified physicians, we do not believe that merely clarifying our existing policy would reduce quality of care. The regulation will continue to require a rehabilitation physician to be a licensed physician with specialized training and experience in inpatient rehabilitation. We are not lowering these requirements. However, we continue to believe that we need to clarify our existing policy that the IRF makes the determination as to whether a given physician qualifies as a rehabilitation physician in order to eliminate any unnecessary uncertainty on this issue. Over the past year, we have received questions regarding how this provision can be enforced, and we believe that this clarification will promote a shared understanding of how we intend the enforcement to occur. We expect that IRFs will continue to ensure

that the rehabilitation physicians treating patients in their facilities have the necessary training and experience in inpatient rehabilitation. To this end, we will continue to work with stakeholders to refine Medicare's IRF payment policies in the future so that they support IRFs in providing the highest quality care to beneficiaries.

After careful consideration of the comments we received, we are finalizing our proposal 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. However, based on the stakeholder feedback, we will continue to assess whether future refinements to this policy may be needed.

For clarity, we are also removing this definition from § 412.622(a)(3)(iv) and moving it to a new paragraph (§ 412.622(c)). We are also making 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.

## **IX. Updates to the IRF Quality Reporting Program (QRP)**

### *A. Background*

The 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).

While we did not solicit comments on previously finalized IRF QRP policies, we received comments, which are summarized below.

*Comment:* A few commenters stated that the IRF QRP compliance threshold of 95 percent for assessment-based items is too high given the number of data elements that have been added to the IRF-PAI, and requested that CMS lower it to 80 percent in alignment with other programs.

*Response:* We did not propose any changes to the compliance threshold, which has been codified at § 412.634(f). While these comments were out of scope for this rule, we will take these comments under consideration.

### *B. General Considerations Used for the Selection of Measures for the IRF QRP*

For a detailed discussion of the considerations we use 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 16.

**TABLE 16: Quality Measures Currently Adopted for the FY 2020 IRF QRP**

Short Name		Measure Name & Data Source	
<b>IRF-PAI</b>			
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)	
<b>NHSN</b>			
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 <i>Clostridium difficile</i> Infection (CDI) Outcome Measure (NQF #1717)	
HCP Influenza Vaccine		Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431)	
<b>Claims-Based</b>			
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	

While we did not solicit comments on currently adopted measures (with the exception of the Discharge to Community Measure discussed in section IX.D.3 of this rule and the policies regarding public display of the Drug Regimen Review Conducted With Follow-Up for Identified Issues—PAC IRF QRP in section IX.I of this rule), we received several comments.

*Comment:* A few commenters had suggestions for removing measures they believe were “topped out” according to the Hospital Inpatient Quality Reporting (IQR) Program definition (83 FR 20408) and did not demonstrate variation across facilities, including Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) and 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 Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. One commenter had suggestions for

improving the training manual for the Drug Regimen Review measure in terms of considered clinically significant medication issue.

*Response:* We did not propose any changes to these previously finalized measures, nor did we propose measure removals from the IRF QRP. We wish to clarify that the IRF QRP has not adopted the Hospital Inpatient Quality Reporting (IQR) definition of “topped out” in the measure removal criteria finalized for the IRF QRP at § 412.634(2). We also note that we do not automatically remove high performing measures, and wish to reiterate that such measures may be retained for other specified reasons. For example, a particular measure with high performance rates may be retained if the measure addresses a topic related to quality that is so significant that we do not want to risk a decline in quality that could result if we removed the measure, or if the measure addresses a topic that is statutorily required. We will continue to monitor and evaluate the data from all IRF QRP measures.

With regard to the commenter’s suggestions about the Drug Regimen Review measure, we interpret that the commenter is requesting additional clarification for coding. We will take these comments into account as we develop training materials for the IRF QRP.

*D. Adoption of Two New Quality Measures and Updated Specifications for a Third Quality Measure Beginning With the FY 2022 IRF QRP*

In the FY 2020 IRF PPS proposed rule (84 FR 17286 through 17291), we proposed 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 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 proposed 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 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 proposed 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 sought public comment on each of these proposals. These comments are summarized after each proposal below.

#### 1. Transfer of Health Information to the Provider—Post-Acute Care (PAC) Measure

The Transfer of Health Information to the Provider—Post-Acute Care (PAC) Measure that we proposed to adopt beginning with the FY 2022 IRF QRP 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 9 percent who were discharged to SNFs.<sup>2</sup> The proportion of patients being discharged from an acute care hospital to a PAC setting was greater among beneficiaries enrolled in Medicare 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 1

percent were discharged to an LTCH.<sup>3</sup> 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).<sup>4</sup>

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

<sup>3</sup> Ibid.

<sup>4</sup> RTI International analysis of Medicare claims data for index stays in IRF 2016/2017. (RTI program reference: MM150).

<sup>5</sup> 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.

<sup>6</sup> Boockvar, K.S., Blum, S., Kugler, A., Livote, E., Mergenhausen, K.A., Nebeker, J.R., & Yeh, J., “Effect of admission medication reconciliation on adverse drug events from admission medication changes,” *Archives of Internal Medicine*, 2011, Vol. 171(9), pp. 860–861.

<sup>7</sup> 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.

<sup>8</sup> 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.

<sup>9</sup> Desai, R., Williams, C.E., Greene, S.B., Pierson, S., & Hansen, R.A., “Medication errors during patient transitions into nursing homes: characteristics and association with patient harm,” *The American Journal of Geriatric Pharmacotherapy*, 2011, Vol. 9(6), pp. 413–422.

<sup>10</sup> Boling, P.A., “Care transitions and home health care,” *Clinical Geriatric Medicine*, 2009, Vol. 25(1), pp. 135–48.

<sup>11</sup> 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.

<sup>12</sup> 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.

<sup>13</sup> 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.

<sup>14</sup> 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>.

medication information, that is incomplete or missing increases the likelihood of a patient or resident safety risk, and is often life-threatening.<sup>5 6 7 8 9 10</sup> Poor communication and coordination across health care settings contributes to patient complications, hospital readmissions, emergency department visits, and medication errors.<sup>11 12 13 14 15 16 17 18 19 20</sup>

Communication has been cited as the third most frequent root cause in sentinel events, which The Joint Commission defines<sup>21</sup> 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.<sup>22</sup> 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.<sup>23 24 25 26 27</sup>

<sup>15</sup> 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.

<sup>16</sup> 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.

<sup>17</sup> 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>.

<sup>18</sup> 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.

<sup>19</sup> 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.

<sup>20</sup> King, B.J., Gilmore-Bikovskiy, A.L., Roiland, R.A., Polnaszek, B.E., Bowers, B.J., & Kind, A.J., “The consequences of poor communication during transitions from hospital to skilled nursing facility: a qualitative study,” *Journal of the American Geriatrics Society*, 2013, Vol. 61(7), 1095–1102.

<sup>21</sup> The Joint Commission, “Sentinel Event Policy” available at [https://www.jointcommission.org/sentinel\\_event\\_policy\\_and\\_procedures/](https://www.jointcommission.org/sentinel_event_policy_and_procedures/).

<sup>22</sup> 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](https://www.jointcommission.org/assets/1/23/jconline_Mar_2_2016.pdf).

<sup>23</sup> 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.

<sup>24</sup> 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>.

<sup>25</sup> 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

<sup>2</sup> 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>.

Care transitions across health care settings have been characterized as complex, costly, and potentially hazardous, and may increase the risk for multiple adverse outcomes.<sup>28 29</sup> 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.<sup>30</sup> The communication of health information and patient care preferences is critical to ensuring safe and effective transitions from one health care setting to another.<sup>31 32</sup>

Patients in PAC settings often have complicated medication regimens and require efficient and effective

preventable adverse events among hospitalized children following implementation of a resident handoff bundle," *JAMA*, 2013, Vol. 310(21), pp. 2262–2270.

<sup>26</sup> Pronovost, P., M.M.E. Johns, S. Palmer, R.C. Bono, D.B. Fridsma, A. Gettinger, J. Goldman, A. Johnson, M. Karney, C. Samitt, R.D. Sriram, A. Zenoos, and Y.C. Wang, Editors. *Procuring Interoperability: Achieving High-Quality, Connected, and Person-Centered Care*. Washington, DC, 2018 National Academy of Medicine. Available at [https://nam.edu/wp-content/uploads/2018/10/Procuring-Interoperability\\_web.pdf](https://nam.edu/wp-content/uploads/2018/10/Procuring-Interoperability_web.pdf).

<sup>27</sup> Balaban RB, Weissman JS, Samuel PA, & Woolhandler, S., "Redefining and redesigning hospital discharge to enhance patient care: a randomized controlled study," *J Gen Intern Med*, 2008, Vol. 23(8), pp. 1228–33.

<sup>28</sup> 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.

<sup>29</sup> Simmons, S., Schnelle, J., Slagle, J., Sathe, N.A., Stevenson, D., Carlo, M., & McPheeters, M.L., "Resident safety practices in nursing home settings." Technical Brief No. 24 (Prepared by the Vanderbilt Evidence-based Practice Center under Contract No. 290–2015–00003–I.) AHRQ Publication No. 16–EHC022–EF. Rockville, MD: Agency for Healthcare Research and Quality. May 2016. Available at <https://www.ncbi.nlm.nih.gov/books/NBK384624/>.

<sup>30</sup> Berwick, D.M. & Hackbarth, A.D. "Eliminating Waste in US Health Care," *JAMA*, 2012, Vol. 307(14), pp.1513–1516.

<sup>31</sup> McDonald, K.M., Sundaram, V., Bravata, D.M., Lewis, R., Lin, N., Kraft, S.A. & Owens, D.K. *Care Coordination*. Vol. 7 of: Shojania K.G., McDonald K.M., Wachter R.M., Owens D.K., editors. "Closing the quality gap: A critical analysis of quality improvement strategies." Technical Review 9 (Prepared by the Stanford University-UCSF Evidence-based Practice Center under contract 290–02–0017). AHRQ Publication No. 04(07)–0051–7. Rockville, MD: Agency for Healthcare Research and Quality. June 2006. Available at <https://www.ncbi.nlm.nih.gov/books/NBK44015/>.

<sup>32</sup> Lattimer, C., "When it comes to transitions in patient care, effective communication can make all the difference," *Generations*, 2011, Vol. 35(1), pp. 69–72.

communication and coordination of care between settings, including detailed transfer of medication information.<sup>33 34 35</sup> 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.<sup>36 37</sup> Preventable adverse drug events (ADEs) may occur after hospital discharge in a variety of settings including PAC.<sup>38</sup> 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.<sup>39</sup> 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.<sup>40 41</sup>

<sup>33</sup> Starmer A.J, Spector N.D., Srivastava R., West, D.C., Rosenbluth, G., Allen, A.D., Noble, E.L., & Landrign, C.P., "Changes in medical errors after implementation of a handoff program," *N Engl J Med*, 2014, Vol. 37(1), pp. 1803–1812.

<sup>34</sup> Kruse, C.S. Marquez, G., Nelson, D., & Polomares, O., "The use of health information exchange to augment patient handoff in long-term care: a systematic review," *Applied Clinical Informatics*, 2018, Vol. 9(4), pp. 752–771.

<sup>35</sup> 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 of the American Geriatrics Society*, 2016, Vol. 64(11), pp. e166–e170.

<sup>36</sup> Chhabra, P.T., Rattinger, G.B., Dutcher, S.K., Hare, M.E., Parsons, K., L., & Zuckerman, I.H., "Medication reconciliation during the transition to and from long-term care settings: a systematic review," *Res Social Adm Pharm*, 2012, Vol. 8(1), pp. 60–75.

<sup>37</sup> Levinson, D.R., & General, I., "Adverse events in skilled nursing facilities: national incidence among Medicare beneficiaries." Washington, DC: U.S. Department of Health and Human Services, Office of the Inspector General, February 2014. Available at <https://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf>.

<sup>38</sup> Battles J., Azam I., Grady M., & Reback K., "Advances in patient safety and medical liability," AHRQ Publication No. 17–0017–EF. Rockville, MD: Agency for Healthcare Research and Quality, August 2017. Available at [https://www.ahrq.gov/sites/default/files/publications/files/advances-complete\\_3.pdf](https://www.ahrq.gov/sites/default/files/publications/files/advances-complete_3.pdf).

<sup>39</sup> Health and Human Services Office of Inspector General. *Adverse Events in Rehabilitation Hospitals: National Incidence Among Medicare Beneficiaries*. (OEI–06–14–00110). 2018. Available at <https://oig.hhs.gov/oei/reports/oei-06-14-00110.asp>.

<sup>40</sup> 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.

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.<sup>42</sup> Medication discrepancies are common<sup>43</sup> and found to occur in 86 percent of all transitions, increasing the likelihood of ADEs.<sup>44 45 46</sup> 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.<sup>47 48</sup>

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<sup>49 50 51</sup>

<sup>41</sup> Gleason, K.M., Groszek, J.M., Sullivan, C., Rooney, D., Barnard, C., Noskin, G.A., "Reconciliation of discrepancies in medication histories and admission orders of newly hospitalized patients," *American Journal of Health System Pharmacy*, 2004, Vol. 61(16), pp. 1689–1694.

<sup>42</sup> Patterson M., Foust J.B., Bollinger, S., Coleman, C., Nguyen, D., "Inter-facility communication barriers delay resolving medication discrepancies during transitions of care," *Research in Social & Administrative Pharmacy* (2018), doi: 10.1016/j.sapharm.2018.05.124.

<sup>43</sup> Manias, E., Annaikis, N., Considine, J., Weerasuriya, R., & Kusljic, S. "Patient-, medication- and environment-related factors affecting medication discrepancies in older patients," *Collegian*, 2017, Vol. 24, pp. 571–577.

<sup>44</sup> Tjia, J., Bonner, A., Briesacher, B.A., McGee, S., Terrill, E., Miller, K., "Medication discrepancies upon hospital to skilled nursing facility transitions," *J Gen Intern Med*, 2009, Vol. 24(5), pp. 630–635.

<sup>45</sup> Sinvani, L.D., Beizer, J., Akerman, M., Pekmezaris, R., Nouryan, C., Lutsky, L., Cal, C., Dlugacz, Y., Masick, K., Wolf-Klein, G., "Medication reconciliation in continuum of care transitions: a moving target," *J Am Med Dir Assoc*, 2013, Vol. 14(9), 668–672.

<sup>46</sup> Coleman E.A., Parry C., Chalmers S., & Min, S.J., "The Care Transitions Intervention: results of a randomized controlled trial," *Arch Intern Med*, 2006, Vol. 166, pp. 1822–28.

<sup>47</sup> Corbett C.L., Setter S.M., Neumiller J.J., & Wood, I.D., "Nurse identified hospital to home medication discrepancies: implications for improving transitional care," *Geriatr Nurs*, 2011, Vol. 31(3), pp. 188–96.

<sup>48</sup> Setter S.M., Corbett C.F., Neumiller J.J., Gates, B.J., Sclar, D.A., & Sonnett, T.E., "Effectiveness of a pharmacist-nurse intervention on resolving medication discrepancies in older patients transitioning from hospital to home care: impact of a pharmacy/nursing intervention," *Am J Health Syst Pharm*, 2009, Vol. 66, pp. 2027–31.

<sup>49</sup> Boockvar, K.S., Blum, S., Kugler, A., Livote, E., Mergenhagen, K.A., Nebeker, J.R., & Yeh, J., "Effect of admission medication reconciliation on adverse drug events from admission medication changes," *Archives of Internal Medicine*, 2011, Vol. 171(9), pp. 860–861.

<sup>50</sup> Kwan, J.L., Lo, L., Sampson, M., & Shojania, K.G., "Medication reconciliation during transitions

Continued

especially when medications are reviewed by a pharmacist using electronic medical records.<sup>52</sup>

#### 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,<sup>53</sup> January 27, 2017,<sup>54</sup> and August 3, 2017<sup>55</sup> 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

of care as a patient safety strategy: a systematic review," *Annals of Internal Medicine*, 2013, Vol. 158(5), pp. 397–403.

<sup>51</sup> Chhabra, P.T., Rattinger, G.B., Dutcher, S.K., Hare, M.E., Parsons, K., L., & Zuckerman, I.H., "Medication reconciliation during the transition to and from long-term care settings: a systematic review," *Res Social Adm Pharm*, 2012, Vol. 8(1), pp. 60–75.

<sup>52</sup> 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.

<sup>53</sup> 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](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).

<sup>54</sup> 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](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).

<sup>55</sup> Ibid.

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 noted 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 we 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](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 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 IPF, 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 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, “Final 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 proposed for this measure, we refer readers to section VIII.G.3. of this final rule.

Commenters submitted the following comments related to the proposed rule’s discussion of the IRF QRP Quality Measure Proposals beginning with the FY 2022 IRF QRP. A discussion of these comments, along with our responses, appears below. We also address comments on the proposed Transfer of Health Information to the Patient—Post-Acute Care measure (discussed further in a subsequent section of this final rule) in this section because commenters frequently addressed both Transfer of Health Information measures together.

*Response:* We thank the commenters for their support of the Transfer of Health Information measures.

*Comment:* One commenter suggested that other providers, such as outpatient physical therapists, should be included in the definition of a subsequent provider for the Transfer of Health Information to the Provider—Post-Acute Care measure.

*Response:* We appreciate the suggestion to expand the Transfer of Health Information to the Provider—Post-Acute Care measure outcome to assess the transfer of health information to other providers such as outpatient physical therapists. We recognize that sharing medication information with outpatient providers is important, and will take into consideration additional providers in future measure modifications. Through our measure development and pilot testing we learned that outpatient providers cannot always be readily identified by the PAC provider. For this process measure, which serves as a building block for improving the transfer of medication information, we specified providers who will be involved in the care of the patient and medication management after discharge and can be readily identified through the discharge location item on the IRF-PAI. The clear

delineation of the recipient of the medication list in the measure specifications will improve measure reliability and validity.

*Comment:* A commenter recommended that the Transfer of Health Information to the Provider—Post-Acute Care measure be expanded to include the transfer of information that would help prevent infections and facilitate appropriate infection prevention and control interventions during care transitions in addition to the medication information in the finalized measure.

*Response:* The Transfer of Health Information to the Provider—Post-Acute Care measure focuses on the transfer of a reconciled medication list. The measure was designed after input from TEPs, public comment, and other stakeholders that suggested the quality measures focus on the transfer of the most critical pieces of information to support patient safety and care coordination. However, we acknowledge that the transfer of many other forms of health information is important, and while the focus of this measure is on a reconciled medication list, we hope to expand our measures in the future.

*Comment:* Several commenters raised concerns about both of the Transfer of Health Information measures not being endorsed by the National Quality Forum (NQF). A few commenters requested that we consider delaying rollout of these two new measures until endorsed by NQF. A few commenters recommended that we only adopt measures that have NQF approval. One commenter was opposed to the measures because they have not been endorsed by NQF.

*Response:* While this measure is not currently NQF-endorsed, we recognize that the NQF endorsement process is an important part of measure development. As discussed in the FY 2020 IRF PPS proposed rule (84 FR 17286 through 17291), we believe the measures better address 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, than any endorsed measures. While 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), 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 has been endorsed or adopted by a consensus organization identified by the Secretary. We plan to submit the measure for NQF endorsement consideration as soon as feasible.

*Comment:* Several commenters stated that the Transfer of Health Information measures will add burden. Two commenters did not support the measures for this reason. One commenter stated that achieving high performance on the measures will add administrative burden. Another commenter stated that the measures will add burden with no added value.

Another commenter stated that while there will be additional burden on IRFs to collect and report data for these new measures, the benefit to patients and the CMS program outweighs the additional burden on providers.

*Response:* We agree that the benefit to patients outweighs any additional burden on providers. We are also very mindful of burden that may occur from the collection and reporting of our measures, as supported by the Meaningful Measures and Patients over Paperwork initiatives. We emphasize that both measures are comprised of one item, and further, the activities associated with the measure align with existing requirements related to transferring information at the time of discharge to safeguard patients. Additionally, TEP feedback and pilot test found that the burden of reporting will not be significant. We believe that these measures will likely drive improvements in the transfer of medication information between providers and with patients, families, and caregivers.

*Comment:* One commenter stated that there will be no additional burden to IRFs, because providing medication information as part of discharge planning is a Condition of Participation requirement for Medicaid and Medicare, and the medication list can be generated from the electronic medical record.

*Response:* We believe that the Transfer of Health Information measures will not substantially increase burden because we understand that many hospitals already generate medication lists as a best practice.

*Comment:* We received comments related to the validity and reliability of both Transfer of Health Information measures. One commenter suggested that CMS should ensure accuracy of these measures. Other commenters suggested that additional testing is

needed to ensure that these measures will be able to differentiate among IRF providers. Another commenter questioned if the measures would be topped out shortly after adoption, since medication reconciliation is already completed by facilities at discharge.

*Response:* Elements of validity and reliability were analyzed during pilot testing of these measures, with good results, including inter-rater reliability of at least 87 percent for all tested items. Pilot testing also indicated that there is room for improvement for IRFs and other settings, so we do not expect the measure to be topped out shortly after adoption. As we monitor the outcomes of these measures, we will ensure that reliability and validity of the measures meet acceptable standards.

*Comment:* Some commenters recommended ways in which the Transfer of Health Information measures specifications could be updated or changed. A few commenters suggested that the “not applicable” (NA) answer choice available in the home health version of the measure be made available in all settings, including IRFs. A few commenters also requested clarification about why patients discharged home under the care of an organized home health service or hospice would be captured in the denominators of both Transfer of Health Information measures.

*Response:* We are appreciative of the measure modification suggestions and clarify why the response option of N/A was considered only for the HH version of this measure. The coding response N/A, or “not applicable” is used when the HHA was not made aware of the transfer in a timely manner and, therefore, the HHA is not able to provide the medication list at the time of transfer to the subsequent provider. For example, a HHA may not be immediately aware when a patient is taken to the emergency room. For facility settings, such as the IRF setting, where 24-hour care is being provided, the facility should always be aware and actively involved in the discharge of the patient, and therefore, able to provide the current reconciled medication list at the time of discharge. Therefore, we believed the coding option of “N/A” would not be useful in the facility-based measure as the facility is aware and involved in the discharge. We wish to note that while the N/A option is considered for the HHA version of the measure, the measure specifications indicate that these patients are not removed from the denominator. In addition, discharge to home under the care of an organized HHA or hospice is captured in the denominator of both the

Transfer of Health Information to Provider and Transfer of Health Information to Patient measures because this type of discharge represents two opportunities to transfer the medication list. These measures aim to assure that each of these transfers is taking place. We refer readers to the measure specifications where updates or changes can be found and are 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>.

*Comment:* One commenter suggested that the Transfer of Health Information measures should include a measure of the timeliness of the transfer. The commenter stated that, as currently specified, the measures give equal credit for information that is sent immediately and information sent days later.

*Response:* We appreciate the suggestions that CMS develop and adopt measures that assess for the timeliness of transfer. We agree that measure concepts of this type are important and would complement the measures that focus for whether information was transferred at the time the patient leaves the facility. We clarify that the measures do not give credit for when information was sent, whether immediately or days later. This is because there may be circumstances where information may not be sent at the immediate time of discharge. However, the measures do require that information be shared with the subsequent provider and/or the patient as close to the time of discharge as this is actionable, allows for shared decision making, and will increase coordinated care. We are not establishing a new standard of transfer at discharge; we are simply assessing if information was sent at the time a patient leaves the facility. As we move through future measure development work, we will consider a “timeliness” component for these measure concepts.

*Comment:* A commenter noted that although CMS provided guidelines regarding what should be included in the transfer of medication information, the data collection on this measure does not require that these guidelines be met. The commenter questioned if CMS intends to audit IRFs to ensure that the measure values are consistent with the information being shared.

*Response:* The Transfer of Health Information measures serve as a check to ensure that a reconciled medication list is provided as the patient changes care settings. Defining the completeness of that medication list is left to the discretion of the providers and patient

who are coordinating this care. We interpret the comment about audits to be referring to data validation. While we do not have a data validation program in place at this time, we are exploring such a program akin to that of the hospital QRPs. For all measures and data collected for the IRF QRP, we monitor and evaluate our data to assess for coding patterns, errors, reliability, and soundness of the data. Through data monitoring, we are able to assess if measure outcomes are consistent with the information that is collected. We note that all data are subject to review and audit.

*Comment:* A few comments included concerns that the Transfer of Health Information measures are not indicative of provider quality and questioned the ability of the measures to improve patient outcomes. Two commenters did not support the measures for this reason. Commenters noted that the measures assess whether a medication list was transferred and not whether that medication list was accurate and received by the subsequent provider.

*Response:* The Transfer of Health Information to the Provider—Post-Acute Care and Transfer of Health Information to the Patient—Post-Acute Care measures are process measures designed to address and improve an important aspect of care quality. Lack of timely transfer of medication information at transitions has been demonstrated to lead to increased risk of adverse events, medication errors, and hospitalizations. In addition, public commenters and our TEP members identified many problems and gaps in the timely transfer of medication information at transitions. Process measures, such as these, are building blocks toward improved coordinated care and discharge planning, providing information that will improve shared decision making and coordination. Further, process measures hold a lot of value as they delineate negative and/or positive aspects of the health care process. These measures will capture the quality of the process of medication information transfer and, we believe, help to improve those processes. When developing future measures, we will take into consideration suggestions about measures that assess the accuracy of the medication list and whether it was received by the subsequent provider.

*Comment:* One commenter suggested that CMS work to identify interoperability solutions as a means of decreasing opportunities for errors by providing clinicians and patients secure access to the most up-to-date medication-related information. The

commenter also suggests that if CMS is required by the IMPACT Act to adopt these measures, that we do so as an interim step, within a defined timeframe, while interoperability solutions are explored and tested.

*Response:* We agree with the comments on the importance of interoperability solutions to support health information transfer. CMS and ONC are focused on improving interoperability and the timely sharing of information between providers, patients, families and caregivers. We believe that PAC provider health information exchange supports the goals of high quality, personalized, efficient healthcare, care coordination, person-centered care, and supports real-time, data driven, clinical decision making. We are optimistic that this measure will encourage the electronic transfer of current and important medication information at transitions. These measures and related efforts may help accelerate interoperability solutions. The Transfer of Health Information measures assess the process of medication transfer, which can occur through both electronic and non-electronic means. We clarify that these measures are an interim step in improving coordinated care, and we also believe that other interoperable solutions should be explored. Finalizing these Transfer of Health measures will be a first step in measuring the transfer of this medication-related information.

After consideration of the public comments, we are finalizing our proposal to adopt the Transfer of Health Information to the Provider—Post Acute Care (PAC) measure, under section 1899B(c)(1)(E) of the Act, with data collection for discharges beginning October 1, 2020.

## 2. Transfer of Health Information to the Patient—Post-Acute Care (PAC) Measure

Beginning with the FY 2022 IRF QRP, we proposed 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.<sup>56</sup> Of the Medicare FFS beneficiaries with an IRF stay in FYs 2016 and 2017, an estimated 51 percent were discharged home with home health services, 21 percent were discharged home with self-care, and 0.5 percent were discharged with home hospice services.<sup>57</sup>

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.<sup>58 59 60 61 62</sup> 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.<sup>63 64</sup> Upon discharge to home,

<sup>56</sup> 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>.

<sup>57</sup> RTI International analysis of Medicare claims data for index stays in IRF 2016/2017. (RTI program reference: MM150).

<sup>58</sup> 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.

<sup>59</sup> Boockvar, K.S., Blum, S., Kugler, A., Livote, E., Mergenhagen, K.A., Nebeker, J.R., & Yeh, J., "Effect of admission medication reconciliation on adverse drug events from admission medication changes," *Archives of Internal Medicine*, 2011, Vol. 171(9), pp. 860–861.

<sup>60</sup> Bell, C.M., Brenner, 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.

<sup>61</sup> 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.

<sup>62</sup> Desai, R., Williams, C.E., Greene, S.B., Pierson, S., & Hansen, R.A., "Medication errors during patient transitions into nursing homes: Characteristics and association with patient harm," *The American Journal of Geriatric Pharmacotherapy*, 2011, Vol. 9(6), pp. 413–422.

<sup>63</sup> 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 of the American Geriatrics Society*, 2016, Vol. 64(11), pp. e166–e170.

individuals in PAC settings may be faced with numerous medication changes, new medication regimes, and follow-up details.<sup>65 66 67</sup> The efficient 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.<sup>68 69</sup>

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.<sup>70 71</sup> 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

<sup>64</sup> Chhabra, P.T., Rattinger, G.B., Dutcher, S.K., Hare, M.E., Parsons, K., L., & Zuckerman, I.H., "Medication reconciliation during the transition to and from long-term care settings: A systematic review," *Res Social Adm Pharm*, 2012, Vol. 8(1), pp. 60–75.

<sup>65</sup> 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 of the American Geriatrics Society*, 2016, Vol. 64(11), pp. e166–e170.

<sup>66</sup> 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.

<sup>67</sup> Sheehan, O.C., Kharrazi, H., Carl, K.J., Leff, B., Wolff, J.L., Roth, D.L., Gabbard, J., & Boyd, C.M., "Helping older adults improve their medication experience (HOME) by addressing medication regimen complexity in home healthcare," *Home Healthcare Now*, 2018, Vol. 36(1) pp. 10–19.

<sup>68</sup> 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.

<sup>69</sup> 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.

<sup>70</sup> 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>.

<sup>71</sup> 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](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf).

improving patient outcomes and transitional care.<sup>72</sup>

#### 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,<sup>73</sup> January 27, 2017,<sup>74</sup> and August 3, 2017<sup>75</sup> 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

<sup>72</sup> 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.

<sup>73</sup> 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](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).

<sup>74</sup> 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](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).

<sup>75</sup> Ibid.

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/2019/02/MAP\\_2019\\_Considerations\\_for\\_Implementing\\_Measures\\_Final\\_Report\\_-\\_PAC-LTC.aspx](http://www.qualityforum.org/Publications/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 PAC 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 “Final 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 proposed for this measure, we refer readers to section VIII.G.3. of this rule.

Commenters submitted the following comments related to the proposed rule's discussion of the IRF QRP Quality Measure Proposals Beginning with the FY 2022 IRF QRP. A discussion of these comments, along with our responses, appears below. We received many comments that addressed both of the Transfer of Health Information measures. Comments that applied to both measures are discussed above in IX.D.1 of this rule.

*Comment:* One commenter suggested that CMS use the field's experience with transferring information to patients and reporting on this measure to disseminate best practices about how to best convey the medication list and suggested this include formats and informational elements helpful to patients and families.

*Response:* We have interpreted “the field” to mean PAC providers. Facilities and clinicians should use clinical judgement to guide their practices around transferring information to patients and how to best convey the medication list, including identifying the best formats and informational elements. This may be determined by the patient's individualized needs in response to their medical condition. We do not determine clinical best practices standards and facilities are advised to

refer to other sources, such as professional guidelines.

*Comment:* One commenter suggested that the Transfer of Health Information to the Patient—Post-Acute Care (PAC) Measure require transfer of the medication list to both the patient and family or caregiver.

*Response:* We agree there are times when it is appropriate for the IRF to provide the medication list to the patient and family and this decision should be based on clinical judgement. However, because it is not always necessary or appropriate to provide the medication list to both the patient and family, we are not requiring this for the measure.

After consideration of the public comments, we are finalizing our proposal to adopt the Transfer of Health Information to the Patient—Post Acute Care (PAC) measure, under section 1899B(c)(1)(E) of the Act, with data collection for discharges beginning October 1, 2020.

3. Update to the Discharge to Community—Post Acute Care (PAC) Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP) Measure

In the FY 2020 IRF PPS proposed rule (84 FR 17291), we proposed 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 proposed 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 “Final 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 comment on this proposal and received several comments. A discussion of these comments, along with our responses, appears below.

*Comment:* Several commenters supported the proposed exclusion of baseline NF residents from the Discharge to Community—PAC IRF QRP

measure. Commenters referred to their recommendation of this exclusion in prior years and appreciated CMS’ willingness to consider and implement stakeholder feedback. One commenter stated they did not foresee any negative impacts of the exclusion. One commenter suggested that CMS instead consider other quality measures for NF residents, such as functional status measures, to determine whether residents receive the appropriate standard of care they need in a long-term NF stay.

*Response:* We thank the commenters for their support of the proposed exclusion of baseline nursing facility residents from this measure and for recommending other measures for consideration for baseline NF residents.

*Comment:* MedPAC did not support the proposed exclusion of baseline nursing facility residents from the Discharge to Community—PAC IRF QRP measure. They suggested that CMS instead expand their definition of “return to the community” to include baseline nursing home residents returning to the nursing home where they live, as this represents their home or community. MedPAC also stated that providers should be held accountable for the quality of care they provide for as much of their Medicare patient population as feasible.

*Response:* We agree that providers should be accountable for quality of care for as much of their Medicare population as feasible; we endeavor to do this as much as possible, only specifying exclusions we believe are necessary for measure validity. We also believe that monitoring quality of care and outcomes is important for all PAC patients, including baseline NF residents who return to a NF after their PAC stay. We publicly report several long-stay resident quality measures on Nursing Home Compare including measures of hospitalization and emergency department visits.

Community is traditionally understood as representing non-institutional settings by policy makers, providers, and other stakeholders. Including long-term care NF in the definition of community would confuse this long-standing concept of community and would misalign with CMS’ definition of community in patient assessment instruments. We conceptualized this measure using the traditional definition of “community” and specified the measure as a discharge to community measure, rather than a discharge to baseline residence measure.

Baseline NF residents represent an inherently different patient population with not only a significantly lower

likelihood of discharge to community settings, but also a higher likelihood of post-discharge readmissions and death compared with PAC patients who did not live in a NF at baseline. The inherent differences in patient characteristics and PAC processes and goals of care for baseline NF residents and non-NF residents are significant enough that we do not believe risk adjustment using a NF flag would provide adequate control. While we acknowledge that a return to nursing home for baseline NF residents represents a return to their home, this outcome does not align with our measure concept. Thus, we have chosen to exclude baseline NF residents from the measure.

*Comment:* One commenter suggested the definition of “long-term” NF stay in the proposed measure exclusion, requesting further clarification in the measure specifications.

*Response:* We have further clarified the definition of long-term NF stay in the final measure specifications, Final 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>. A long-term NF stay is identified by the presence of a non-SNF PPS MDS assessment in the 180 days preceding the qualifying prior acute care admission and index SNF stay.

*Comment:* One commenter questioned whether the methodology for calculating confidence intervals for performance categories used in public display of the Discharge to Community—PAC measures has been updated.

*Response:* On May 31, 2019, we announced an update to the methodology used for calculating confidence intervals for provider assignment to performance categories for public display of the Discharge to Community—PAC measures. For more information, we refer readers to the “Fact Sheet for Discharge to Community Post-Acute Care Measures” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/Downloads/Fact-Sheet-for-Discharge-to-Community-Post-Acute-Care-Measures.pdf> and the “FAQ for Discharge to Community Post-Acute Care Measures” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/Downloads/FAQ-for-Discharge-to-Community-Post-Acute-Care-Measures.pdf>.

*Community-Post-Acute-Care-Measures.pdf.*

After consideration of the public comments, we are finalizing our proposal to exclude baseline NF residents from the Discharge to Community—PAC IRF QRP measure as proposed beginning with the FY 2020 IRF QRP.

*E. IRF QRP Quality Measures, Measure Concepts, and Standardized Patient Assessment Data Elements Under Consideration for Future Years: Request for Information*

We sought 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 17 for future years in the IRF QRP.

**TABLE 17: 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, we intend to use this input to inform our future measure and SPADE development efforts.

We received several comments on this RFI, which are summarized below.

*Comment:* Several commenters supported the inclusion of all of the proposed measures and SPADEs listed in Table 17. One commenter agreed that the SPADE categories will provide a fuller picture of the patients in the IRF setting and could be used for creating and risk adjusting quality measures.

Many commenters supported the dementia SPADE, since dementia can affect a beneficiary's ability to participate in his or her care in the PAC setting, in addition to managing chronic conditions and medications after discharge. One commenter also agreed that regularly assessing cognitive function and mental health status presents opportunities for better care and quality of life.

One commenter did not support the cognitive complexity SPADEs, since there is no singular assessment tool designed to assess executive function and memory, and it would be overly burdensome for IRFs to conduct testing on every patient. The commenter recommended that CMS work with stakeholders to prioritize which patient conditions would benefit from a

cognitive complexity assessment and screen for those cases.

Many commenters supported the caregiver status SPADE; one commenter stated that regular assessment of caregivers will result in better care for the beneficiary and quality of life for both individuals. Another commenter encouraged CMS to capture caregiver status, along with the caregiver's willingness and ability, and account for it in discharge disposition outcomes.

With regard to an opioids-based quality measure, providers had some concerns about unintended consequences of reporting of opioid use, including the over- or under-prescribing of opioids or limiting patients access to critical treatments for pain management.

Many commenters were supportive of SPADEs focused on bowel and bladder continence. One commenter noted that this is already collected on admission and did not support a bowel and bladder SPADE on discharge, citing that IRFs already communicate continence needs at discharge and this would be duplicative. A few commenters had concerns about the burden of future measures and SPADEs. One commenter recommended that prior to adding measures or data elements, CMS reassess and analyze all of the measures and data elements currently collected to limit administrative burden and create a meaningful set of measures and data elements. Another commenter supported utilization of data from the

suggested measures and SPADEs and suggested using existing data sources, such as Medicare claims data. One commenter did not support any future SPADE concepts that were not required by the IMPACT Act. Another commenter suggested that CMS should explore beneficiary-matching methods with the Department of Veteran's Affairs to collect veteran status without additional IRF data collection burden.

*Response:* We appreciate the input provided by commenters. While we will not be responding to specific comments submitted in response to this Request for Information, we intend to use this input to inform our future measure and SPADE development efforts.

*F. Standardized Patient Assessment Data Reporting Beginning With the FY 2022 IRF QRP*

Section 1886(j)(7)(F)(ii) of the Act requires that, for FY 2019 and each subsequent fiscal year, IRFs must report standardized patient assessment data 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) of the Act 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 noted 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 proposed to adopt many of the same SPADEs that we previously proposed to adopt, along with other SPADEs.

We proposed 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 Medicare Part A and Medicare Advantage patients discharged between October 1, 2020, and December 31, 2020 for the FY 2022 IRF QRP. Beginning with the FY 2023 IRF QRP, we proposed that IRFs must report data with respect to Medicare Part A and Medicare Advantage 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 also proposed that IRFs that submit the Hearing, Vision, Race, and Ethnicity SPADEs with respect to admission 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 SPADEs. In selecting the 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 PAC facilities (26 LTCHs, 60 SNFs, 22 IRFs, and 35 HHAs) from November 2017 to August 2018 to evaluate the feasibility, reliability, and validity of the candidate data elements across PAC settings. The 3,121 patients and residents with an admission assessment included 507 in LTCHs, 1,167 in SNFs, 794 in IRFs, and 653 in HHAs. 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.

*Comment:* Several commenters were supportive of the SPADE proposals. A commenter recognized that the proposed SPADEs may influence care, impact case mix and risk adjustment scores, and drive planning for future management. Other commenters supported the proposals to add the proposed SPADEs to the IRF-PAI, with one noting that many of the data elements are already collected and reported on, and the other stating that the items are important to describing current IRF patients and are applicable to determining patient acuity. Another

commenter stated that data standardization as accomplished by the SPADEs will help facilitate appropriate payment reforms and appropriate quality measures.

*Response:* We thank the commenters for their support. We selected the proposed SPADEs in part because of the attributes that the commenters noted, such as their ability to describe IRF patients and to support future quality measurement.

*Comment:* Some commenters stated support but noted reservations. One commenter described the SPADEs as an appropriate start, but noted that the SPADEs cannot stand alone, and must be built upon in order to be useful for risk adjustment and quality measurement. Similarly, another commenter suggested CMS continue working with clinicians and researchers to ensure that the SPADEs are collecting valid, reliable, and useful data, and to continue to refine and explore new data elements for standardization.

*Response:* We agree with the commenter's statement that the SPADEs are an appropriate start for standardization, but we disagree that they cannot stand alone. While we intend to evaluate the SPADEs as they are submitted and explore additional opportunities for standardization, we also believe that the SPADEs as proposed represent an important core set of information about clinical status and patient characteristics and they will be useful for quality measurement. We will continue to explore the use of the SPADEs across our PAC setting, continuing our efforts to explore the feasibility, reliability, validity, and usability of the data elements in our measure models and QRPs. We would welcome continued input, recommendations, and feedback from stakeholders about ways to improve assessment and quality measurement for PAC providers, including ways that the SPADEs could be used in the IRF QRP. Input can be shared with CMS through our PAC Quality Initiatives email address [PACQualityInitiative@cms.hhs.gov](mailto:PACQualityInitiative@cms.hhs.gov).

*Comment:* One commenter noted support for the goals of the IMPACT Act, but expressed concern about the scope and timing of proposed changes, including the SPADEs. The same commenter suggested that CMS share with the public a data use strategy and analysis plan for the SPADEs so that providers better understand how CMS will assess the potential usability of the SPADEs to support changes to payment and quality programs.

*Response:* We thank the commenter for the support and appreciate their

concern about the proposed changes. We intend to monitor and evaluate SPADEs as they are submitted, and to continue to engage stakeholders around ways the SPADEs could be best used in the PAC quality programs. We will continue to communicate and collaborate with stakeholders by soliciting input on use of the SPADEs in the IRF QRP through future rulemaking.

*Comment:* One commenter was generally critical of the set of SPADEs proposed, stating they fail to adequately describe a patient's clinical situation with regard to their level of independence, including swallowing function, communication, and cognitive function.

*Response:* The proposed SPADEs were selected based on their overall clinical relevance to PAC providers, including IRFs, their ability to facilitate care coordination during transitions, their ability to capture medical complexity and risk factors, and their scientific reliability and validity. We have strived to balance the scope and level of detail of the data elements against the potential burden placed on patients and providers. At this time, SPADEs focused on impairments are limited to sensory impairments (that is, hearing and vision) and do not include swallowing. The patient's ability to communicate is also not captured with a SPADE, although we note that the IRF-PAI includes two data elements on communication: Expression of Ideas and Wants, and Understanding Verbal and Non-Verbal Content. However, in combination with other sections of the IRF-PAI that have been standardized across PAC providers, we believe the proposed SPADEs capture key clinical information (for example, cognitive function for patients who are able to communicate, as collected by the BIMS) and form an important foundation of standardized assessment on which to build.

*Comment:* One commenter described several concerns about the scope and implementation of the National Beta Test, including the representativeness of IRFs included in the sample, the share of total IRF patients included in the National Beta Test, the reported exclusion of patients with communication and cognitive impairments, and the exclusion of non-English speaking patients, and described how these concerns compromise their confidence in the findings of the National Beta Test.

*Response:* In a supplementary document to the proposed rule, we described key findings from the National Beta Test related to the proposed SPADEs. We also referred

readers to an initial volume of the National Beta Test report that details the methodology of the field test ("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>). Additional volumes of the National Beta Test report will be available in late 2019.

To address the commenter's specific concerns, we note that the National Beta Test was designed to generate valid and robust national SPADE performance estimates for each of the four PAC provider types, which required acceptable geographic diversity, sufficient sample size, and reasonable coverage of the range of clinical characteristics. To meet these requirements, the National Beta Test was carefully designed so that data could be collected from a wide range of environments, allowing for thorough evaluation of candidate SPADE performance in all PAC settings. The approach included a stratified random sample, to maximize generalizability, and subsequent analyses included extensive checks on the sampling design.

The commenter further implied that the small share of overall IRF admissions included in the Beta test is indicative of inadequate representativeness. The objective of the National Beta Test was to evaluate the performance of candidate SPADEs for cross-setting use. It is true that the proportion of IRFs may not reflect actual proportion in the United States, but our sampling design ensured that sufficient spread of IRFs across randomly selected markets, and adequate numbers to provide ample data with which to evaluate SPADE performance in IRFs relative to other settings.

The National Beta Test did not exclude non-communicative patients/residents; rather, it had two distinct samples, one of which focused on patients/residents who were able to communicate, and one of which focused on patient/residents who were not able to communicate. The assessment of non-communicative patients/residents differed primarily in that observational assessments were substituted for some interview assessments. Non-English-speaking patients were excluded from the National Beta Test due to feasibility constraints during the field test. Including limited English proficiency patients/residents in the sample would

have required the Beta test facilities to engage or involve translators during the test assessments. We anticipated that this would have added undue complexity to what facilities/agencies were being requested to do, and would have undermined the ability of facility/agency staff to complete the requested number of assessments during the study period. Moreover, there is strong existing evidence for the feasibility of all clinical patient/resident interview SPADEs included in this final rule (BIMS [section IX.G.1 in this final rule], Pain Interference [section IX.G.3 in this final rule], PHQ [section IX.G.1 in this final rule]) when administered in other languages, either through standard PAC workflow, as tested and currently collected in the MDS 3.0, or through rigorous translation and testing, such as the PHQ. For all these reasons, we determined that the performance of translated versions of these patient/resident interview SPADEs did not need to be further evaluated. In addition, because their exclusion did not threaten our ability to achieve acceptable geographic diversity, sufficient sample size, and reasonable coverage of the range of PAC patient/resident clinical characteristics, the exclusion of limited English proficiency patients/residents was not considered a limitation to interpretation of the National Beta Test results.

*Comment:* Two commenters wanted CMS to share more information from the National Beta Test. One of the commenters remarked on the lack of information about clinical characteristics that has been shared with stakeholders, limiting their ability to draw conclusions about the data, and requested that CMS release the data from the National Beta Test to be analyzed by third parties. The other commenter noted that CMS has not shared quantitative results of the National Beta Test which has limited the ability of stakeholders to determine if these items will yield useful information for quality and/or payment purposes, and suggested CMS release additional information, such as response frequencies, and analysis from the field test to provide evidence of the validity and utility of the SPADEs for quality and payment.

*Response:* We shared both quantitative and qualitative findings from the National Beta Test with stakeholders at a public meeting on November 27, 2018. For each SPADE proposed in this rule within the clinical categories in the IMPACT Act, we provided information in the supplementary documents to the proposed rule (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>) on the feasibility and reliability based on findings from the National Beta Test.

We are in the process of writing the final report for the National Beta Test, which includes the clinical SPADEs in this rule as well as additional data elements. Volume 2 of that report (“Development and Evaluation of Candidate Standardized Patient Assessment Data Elements. Findings from the National Beta Test (Volume 2)”) was posted on CMS’ website in March 2019. The other volumes will be available in late 2019. In addition, we are committed to making data available for researchers and the public to analyze, and to doing so in a way that protects the privacy of patients and providers who participated in the National Beta Test. We are in the process of creating research identifiable files that we anticipate will be available through a data use agreement sometime in 2019.

*Comment:* Many commenters expressed concerns with respect to the standardized patient assessment data proposals. Several commenters stated that the standardized patient assessment data reporting requirements will impose significant burden on providers, given the volume of new standardized patient assessment data elements, and corresponding sub-elements, that were proposed to be added to the IRF–PAI. One commenter noted that the addition of the proposed standardized patient assessment data elements would require an expanded timeline to implement to ensure necessary operational and workflow revisions.

*Response:* We acknowledge the additional burden that the SPADEs will impose on providers and patients. Our development and selection process for the SPADEs we are adopting in this final rule prioritized data elements that are essential to comprehensive patient care. We maintain that there will be significant benefit associated with each of the SPADEs to providers and patients, in that they are clinically useful (for example, for care planning), they support patient-centered care, and they will promote interoperability and data exchange between providers. During the SPADE development process, we were cognizant of the changes that providers will need to make to implement these additions to

the IRF–PAI. In the last two rules (82 FR 36287 through 36289, 83 FR 38555), we provided information about goals, scope, and timeline for implementing SPADEs, as well as updated IRFs about ongoing development and testing of data elements through other public forums. We believe that IRFs have had an opportunity to familiarize themselves with other new reporting requirements that we have adopted under the IMPACT Act and prepare for additional changes.

*Comment:* Some commenters expressed concern that this additional burden was not justified because, in their view, there was limited or no evidence for the SPADEs to describe case mix, measure quality, or improve care. One of these commenters noted that CMS has provided evidence of validity, reliability, and feasibility through documents related to the National Beta Test, but stated that CMS has not provided any evidence that the proposed SPADEs have the “potential for improving quality” or “utility for describing case mix.”

*Response:* The clinical SPADEs proposed in this rule were the result of an extensive consensus vetting process in which experts and stakeholders were engaged through Technical Expert Panels, Special Open Door Forums, and posting of interim reports and other documents on the CMS website. Results of these activities provide evidence that experts and providers believe that the proposed SPADEs have the potential for measuring quality, for describing case mix, and improving care. We refer the commenter to the most recent TEP report: A summary of the September 17, 2018 TEP meeting titled “SPADE Technical Expert Panel Summary (Third Convening)”, which 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 this report, we summarize the TEP’s discussion of individual SPADEs in which they reflect on the clinical usefulness and importance of the SPADEs for describing patient acuity (case mix) and providing high-quality clinical care (improving quality). Therefore, we have provided evidence that the SPADEs have the potential for improving quality and utility for describing case mix.

*Comment:* One commenter believes that the expansion of the IRF–PAI assessment will prove to be intrusive and prove challenging for patients who are elderly, frail, in pain, or have cognitive deficits, causing the patients

to lose focus, and thus, impact the accuracy of the data.

*Response:* We acknowledge that several SPADEs in this rule require the patient to be asked questions directly. We believe that direct patient assessment and patient-reported outcomes on these topics have benefits for providers and patients. These data elements support patient-centered care by soliciting the patient's perspective, and better information on a patient's status is expected to improve the care the patient receives.<sup>76 77 78</sup> The burden the patient-interview data elements place on patients is necessary for accurate assessment of the patient's status. Regarding the validity and performance of interview-based data elements, we note that many of these data elements (for example, the BIMS, PHQ, and Pain Interference data elements) are currently used in the MDS in SNFs. Evidence from that setting, as well as from the National Beta Test, demonstrates feasibility of these data elements for even very sick patients, such as many patients receiving care from IRFs.

*Comment:* Commenters also stated that the time burden (as in, "time-to-complete") associated with the clinical SPADEs was underestimated, with some commenters noting that it did not account for clinician time to review charts and update treatment plans or that test conditions do not represent conditions of day-to-day operation. One commenter stated that the estimated time to complete reported in the National Beta Test was based only on the time needed to enter a value on a tablet and did not include the time to evaluate the patient on each item. Another commenter stated that because testing conditions focused on cognitively intact, English-speaking patients with no speech or language deficits, the estimates of impact to providers' time and resources is inadequate.

*Response:* We disagree with the commenters that the National Beta Test time-to-complete estimates are underestimates. Contrary to what one

commenter noted, we wish to clarify that time-to-complete estimates from the National Beta Test included the time spent both to collect data, including the review of the medical record, if needed, and to enter the data elements into a tablet. We note that time-to-complete estimates were calculated using the data from Facility/Agency Staff only, and not Research Nurses, who completed more training and conducted more assessments overall than the Facility/Agency staff. This decision to calculate time-to-complete estimates from Facility/Agency Staff only supports our claim that the time-to-complete estimates are accurate reflections of the time the SPADEs will require when implemented by PAC providers in day-to-day operations. Contrary to another commenter's statement, we also wish to clarify that National Beta Test did exclude patients/residents who were not able to communicate in English, but did not categorically exclude patients with cognitive impairment or patients with speech or language deficits. Therefore, we believe that our estimates of time-to-complete capture the general population of IRF patients, including those with communication impairments.

*Comment:* Some commenters recommended changes to when and how SPADEs would be collected in order to reduce administrative burden. These recommendations included collecting data only at admission when answers are unlikely to change between admission and discharge, adopting a staged implementation or only a subset of the proposed data elements, and that CMS explore options for obtaining these data via claims or voluntary reporting only, particularly as many of the proposed SPADEs are not relevant to IRF patients.

*Response:* We appreciate the commenters' recommendations. To support data exchange between settings, and to support quality measurement, section 1899B(b)(1)(A) of the Act requires that the SPADEs be collected with respect to both admission and discharge. In the FY 2020 IRF PPS proposed rule (84 FR 17292), we proposed that IRFs that submit four SPADEs with respect to admission will be deemed to have submitted those SPADEs with respect to both admission and discharge, because we stated that it is unlikely that the assessment of those SPADEs at admission would differ from the assessment of the same SPADEs at discharge. We note that a patient's ability to hear or ability to see are more likely to change between admission and discharge than, for example, a patient's self-report of his or her race, ethnicity, preferred language, or need for

interpreter services. The Hearing and Vision SPADEs are also different from the other SPADEs (that is, Race, Ethnicity, Preferred Language, and Interpreter Services) because evaluation of sensory status is a fundamental part of the ongoing nursing assessment conducted for IRF patients. Therefore, clinically significant changes that occur in a patient's hearing or vision status during the IRF stay would be captured as part of the clinical record and communicated to the next setting of care, as well as taken into account during discharge planning as a part of standard best practice.

After consideration of public comments discussed in sections IX.G.4 and IX.G.4.b in this final rule, we will deem IRFs that submit the Hearing, Vision, Race, Ethnicity, Preferred Language, and Interpreter Services SPADEs with respect to admission to have submitted with respect to both admission and discharge. We will take into consideration the recommendation to obtain patient data from claims data in future work.

*Comment:* A commenter recommended that CMS limit the number and type of data elements implemented in the coming year, continue ongoing dialogue with stakeholders, and develop and implement a process to assess the value of specific indicators for all patient types. Another commenter recommended that CMS conduct a thorough analysis of SPADEs currently collected to determine if any current data elements could be eliminated. One commenter believed that CMS should not finalize the implementation of the SPADEs until they evaluate alternative means of data collection (such as via billing/claims data), or measures to reduce burden (such as removal of duplicative data elements and elimination of data collection at discharge).

*Response:* We note that we adopted SPADEs in the last two rule cycles to support the adoption of the IRF Functional Outcomes Measures (Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (80 FR 47111); Change in Self-Care for Medical Rehabilitation Patients (80 FR 47117); Change in Mobility Score for Medical Rehabilitation Patients (80 FR 47118); Discharge Self-Care Score for Medical Rehabilitation Patients (80 FR 47119); Discharge Mobility Score for Medical Rehabilitation Patients (80 FR 47120)) and drug regimen review (Drug Regimen Review Conducted with Follow-Up for

<sup>76</sup> Boyce MB, Browne JP, Greenhalgh J. The experiences of professionals with using information from patient-reported outcome measures to improve the quality of healthcare: A systematic review of qualitative research. *BMJ Quality & Safety* 2014;23:508–518.

<sup>77</sup> Chen J, Ou L, Hollis SJ. A systematic review of the impact of routine collection of patient reported outcome measures on patients, providers and health organizations in an oncologic setting. *BMC Health Services Research* 2013;13:211.

<sup>78</sup> Marshall, S., Haywood, K. and Fitzpatrick, R. (2006), Impact of patient-reported outcome measures on routine practice: A structured review. *Journal of Evaluation in Clinical Practice*, 12: 559–568. doi:10.1111/j.1365-2753.2006.00650.x.

Identified Issues (81 FR 52111)). We have also communicated about the SPADE development work with stakeholders over the last 2 years through SODFs held on June 20, 2017, September 28, 2017, December 12, 2017, March 28, 2018, June 19, 2018, and July 25, 2018, and at a public meeting of stakeholders on November 27, 2018. Therefore, our implementation to date has been incremental while we have strived to keep stakeholders apprised as to the status of ongoing SPADE development. We have also conducted a large-scale test of feasibility and reliability—the National Beta Test, described in the proposed rule (84 FR 17293)—which, along with the consensus vetting activities described in the proposals for each SPADE, provide evidence of the value of the SPADEs for patients across PAC settings, including IRF patients. We will monitor and conduct analysis on the SPADEs as they are submitted in order to identify any problems and to identify any unnecessary burden or duplication.

*Comment:* One commenter recommended that CMS focus on providing funding and administrative support to allow improvements and standardization to the electronic medical record to allow effective interoperability across all post-acute sites.

*Response:* We appreciate the commenter's recommendation. At this time, funding for electronic medical record adoption and support is not currently authorized for PAC providers.

Final decisions on the SPADEs are given below, following more detailed comments on each SPADE proposal.

### G. 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.<sup>79</sup> 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,<sup>80</sup> and because

<sup>79</sup> 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>.

<sup>80</sup> 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.

these assessments provide opportunity for improving quality of care.

Symptoms of dementia may improve with pharmacotherapy, occupational therapy, or physical activity,<sup>81 82 83</sup> and promising treatments for severe traumatic brain injury are currently being tested.<sup>84</sup> For older patients and residents diagnosed with depression, treatment options to reduce symptoms and improve quality of life include antidepressant medication and psychotherapy,<sup>85 86 87 88</sup> and targeted services, such as therapeutic recreation, exercise, and restorative nursing, to increase opportunities for psychosocial interaction.<sup>89</sup>

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

<sup>81</sup> Casey D.A., Antimisiaris D., O'Brien J. (2010). Drugs for Alzheimer's Disease: Are They Effective? *Pharmacology & Therapeutics*, 35, 208–11.

<sup>82</sup> 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.

<sup>83</sup> 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.

<sup>84</sup> 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.

<sup>85</sup> 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.

<sup>86</sup> Arean P.A., Cook B.L. (2002). Psychotherapy and combined psychotherapy/pharmacotherapy for late life depression. *Biological Psychiatry*, 52(3), 293–303.

<sup>87</sup> 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.

<sup>88</sup> Wagenaar D., Colenda C.C., 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.

<sup>89</sup> 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 Health Qual*. 2016. Vol. 38, No. 6, pp. e76–e88.

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 degenerative conditions, such as dementia, and appropriate use of medications for behavioral and psychological symptoms of dementia.

We sought comment on our proposals to collect as standardized patient assessment data the following data with respect to cognitive function and mental status.

Commenters submitted the following comments related to the proposed rule's discussion of the cognitive function and mental status data elements.

*Comment:* A few commenters were supportive of the proposal to adopt the BIMS, CAM, and PHQ–2 to 9 as SPADEs on the topic of cognitive function and mental status. One commenter agreed that standardizing cognitive assessments will allow providers to identify changes in status, support clinical decision-making, and improve care continuity and interventions.

*Response:* We thank the commenters for their support. We selected the

Cognitive Function and Mental Status data elements for proposal as standardized data in part because of the attributes that the commenters noted.

*Comment:* A few commenters noted limitations of these SPADEs to fully assess all areas of cognition and mental status, particularly mild to moderate cognitive impairment, and performance deficits that may be related to cognitive impairment. Some commenters suggested CMS continue exploring assessment tools on the topic of cognition and to include a more comprehensive assessment of cognitive function for use in PAC settings, noting that highly vulnerable patients with a mild cognitive impairment cannot be readily identified through the current SPADEs.

*Response:* We have strived to balance the scope and level of detail of the data elements against the potential burden placed on patients and providers. In our past work, we evaluated the potential of several different cognition assessments for use as standardized data elements in PAC settings. We ultimately decided on the BIMS, CAM, and PHQ-2 to 9 data elements in our proposal as a starting point. We would welcome continued input, recommendations, and feedback from stakeholders about additional data elements for standardization, which can be shared with CMS through our PAC Quality Initiatives email address: [PACQualityInitiative@cms.hhs.gov](mailto:PACQualityInitiative@cms.hhs.gov).

*Comment:* A commenter stated that cognitive assessment should be individualized, rather than standardized, and performed as determined by patient needs.

*Response:* We believe that the standardized assessment of cognitive function is essential to achieving the goals of the IMPACT Act. We also wish to clarify that the proposed SPADEs are not intended to replace comprehensive clinical evaluation and in no way preclude providers from conducting further patient evaluation or assessments in their settings as they believe are necessary and useful.

*Comment:* Regarding future use of these data elements, one commenter recommended that CMS monitor the use of the cognition and mental status SPADEs as risk adjusters and make appropriate adjustments to methodology as needed.

*Response:* We intend to monitor data submitted via the proposed SPADEs and will consider these uses in the future. We will also continue to review recommendation and feedback from stakeholders regarding data elements that would both satisfy the categories listed in the IMPACT Act and provide meaningful data.

Final decisions on the SPADEs are given below, following more detailed comments on each SPADE proposal.

- Brief Interview for Mental Status (BIMS)

In the FY 2020 IRF PPS proposed rule (84 FR 17294 through 17295), we proposed 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.<sup>90</sup> 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.<sup>91</sup>

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 “Final Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at <https://>

<sup>90</sup> 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.

<sup>91</sup> RTI International. Proposed Measure Specifications for Measures Proposed in the FY 2017 IRF QRP NPRM. Research Triangle Park, NC. 2016.

[www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html](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, noted 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 “Final 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 (SODFs) 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 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 patient assessment data elements. However, taking together the importance of assessing for cognitive status, stakeholder input, and strong test results, we proposed 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.

Commenters submitted the following comments related to the proposed rule’s discussion of the BIMS data elements.

*Comment:* One commenter supported the collection of BIMS at both admission and discharge and believes it will result in more complete data and better care.

*Response:* We thank the commenter for the support of the BIMS data element.

*Comment:* One commenter stated that the BIMS fails to detect mild cognitive impairment, differentiate cognitive impairment from a language impairment to functional limitation, or identify issues with problem solving and executive function. This commenter recommended use of the Development of Outpatient Therapy Payment Alternatives (DOTPA) items for PAC, as well as a screener targeting functional cognition. Another commenter also recommended CMS identify a better cognitive assessment and not to move forward with the proposal.

*Response:* We recognize that the BIMS assesses components of cognition and does not, alone, provide a comprehensive assessment of potential cognitive impairment. We clarify that any SPADE is intended as a minimum assessment and does not limit the ability of providers to conduct a more comprehensive assessment of cognition to identify the complexities or potential impacts of cognitive impairment that the commenter describes.

We evaluated the suitability of the DOTPA, as well as other screening tools that targeted functional cognition, by engaging our TEP, through “alpha” feasibility testing, and through soliciting input from stakeholders. At the second meeting of TEP in March 2017, members questioned the use of data elements that rely on assessor observation and judgment, such as DOTPA CARE tool items, and favored other assessments of cognition that required patient interview or patient actions. The TEP also discussed performance-based

assessment of functional cognition. These are assessments that require patients to respond by completing a simulated task, such as ordering from a menu, or reading medication instructions and simulating the taking of medications, as required by the Performance Assessment of Self-Care Skills (PASS) items.

In Alpha 2 feasibility testing, which was conducted between April and July 2017, we included a subset of items from the DOTPA as well as the PASS. Findings of that test identified several limitations of the DOTPA items for use as SPADEs, such as relatively long to administer (5 to 7 minutes), especially in the LTCH setting. Assessors also indicated that these items had low relevance for SNF and LTCH patients. In addition, interrater reliability was highly variable among the DOTPA items, both overall and across settings, with some items showing very low agreement (as low as 0.34) and others showing excellent agreement (as high as 0.81). Similarly, findings of the Alpha 2 feasibility test identified several limitations of the PASS for use as SPADEs. The PASS was relatively time-intensive to administer (also 5 to 7 minutes), many patients in HHAs and IRFs needed assistance completing the PASS tasks, and missing data were prevalent. Unlike the DOTPA items, interrater reliability was consistently high overall for PASS (ranging from 0.78 to 0.92), but the high reliability was not deemed to outweigh fundamental feasibility concerns related to administration challenges. A summary report for the Alpha 2 feasibility testing titled “Development and Maintenance of Standardized Cross Setting Patient Assessment Data for Post-Acute Care: Summary Report of Findings from Alpha 2 Pilot Testing” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Alpha-2-SPADE-Pilot-Summary-Document.pdf>.

Feedback was obtained on the DOTPA and other assessments of functional cognition through a call for input that was open from April 26, 2017 to June 26, 2017. While we received support for the DOTPA, PASS, and other assessments of functional cognition, commenters also raised concerns about the reliability of the DOTPA, given that it is based on staff evaluation, and the feasibility of the PASS, given that the simulated medication task requires props, such as a medication bottle with printed label and pill box, which may not be accessible in all settings. A summary report for the April 26 to June 26, 2017 public comment period titled

“Public Comment Summary Report 2” is available at [https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Public-Comment-Summary-Report-Standardized-Patient-Assessment-Data-Element-Work\\_PC2\\_Jan-2018.pdf](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Public-Comment-Summary-Report-Standardized-Patient-Assessment-Data-Element-Work_PC2_Jan-2018.pdf).

Based on the input from our TEP, results of alpha feasibility testing, and input from stakeholders, we decided to propose the BIMS for standardization at this time due to the body of research literature supporting its feasibility and validity, its relative brevity, and its existing use in the MDS and IRF–PAI.

*Comment:* A few commenters noted that BIMS is currently collected by IRFs and has not been demonstrated to predict costs or differentiate case-mix and believes that CMS has not provided any evidence that the BIMS is capable of being utilized for quality purposes to support the collection of these data elements at discharge. Another commenter stated that CMS has not provided quantitative evidence that the BIMS data elements are capable of measuring provider performance for quality or of differentiating case-mix for payment.

*Response:* We reiterate that the purpose of standardizing data elements, in accordance with the IMPACT Act, is to support care planning, clinical decision support, inform case-mix and quality measurement, support care transitions, and enable interoperable data exchange and data sharing between PAC settings. Before being identified as a SPADE, the BIMS underwent an extensive consensus vetting process in which experts and stakeholders were engaged through TEPs, SODFs, and posting of interim reports and other documents on the *CMS.gov* website. A summary of the most recent TEP meeting (September 17, 2018) 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>. Results of these activities provide evidence that experts and providers believe that the BIMS data elements have the potential for measuring quality, describing case mix, and improving care.

*Comment:* A commenter believes that assessing BIMS at discharge would not be clinically useful and would not contribute to improved patient care or outcomes. The commenter noted that assessing BIMS at discharge was not evaluated during the National Beta Test,

and objected to the BIMS being proposed for use at discharge.

*Response:* We maintain that a standardized cognitive assessment using the BIMS is clinically useful and has the potential to improve patient care and outcomes. The commenter stated that the BIMS was not administered at discharge in the National Beta Test. However, the BIMS was in fact assessed at both admission and discharge in the National Beta Test. Moreover, to support data exchange between settings, and to support quality measurement, the IMPACT Act requires that the SPADEs be collected with respect to both admission and discharge. After careful consideration of the public comments we received, we are finalizing our proposal to adopt the BIMS as standardized patient assessment data beginning with the FY 2022 IRF QRP as proposed.

- Confusion Assessment Method (CAM)

In the FY 2020 IRF PPS proposed rule (84 FR 17295), we proposed 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.<sup>92</sup> 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 proposed the four-item version of the CAM that assesses acute change in mental status, inattention, disorganized thinking, and

<sup>92</sup> 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.

altered level of consciousness. For more information on the CAM, we refer readers to the document titled “Final 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 noted 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 “Final 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 SODFs 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 proposed 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.

Commenters submitted the following comments related to the proposed rule’s discussion of the proposed CAM data elements.

*Comment:* A few commenters stated that the CAM would be redundant with other cognitive assessments, such as BIMS. One commenter stated that delirium would be assessed prior to discharge from the acute care setting, making the assessment of delirium at admission to the IRF redundant. Another commenter stated that concerns about burden outweighed the value that the CAM might have for some populations, and noted that daily physician visits and daily assessments of patients by the interdisciplinary team were sufficient to assess cognitive needs.

*Response:* The CAM specifically screens for change in mental status, inattention, disorganized thinking and altered level of consciousness, which can indicate symptoms of delirium. These symptoms are not assessed by other cognitive assessments in the IRF-PAI. We believe the assessment of delirium at admission and discharge is important to informing patient care. Delirium occurs in up to half of patients/residents receiving PAC services,<sup>93</sup> and signs and symptoms of delirium are associated with poor functional recovery,<sup>94</sup> re-hospitalization, and mortality.<sup>95</sup> Because the majority of delirium episodes are transient,<sup>96</sup> we would not expect assessment of delirium prior to discharge from the acute care setting to capture all cases of delirium in PAC, as there may be an acute change in mental status from the patient’s baseline or

fluctuations in the patient’s behaviors that are identified after PAC admission.

*Comment:* Several commenters noted doubts about the usefulness of the CAM. One commenter was unsure if CAM will identify differences in cognitive status or measure changes during the stay resulting from therapeutic interventions. A few commenters stated that the CAM would not provide information that would be useful clinically, that it was not specific enough or too narrowly focused, and that it should not be required at discharge. Another commenter suggested that CMS not include the CAM as SPADE because they believe delirium is clinically apparent, and therefore, doubt that a standardized assessment of delirium will contribute to improving patient care or outcomes. Another commenter expressed concern that the CAM data elements would not identify cognitive needs that would impact quality in therapeutic intervention across facilities.

*Response:* As with any brief screening tool, we believe that the CAM has value as a universal assessment to identify patients in need of further clinical evaluation. Delirium occurs in up to 50 percent of patients/residents in PAC<sup>97</sup> and is associated with poor outcomes.<sup>98-99</sup> Hyperactive delirium—the type of delirium that manifests with agitation—makes up only a quarter of delirium cases.<sup>100-101</sup> Delirium more commonly manifests as hypoactive, or “quiet” delirium,<sup>102</sup> suggesting that brief, universal screening is appropriate. Moreover, because there are treatments for delirium that can be developed based on medication review, physical examination, laboratory tests, and evaluation of environmental factors,<sup>103</sup>

<sup>97</sup> Kiely DK, Jones RN, Bergmann MA, Marcantonio ER. Association between psychomotor activity delirium subtypes and mortality among newly admitted post-acute facility patients. *J Gerontol A Biol Sci Med Sci* 2007;62:174–179.

<sup>98</sup> Marcantonio, Edward R., Samuel E. Simon, Margaret A. Bergmann, Richard N. Jones, Katharine M. Murphy, and John N. Morris. “Delirium Symptoms in Post-Acute Care: Prevalent, Persistent, and Associated with Poor Functional Recovery.” *Journal of the American Geriatrics Society*, Vol. 51, No. 1, January 2003, pp. 4–9.

<sup>99</sup> Edward R. Marcantonio et al., Outcomes of Older People Admitted to Postacute Facilities with Delirium,” *Journal of the American Geriatrics Society*, Vol. 53, No. 6, June 2005.

<sup>100</sup> Inouye SK, Westendorp RG, Saczynski JS. Delirium in elderly people. *Lancet* 2014;383:911–922.

<sup>101</sup> Marcantonio ER. In the clinic: Delirium. *Ann Intern Med* 2011;154:ITC6–1–ITC6–1.

<sup>102</sup> Yang FM, Marcantonio ER, Inouye SK, et al. Phenomenological subtypes of delirium in older persons: Patterns, prevalence, and prognosis. *Psychosomatics* 2009;50:248–254.

<sup>103</sup> Marcantonio ER. Delirium in Hospitalized Older Adults. *N Engl J Med*. 2017 Oct 12;377(15):1456–1466.

<sup>93</sup> Dan K. Kiely et al., “Characteristics Associated with Delirium Persistence Among Newly Admitted Post-Acute Facility Patients,” *Journals of Gerontology: Series A (Biological Sciences and Medical Sciences)*, Vol. 59, No. 4, April 2004; Edward R. Marcantonio et al., “Delirium Symptoms in Post-Acute Care: Prevalent, Persistent, and Associated with Poor Functional Recovery,” *Journal of the American Geriatrics Society*, Vol. 51, No. 1, January 2003.

<sup>94</sup> Marcantonio, Edward R., Samuel E. Simon, Margaret A. Bergmann, Richard N. Jones, Katharine M. Murphy, and John N. Morris. “Delirium Symptoms in Post-Acute Care: Prevalent, Persistent, and Associated with Poor Functional Recovery,” *Journal of the American Geriatrics Society*, Vol. 51, No. 1, January 2003, pp. 4–9.

<sup>95</sup> Edward R. Marcantonio et al., Outcomes of Older People Admitted to Postacute Facilities with Delirium,” *Journal of the American Geriatrics Society*, Vol. 53, No. 6, June 2005.

<sup>96</sup> Cole MG, Ciampi A, Belzile E, Zhong L. Persistent delirium in older hospital patients: A systematic review of frequency and prognosis. *Age Ageing* 2009;38:19–26.

we believe that screening for delirium would support care planning and care transitions for these patients.

*Comment:* A few commenters believe the CAM would be difficult to administer and raised concerns about the training that staff would receive in order to ensure that administration is consistent and valid.

*Response:* We appreciate the commenters' recommendation to provide clear training for administering the CAM, and will take it into consideration as we revise the current training for the IRF-PAI. We intend to reinforce assessment tips and item rationale through training, open door forums, and future rulemaking efforts.

*Comment:* One commenter disagreed that delirium assesses a dimension of cognitive function.

*Response:* The CAM data elements were proposed to meet the definition of the standardized patient assessment data with respect to cognitive function and mental status. Section 1899B(b)(1)(B)(ii) of the Act specifies that PAC providers shall be required to submit standardized patient assessment data for the category of cognitive function, such as the ability to express ideas and to understand, and mental status, such as depression and dementia. A recent deterioration in cognitive function or present and fluctuating behaviors of inattention, disorganized thinking, or altered level of consciousness may indicate delirium.<sup>104</sup> Delirium can also be misdiagnosed as dementia.<sup>105</sup>

*Comment:* A commenter stated that CMS has not provided quantitative evidence that the CAM data elements are capable of measuring provider performance for quality or of differentiating case-mix for payment.

*Response:* The clinical SPADEs proposed in this rule, including CAM, were the result of an extensive consensus vetting process. Over the past several years, we have engaged experts and a wide range of stakeholders through TEPs, Special Open Door Forums, and documents made available on the *CMS.gov* website. A summary of the most recent TEP meeting (September 17, 2018) titled "SPADE Technical Expert Panel Summary (Third Convening)" is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment->

<sup>104</sup> Inouye SK, van Dyck CH, Alessi CA, Balkin S, Siegel AP, Horwitz RI. Clarifying confusion: The confusion assessment method. A new method for detection of delirium. *Ann Intern Med.* 1990 Dec 15;113(12):941-8.

<sup>105</sup> Marcantonio ER. Delirium in Hospitalized Older Adults. *N Engl J Med.* 2017 Oct 12;377(15):1456-1466.

*Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*. Results of these activities provide evidence that experts and providers believe that the proposed SPADEs, including the CAM data elements, have the potential for measuring quality, describing case mix, and improving care.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the CAM as standardized patient assessment data beginning with the FY 2022 IRF QRP as proposed.

- Patient Health Questionnaire-2 to 9 (PHQ-2 to 9)

In the FY 2020 IRF PPS proposed rule (84 FR 17296 through 17297), we proposed 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 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.<sup>106 107</sup> 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 "Final 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>.

The 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

<sup>106</sup> 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.

<sup>107</sup> 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.

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 noted 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,<sup>108</sup> 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 “Final 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 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 SODFs 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>.

*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 proposed 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.

Commenters submitted the following comments related to the proposed rule’s discussion of the PHQ-2 to 9 data elements.

*Comment:* Some commenters supported the inclusion of the PHQ-2 to 9. One of these commenters was particularly supportive of the use of the 2-item gateway in the PHQ-2 to 9 approach to improve efficiency.

*Response:* We thank the commenters for their support of the PHQ-2 to 9, including the gateway approach as a way to decrease burden for providers and patients.

*Comment:* One commenter was unsure if PHQ-2 to 9 will identify differences in cognitive status or measure changes during the stay resulting from therapeutic interventions. Another commenter expressed concern that the PHQ-2 to 9 data elements would not identify cognitive needs that would impact quality in therapeutic intervention across facilities.

*Response:* As with any brief screening tool, we believe that the PHQ-2 to 9 has value as a universal assessment to identify patients in need of further clinical evaluation. We believe that applying a brief, standardized assessment of depression across PAC settings, including IRFs, will improve detection based on the PHQ-2 to 9 interview. A universal depression screening is expected to improve patient outcomes by increasing the likelihood that depression will be identified and treated in IRF patients. The proposal of the PHQ-2 to 9 was the result of an extensive consensus vetting process in which experts and stakeholders were engaged through TEPs, SODFs, and posting of interim reports and other documents on *CMS.gov*. These experts and stakeholders were supportive of the clinical usefulness of the PHQ-2 to 9 assessment. A summary of the most recent TEP meeting (September 17, 2018) 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>.

<sup>108</sup> 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.

2014/IMPACT-Act-Downloads-and-Videos.html.

*Comment:* A few commenters raised concerns about administration of the PHQ-2 to 9 to IRF patients. One commenter noted that patients in acute rehabilitation may have limited attention and working memory that affects their ability to complete the PHQ-2 to 9. Another commenter noted doubts that PHQ-9 is a good tool for IRFs because of the likelihood of false positives, given patients who are adjusting to recent injuries, surgeries, conditions, and various disabilities. Rather, the commenter believes that assessment by rehabilitation psychologists, who have specialty training in working with rehabilitation populations, would provide a comprehensive evaluation and informed treatment plan. Another commenter expressed concerns about the use of the PHQ in short-stay IRF patients, suggesting that being assessed for depression, especially if assessed multiple times, will affect the patient's perception of how they should be experiencing their situation.

*Response:* We recognize the challenges faced by patients receiving care from IRF providers. We believe that the PHQ-2 to 9 is the most accurate and appropriate depression screening for the PAC population, including patients in IRFs, and that assessing for depression is necessary for high-quality clinical care. As stated in our proposal above, the PHQ-2 has performed well as a screening tool for identifying depression, to assess depression severity, and to monitor patient mood over time.<sup>109 110</sup> Additionally, the PHQ-2 and PHQ-9 instruments have been validated in primary care populations against a gold standard diagnostic interview.<sup>111</sup> We believe this prior validation research generalizes to the IRF population. We also note that, regardless of the LOS of patients, the timeframe over which they may have been experiencing signs and symptoms of depression, and the types of circumstances that have led to their IRF stay, it is the responsibility of the IRF to deliver high quality care for all the

symptoms or conditions a patient may have. The expectation that the episode of care will be short does not exempt an IRF from screening and treating patients for the full range of physical and mental health problems. Similarly, if a patient self-reports a significant number of depressive symptoms, we do not believe that they should be considered to be a "false positive" because of, for example, a recent trauma or acute care stay. As a screening tool, the PHQ-2 to 9 is intended to capture likely depression to have those patients referred for further evaluation, which will ascertain if their condition is consistent with the full diagnostic criteria for a major depressive disorder. Moreover, standardized screening for the signs and symptoms of depression with the PHQ-2 to 9 does not preclude or provide a substitute for assessment by rehabilitation psychologist or other clinicians, as deemed appropriate by a patient's care team.

*Comment:* Several commenters cited concerns related to the findings from the National Beta Test related to the PHQ-2 to 9, namely, that testing found it to be burdensome for staff and patients and the wording difficult to understand.

*Response:* We acknowledge that some assessors in the National Beta Test noted concerns regarding the burden of the PHQ-2 to 9 for staff and patients and that the wording of some items was challenging for patients to understand. In the National Beta Test, the PHQ-2 to 9 was one of a collection of mood assessments, meaning that assessors and patients completed additional questions about depressed mood and well-being immediately before and after the PHQ-2 to 9. We believe that the perception of burden of the PHQ-2 to 9 was in part due to the larger mood assessment section included in the National Beta Test. Despite the burden and administration challenges noted by National Beta Test assessors, assessors generally appreciated the clinical utility and relevance of the PHQ-2 to 9 and noted the importance of standardizing the assessment of depressive symptoms.

*Comment:* Additional concerns about administration focused on the patient interview format of the PHQ-2 to 9. Some commenters raised concerns about administering the PHQ-2 to 9 to patients with severe cognitive deficits, prior mental health issues, or non-communicative conditions. One commenter suggested that CMS develop exemptions from repeated screenings for short stay patients, and for patients whose medical or cognitive status make it inappropriate to administer the PHQ-2 to 9. Another commenter suggested that the PHQ-2 to 9 have an option to

be self-administered by the patient via a patient-friendly paper and pencil layout, which would reduce time burden placed on assessors.

*Response:* We appreciate commenters' concerns that administering the PHQ-2 to 9 to patients whose medical or cognitive status make it inappropriate to administer. The guidance for completing the data elements will include instructions that if the patient is rarely or never understood verbally, in writing, or using another method, the PHQ-2 to 9 interview will not be completed and the assessor code the responses to the first two items (Little interest or pleasure in doing things; Feeling down, depressed, or hopeless) as 9 (no response). We will take the suggestion to explore the possibility for patient self-administration of the PHQ-2 to 9 into consideration in future SPADE development work.

*Comment:* One commenter noted confusion about how depression relates to cognitive function.

*Response:* Section 1899(b)(1)(B)(ii) of the Act specifies the category of "cognitive function, such as ability to express ideas and to understand, and mental status, such as depression and dementia." We proposed the PHQ-2 to 9 data elements to meet the definition of the standardized patient assessment data with respect to cognitive function and mental status, particularly the "mental status" topic within that category.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the PHQ-2 to 9 data elements as standardized patient assessment data beginning with the FY 2022 IRF QRP as proposed.

## 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

<sup>109</sup> 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.

<sup>110</sup> 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.

<sup>111</sup> 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):348-353.

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 believes 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 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 sought comment on our proposals to collect as standardized patient assessment data the following data with respect to special services, treatments, and interventions.

Commenters submitted the following comments related to the proposed rule's discussion of special services, treatments, and interventions data elements.

*Comment:* One commenter was supportive of collecting these data elements, noting that collection will help to better inform CMS and IRF providers on the severity and needs of patients in this setting.

*Response:* We thank the commenter for the support of these items. We selected the Special Services, Treatments, and Interventions data elements for proposal as standardized data in part because of the attributes noted.

*Comment:* Some commenters were concerned about the reliability of the Special Services, Treatments, and Interventions data elements, noting that the results of the National Beta Test indicated that these data elements had a low interrater reliability kappa statistic relative to other data elements in the test.

*Response:* In the category of Special Services, Treatments, and Interventions, for SPADEs where kappas could be calculated, 1 data element and 2 sub-elements demonstrated overall reliabilities in the moderate range (0.41–0.60) and only 1 sub-element demonstrated an overall reliability in the slight/poor range (0.00–0.20). These overall reliabilities were as follows: 0.60 for the Therapeutic Diet data element; 0.55 for the "Continuous" sub-element of Oxygen Therapy; 0.46 for the "Other" sub-element of IV Medications; and 0.13 for the "Anticoagulant" sub-element of IV Medications. However, the overall reliabilities for all other data elements and sub-elements where kappas could be calculated were substantial/good or excellent/almost perfect. When looking at percent agreement—an alternative measure of interrater agreement—values of overall percent agreement for all Special Services, Treatments, and Interventions SPADEs and sub-elements ranged from 80 to 100 percent.

*Comment:* Commenters also noted concern around the burden of completing these data elements, in particular because of their low frequency of occurrence in IRF settings. To reduce burden around collection of this information, commenters recommended that CMS explore obtaining this data via claims. Additionally, one commenter added that if these data elements are finalized, they should be collected at discharge only, to reduce administrative burden.

*Response:* We appreciate the commenters' concern for burden on clinical staff due to completing assessments with respect to both admission and discharge. We believe that assessment of various special services, treatments, and interventions received by patients in the IRF setting will provide important information for care planning and resource use in IRFs. The assessments of the special services, treatments, and interventions with multiple responses are formatted as a "check all that apply" format. Therefore, when treatments do not apply—as the commenters note, this is the case for many IRF patients—the assessor need only check one row for "None of the Above." We will take under consideration the commenters' recommendation to explore the feasibility of collecting information on special services, treatments, and interventions through claims-based data. Regarding the recommendation to collect these SPADEs at discharge only, we state that it is clinically appropriate and important to the ultimate usefulness of these SPADEs that they are collected with respect to both admission and

discharge. For example, for patients coming from acute care or from the community, the admission assessment establishes a baseline for the IRF stay. For all patients, the admission assessment ensures that each patient is systematically assessed for a broad range of health and well-being issues, which we expect to inform care planning.

*Comment:* One commenter expressed concern that the Special Services, Treatments, and Interventions data elements assess the presence or absence of something rather than the clinical rationale or patient outcomes. This commenter stressed the importance of bringing this assessment to “the next level” in order to determine impact of these treatments on patients’ outcomes.

*Response:* We agree with commenter’s concern that recording the presence or absence of certain treatments is only a first step in characterizing the complexity that is often the cause of a patient’s receipt of special services, treatments, and interventions. We clarify that all the SPADEs we proposed were intended as a minimum assessment and do not limit the ability of providers to conduct a more comprehensive evaluation of a patient’s situation to identify the potential impacts on outcomes that the commenter describes.

*Comment:* One commenter noted that the item numbering in the Special Services, Treatments, and Interventions data elements is extremely confusing and needs to be reworked.

*Response:* Several patient assessment tools have traditionally combined letters and numbers, along with labels, to distinguish between data elements. The proposed data elements in the Special Services, Treatments, and Interventions section follow the conventions established by CMS. However, we will take this feedback into consideration in our evaluation and refinement of patient assessment instruments.

Final decisions on the SPADEs are given below, following more detailed comments on each SPADE proposal.

- Cancer Treatment: Chemotherapy (IV, Oral, Other)

In the FY 2020 IRF PPS proposed rule (84 FR 17297 through 17299), we proposed 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 “Final 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 noted 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 “Final 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 SODFs 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 proposed 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.

A commenter submitted the following comment related to the proposed rule’s discussion of the Chemotherapy data element.

*Comment:* One commenter agreed that it is important to know if a patient is receiving chemotherapy for cancer and the method of administration, but also expressed concern about the lack of an association with a patient outcome. This commenter noted that implications of chemotherapy for patients needing speech-language pathology services include chemotherapy-related cognitive impairment, dysphagia, and speech- and voice-related deficits.

*Response:* We appreciate the commenter’s concern. We agree with the commenter that chemotherapy can create related treatment needs for patients, such as the examples noted by the commenter. However, we believe that it is not feasible for SPADEs to capture all of a patient’s needs related to any given treatment, and we maintain that the Special Services, Treatments, and Interventions SPADEs provide a common foundation of clinical assessment, which can be built on by the individual provider or a patient’s care team.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Chemotherapy (IV, Oral, Other) data element as standardized patient assessment data beginning with the FY 2022 IRF QRP as proposed.

- Cancer Treatment: Radiation

In the FY 2020 IRF PPS proposed rule (84 FR 17299), we proposed 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 “Final 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 noted 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 “Final 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 SODFs 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 [\*Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html\*.](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-</a></p>
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Taking together the importance of assessing for radiation, stakeholder input, and strong test results, we proposed 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.

A commenter submitted the following comment related to the proposed rule’s discussion of the Radiation data element.

*Comment:* One commenter expressed concern that the Radiation data element assesses whether a patient is receiving radiation for cancer treatment, but does not identify the rationale for and outcomes associated with radiation. The commenter noted that implications of radiation for patients needing speech-language pathology services include reduced head and neck range of motion due to radiation or severe fibrosis, scar bands, and reconstructive surgery complications and that these can impact both communication and swallowing abilities.

*Response:* We appreciate the commenter’s concern. We agree with the commenter that radiation can create related treatment needs for patients, such as the examples noted by the commenter. However, we believe that it is not feasible for SPADEs to capture all of a patient’s needs related to any given treatment, and we maintain that the Special Services, Treatments, and Interventions SPADEs provide a common foundation of clinical assessment, which can be built on by the individual provider or a patient’s care team.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Radiation data element as standardized patient assessment data beginning with the FY 2022 IRF QRP as proposed.

- Respiratory Treatment: Oxygen Therapy (Intermittent, Continuous, High-concentration Oxygen Delivery System)

In the FY 2020 IRF PPS proposed rule (84 FR 17299 through 17300), we proposed 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 “Final 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, noted 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 “Final 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 SODFs 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 proposed 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.

We invited public comment on this proposal. While we received support from some commenters on the Special Services, Treatments, and Interventions section (IX.G.2 in this final rule) and its proposals as a whole (section IX.F in this final rule), we did not receive any specific comments on the Oxygen Therapy (Intermittent, Continuous, High-concentration Oxygen Delivery System) data element in particular.

After careful consideration of the public comments we received on the category of Special Services, Treatments, and Interventions, we are finalizing our proposal to adopt the Oxygen Therapy (Intermittent, Continuous, High-Concentration Oxygen Delivery System) data element as standardized patient assessment data beginning with the FY 2022 IRF QRP as proposed.

- Respiratory Treatment: Suctioning (Scheduled, as Needed)

In the FY 2020 IRF PPS proposed rule (84 FR 17300 through 17302), we proposed 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 “Final 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 noted 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 “Final 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 SODFs 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 proposed 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.

A commenter submitted the following comment related to the proposed rule’s discussion of the Suctioning data element.

*Comment:* One commenter requested that this data element also assess the frequency of suctioning, as it can impact resource utilization and potential medication changes in the plan of care.

*Response:* We appreciate the commenter’s feedback that the response options for this data element may not fully capture impacts to resource utilization and care plans. The Suctioning data element does include sub-elements to identify if suctioning is performed on a “Scheduled” or “As Needed” basis, but it does not directly

assess the frequency of suctioning by, for example, asking an assessor to specify how often suctioning is scheduled. As finalized, this data element differentiates between patients who only occasionally need suctioning, and patients for whom assessment of suctioning needs is a frequent and routine part of the care (that is, where suctioning is performed on a schedule according to physician instructions). In our work to identify standardized data elements, we have strived to balance the scope and level of detail of the data elements against the potential burden placed on patients and providers. However, we clarify that any SPADE is intended as a minimum assessment and does not limit the ability of providers to conduct a more comprehensive evaluation of a patient's situation to identify the potential impacts on outcomes that the commenter describes.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Suctioning (Scheduled, As needed) data element as standardized patient assessment data beginning with the FY 2022 IRF QRP as proposed.

- Respiratory Treatment: Tracheostomy Care

In the FY 2020 IRF PPS proposed rule (84 FR 17302), we proposed 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 a 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 "Final 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 noted 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 "Final 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 SODFs 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 proposed 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.

We invited public comment on this proposal. While we received support from some commenters on Special Services, Treatments, and Interventions as a whole (section IX.G.2 in this final rule), we did not receive any specific comments on Tracheostomy Care data element.

After careful consideration of the public comments we received on the category of Special Services, Treatments, and Interventions, we are finalizing our proposal to adopt the Tracheostomy Care data element as standardized patient assessment data beginning with the FY 2022 IRF QRP as proposed.

- Respiratory Treatment: Non-Invasive Mechanical Ventilator (BiPAP, CPAP)

In the FY 2020 IRF PPS proposed rule (84 FR 17303), we proposed 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 “Final 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, noted 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 “Final 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 SODFs 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 proposed 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.

We invited public comment on this proposal. While we received support from some commenters on Special Services, Treatments, and Interventions as a whole (section IX.G.2 in this final rule), we did not receive any specific comments on the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data element.

After careful consideration of the public comments we received on the category of Special Services, Treatments, and Interventions, we are finalizing our proposal to adopt the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data element as standardized patient assessment data beginning with the FY 2022 IRF QRP as proposed.

- Respiratory Treatment: Invasive Mechanical Ventilator

In the FY 2020 IRF PPS proposed rule (84 FR 17304), we proposed 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.<sup>112</sup>

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 “Final 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, noted 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 “Final 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>.

<sup>112</sup> 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.

We also held SODFs 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 proposed 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.

A commenter submitted the following comment related to the proposed rule's discussion of the Invasive Mechanical Ventilator data element.

*Comment:* One commenter noted disappointment over seeing that the SPADE for invasive mechanical ventilator only assesses whether or not a patient is on a mechanical ventilator. The commenter suggested CMS consider collecting data to track functional outcomes related to progress towards independence in communication and swallowing.

*Response:* We have attempted to balance the scope and level of detail of the data elements against the potential burden placed on patients and providers. We believe that assessing the use of an invasive mechanical ventilator will be a useful point of information to inform care planning and further assessment, such as related to functional outcomes, as the commenter suggests.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the

Invasive Mechanical Ventilator data element as standardized patient assessment data beginning with the FY 2022 IRF QRP as proposed.

- Intravenous (IV) Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other)

In the FY 2020 IRF PPS proposed rule (84 FR 17305 through 17306), we proposed 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 proposed 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 Medications 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 "Final 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 “Final 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 SODFs 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 proposed 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.

Commenters submitted the following comments related to the proposed rule’s discussion of the IV Medications data elements.

*Comment:* One commenter noted that the IV Medications data elements seem redundant of the proposed High-Risk Drug Classes: Use and Indication data elements.

*Response:* We wish to clarify that the IV Medications data element collects information on medications received by IV only, with sub-elements specific to antibiotics, anticoagulants, and vasoactive medications only. In contrast, the High Risk Drug Classes: Use and Indication data element collects information on medications received by any route, only for six specific drug classes, and collects information on the presence of an indication. We believe the overlap between these SPADEs is minimal, as it would only occur when a medication in a high-risk drug class is delivered by IV. Additionally, in this case, the High-Risk Drug Classes: Use and Indication data element would assess the presence of an indication in the patient’s medical record, which the IV Medications data element does not do.

*Comment:* Commenters were concerned about the performance of the IV Medications data element in the National Beta Test, noting that its reliability was only fair to good and poor for the anticoagulation sub-element.

*Response:* The kappa for the overarching IV Medications data element was 0.70 across settings, which falls in the range of “substantial/good” agreement. The IV Medications sub-element that had a “slight/poor” reliability (in the range of 0.00–0.20) was the IV Anticoagulants sub-element (kappa = 0.13). The Other IV Medications sub-element had “moderate” reliability (kappa = 0.46). Consultation with assessors suggested that the low kappa for the IV Anticoagulants sub-element was likely due to inconsistent interpretation of the coding instructions. Having identified the likely source of the relatively lower interrater reliability, we are confident that with proper training of IRFs on how to report the data elements, the reliability of these sub-elements will be improved.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other) data element as standardized patient assessment data beginning with the FY 2022 IRF QRP as proposed.

- Transfusions

In the FY 2020 IRF PPS proposed rule (84 FR 17306), we proposed 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 “Final 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 “Final 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 SODFs 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 proposed 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.

Commenters submitted the following comments related to the proposed rule’s discussion of the Transfusions data element.

*Comment:* One commenter applauded CMS for including the Transfusions data element, noting that it will provide information on care planning, clinical decision making, patient safety, care transitions, and resource use in IRFs and will contribute to higher quality and coordinated care for patients who rely on these life-saving treatments.

*Response:* We thank the commenter for their support. We selected the Transfusions data element for proposal as standardized data in part because of the attributes that the commenter noted.

*Comment:* One commenter was concerned that IRFs will not have the resources needed to provide patients with access to blood transfusions and requested that CMS consider whether payments to IRFs are adequate to cover

the cost of this resource intensive, specialized service.

*Response:* We wish to clarify that this item is finalized only to collect information on the complexity of the patient and resources the patient requires. At this time, this item will not be used for any payment purposes, and thus we are not able to comment on cost of this service. We wish to clarify that this SPADE is not intended to measure the ability of an IRF to provide in-house transfusions, only to capture the services a given patient may be receiving. Further, for patients who require services related to blood transfusions, information collected by this data element is a part of common clinical workflow, and thus, we believe that burden on resource intensity would not be affected by the standardization of this data element.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Transfusions data element as standardized patient assessment data beginning with the FY 2022 IRF QRP as proposed.

- Dialysis (Hemodialysis, Peritoneal Dialysis)

In the FY 2020 IRF PPS proposed rule (84 FR 17306 through 17307), we proposed 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 the proposed rule, we proposed 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 “Final 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 proposed 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 “Final 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](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 SODFs 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 proposed 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.

We invited public comment on this proposal. While we received support from some commenters on this Special Services, Treatments, and Interventions as a whole (section IX.G.2 in this final rule), we did not receive any specific comments on the Dialysis (Hemodialysis, Peritoneal dialysis) data element.

After careful consideration of the public comments we received on the category of Special Services, Treatments, and Interventions, we are finalizing our proposal to adopt the Dialysis (Hemodialysis, Peritoneal dialysis) data element as standardized patient assessment data beginning with the FY 2022 IRF QRP as proposed.

- Intravenous (IV) Access (Peripheral IV, Midline, Central Line)

In the FY 2020 IRF PPS proposed rule (84 FR 17307 through 17308), we proposed 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 “Final 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 “Final 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 SODFs 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 proposed 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.

We invited public comment on this proposal. While we received support from some commenters on this Special Services, Treatments, and Interventions as a whole (section IX.G.2 in this final rule), we did not receive any specific comments on the IV Access (Peripheral IV, Midline, Central line) data element.

After careful consideration of the public comments we received on the

category of Special Services, Treatments, and Interventions, we are finalizing our proposal to adopt the IV Access (Peripheral IV, Midline, Central line) data element as standardized patient assessment data beginning with the FY 2022 IRF QRP as proposed.

- **Nutritional Approach: Parenteral/IV Feeding**

In the FY 2020 IRF PPS proposed rule (84 FR 17308 through 17309), we proposed 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 proposed 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 "Final 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 "Final 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 SODFs 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 proposed 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.

A commenter submitted the following comment related to the proposed rule's discussion of the Parenteral/IV Feeding data element.

*Comment:* One commenter was supportive of collecting this data element, but noted that it should not be a substitute for capturing information related to swallowing which reflects additional patient complexity and resource use.

*Response:* We thank the commenter for their support and appreciate the concerns raised. We agree that the Parenteral/IV Feeding SPADE should not be used as a substitute for an assessment of a patient's swallowing

function. The proposed SPADEs are not intended to replace comprehensive clinical evaluation and in no way preclude providers from conducting further patient evaluation or assessments in their settings as they believe are necessary and useful. We agree that information related to swallowing can capture patient complexity. However, we also note that Parenteral/IV Feeding data element captures a different construct than an evaluation of swallowing. That is, the Parenteral/IV Feeding data element captures a patient's need to receive calories and nutrients intravenously, while an assessment of swallowing would capture a patient's functional ability to safely consume food/liquids orally for digestion in their gastrointestinal tract.

After careful consideration of the public comments we received on the category of Special Services, Treatments, and Interventions, we are finalizing our proposal to adopt the Parenteral/IV Feeding data element as standardized patient assessment data beginning with the FY 2022 IRF QRP as proposed.

- **Nutritional Approach: Feeding Tube**

In the FY 2020 IRF PPS proposed rule (84 FR 17309 through 17310), we proposed 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.<sup>113</sup> 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 proposed 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 "Final 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 proposed, 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 "Final 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 SODFs 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

<sup>113</sup>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 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.

Commenters submitted the following comments related to the proposed rule's discussion of the Feeding Tube data element.

*Comment:* One commenter noted that in addition to identifying if the patient is on a feeding tube or not, it would be important to assess the patient's progression towards oral feeding within this data element, as this impacts the tube feeding regimen.

*Response:* We agree that progression to oral feeding is important for care planning and transfer. At this time, we are finalizing a singular Feeding Tube SPADE, which assesses the nutritional approach only and does not capture the patient's prognosis with regard to oral feeding. We wish to clarify that the proposed SPADEs are not intended to replace comprehensive clinical evaluation and in no way preclude providers from conducting further patient evaluation or assessments in their settings as they believe are necessary and useful. We will take this recommendation into consideration in future work on standardized data elements.

*Comment:* One commenter noted that this data element should designate between percutaneous endoscopic gastrostomy (PEG) tube and nasogastric (NG) tube because the different routes of access have different levels of resource requirements.

*Response:* We appreciate the commenter's suggestion, but we have decided to maintain the singular Feeding Tube SPADE. We agree that different routes of access may have different levels of resource requirements. However, we do not believe collecting this level of information about nutritional therapies via a SPADE would be significantly more clinically useful or supportive of care transitions than the singular Feeding Tube SPADE. However, we will take this suggestion into consideration in future refinement of the clinical SPADEs.

After careful consideration of the public comments we received on the category of Special Services, Treatments, and Interventions, we are finalizing our proposal to adopt the Feeding Tube data element as standardized patient assessment data

beginning with the FY 2022 IRF QRP as proposed.

- **Nutritional Approach: Mechanically Altered Diet**

In the FY 2020 IRF PPS proposed rule (84 FR 17310 through 17311), we proposed 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.<sup>114</sup>

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 proposed to replace the existing Modified food consistency/supervision data element in the IRF-PAI to the Mechanically Altered Diet data element.

<sup>114</sup> 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.

For more information on the Mechanically Altered Diet data element, we refer readers to the document titled "Final 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 "Final 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 SODFs 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 proposed 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.

Commenters submitted the following comments related to the proposed rule’s discussion of the Mechanically Altered Diet data element.

*Comment:* Commenters were concerned about the performance of this data element in the National Beta Test, noting that its reliability was only moderate in IRF settings.

*Response:* We provided supplementary information with the proposed rule on the reliability of the SPADEs, described by the kappa statistic and by the “percent agreement” between assessor, another measure of reliability that is in some cases more accurate than the kappa statistic, depending on the underlying distribution. (The document titled “Proposed Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at [\*Videos.html\*\). In this document, we stated that the interrater reliability for Mechanically Altered Diet data element, as measured by kappa, was “substantial/good” across the four PAC provider types \(LTCH, SNF, HHA, and IRF\) in which it was tested \(kappa = 0.65\) and “moderate” in the IRF setting \(kappa = 0.53\). However, percent agreement for the data element was 93 percent across all PAC settings in the National Beta Test \(that is, HHA, IRF, LTCH, and SNF\) and 89 percent in the IRF setting. That is, when assessing if patients required a mechanically altered diet, the facility staff and the external research nurse agreed 89 percent of the time for IRF patients.](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-</a></p>
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*Comment:* One commenter was concerned that the Mechanically Altered Diet data element does not capture clinical complexity and does not provide any insight into resource allocation because it only measures whether the patient needs a mechanically altered diet and not, for example, the extent of help a patient needs in consuming his or her meal.

*Response:* We believe that assessing patients’ needs for mechanically altered diets captures one piece of information about resource intensity. That is, patients with this special nutritional requirement may require additional nutritional planning services, special meals, and staff to ensure that meals are prepared and served in the way the patient needs. Additional factors that would affect resource allocation, such as those noted by the commenter, are not captured by this data element. We have attempted to balance the scope and level of detail of the data elements against the potential burden placed on providers who must complete the assessment. We will take this suggestion into consideration in future refinement of the clinical SPADEs.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Mechanically Altered Diet data element as standardized patient assessment data beginning with the FY 2022 IRF QRP as proposed.

- **Nutritional Approach: Therapeutic Diet**

In the FY 2020 IRF PPS proposed rule (84 FR 17311 through 17312), we proposed 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 “Final 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 “Final Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements,” available at

*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 SODFs 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 proposed 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.

We invited public comment on this proposal. While we received support from some commenters on Special Services, Treatments, and Interventions as a whole (section IX.G.2 in this final

rule), we did not receive any specific comments on the Therapeutic Diet data element.

After careful consideration of the public comments we received on the category of Special Services, Treatments, and Interventions, we are finalizing our proposal to adopt the Therapeutic Diet data element as standardized patient assessment data beginning with the FY 2022 IRF QRP as proposed.

- High-Risk Drug Classes: Use and Indication

In the FY 2020 IRF PPS proposed rule (84 FR 17312 through 17314), we proposed 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.<sup>115</sup> 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.<sup>116</sup>

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,<sup>117</sup> while the rate of ADEs in the long-term care setting is approximately 9.80 ADEs per 100 resident-months.<sup>118</sup>

<sup>115</sup> 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.

<sup>116</sup> 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.

<sup>117</sup> 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.

<sup>118</sup> 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.

In the hospital setting, the incidence has been estimated at 15 ADEs per 100 admissions.<sup>119</sup> 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.<sup>120 121 122</sup> 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.<sup>123</sup>

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.<sup>124</sup> We proposed one High-Risk Drug Class data element with six sub-elements. The response options that correspond to the six medication classes 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;<sup>125 126</sup> fluid retention, heart failure, and lactic acidosis are associated with hypoglycemics;<sup>127</sup>

<sup>119</sup> 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].

<sup>120</sup> Barnsteiner JH. Medication reconciliation: transfer of medication information across settings-keeping it free from error. *J Infus Nurs*. 2005;28(2 Suppl):31-36.

<sup>121</sup> Rozich J, Roger, R. Medication safety: one organization's approach to the challenge. *Journal of Clinical Outcomes Management*. 2001(8):27-34.

<sup>122</sup> 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.

<sup>123</sup> 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.

<sup>124</sup> Ibid.

<sup>125</sup> 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.

<sup>126</sup> 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.

<sup>127</sup> Hamnvik OP, McMahon GT. Balancing Risk and Benefit with Oral Hypoglycemic Drugs. *The Mount Sinai journal of medicine*, New York. 2009; 76:234-243.

misuse is associated with opioids;<sup>128</sup> fractures and strokes are associated with antipsychotics;<sup>129</sup> and various adverse events, such as central nervous systems effects and gastrointestinal intolerance, are associated with antimicrobials,<sup>131</sup> 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.<sup>132</sup> Finally, although a complete medication list should record several important attributes of each medication (for example, dosage, route, stop date), recording an indication for the drug is of crucial importance.<sup>133</sup>

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 the six 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 required 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 "Final 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.<sup>134</sup> 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>.

*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 noted 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, stating 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 "Final 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

<sup>128</sup> Naples JG, Gellad WF, Hanlon JT. The Role of Opioid Analgesics in Geriatric Pain Management. *Clin Geriatr Med*. 2016;32(4):725–735.

<sup>129</sup> 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].

<sup>130</sup> 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.

<sup>131</sup> Faulkner CM, Cox HL, Williamson JC. Unique aspects of antimicrobial use in older adults. *Clin Infect Dis*. 2005;40(7):997–1004.

<sup>132</sup> 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.

<sup>133</sup> 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.

<sup>134</sup> 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.

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 SODFs 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 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 proposed 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.

Commenters submitted the following comments related to the proposed rule’s discussion of the High-Risk Drug Classes: Use and Indication data element.

*Comment:* Some commenters noted that the proposed High-Risk Drug Classes: Use and Indication data elements are redundant of the existing standards in the Hospital Conditions of Participation (CoPs) and that requiring the collection of these data elements would be duplicative, unnecessary, and at odds with the Meaningful Measures framework.

*Response:* We disagree that assessing the extent to which medications from certain drug classes are being taken and the extent to which indications are recorded for medications in these classes is redundant with the existing CoPs. The CoPs provide guidance on clinical practice, while the proposed SPADEs attempt to collect information about individual patients in order to understand clinical acuity and to populate a core set of information that can be exchanged with the patient across care transitions.

*Comment:* Commenters noted that because adverse drug events (ADEs) are not limited to high-risk drugs, this data element has limited utility.

*Response:* We acknowledge that not all ADEs are associated with “high-risk” drugs, and we also note that medications in the named drug classes are mostly used in a safe manner. Prescribed high-risk medications are defined as a “proximate factor” to preventable ADEs by the Joint Commission.<sup>135</sup> However, the Joint Commission’s conceptual model of preventable ADEs also includes provider, patient, health care system, organization, and technical factors, all of which present many opportunities for disrupting preventable ADEs. We have decided to focus on a selection of drug classes that are commonly used by older adults and are related to ADEs which are clinically significant, preventable, and measurable. Anticoagulants, antibiotics, and diabetic agents have been implicated in an estimated 46.9 percent (95 percent CI, 44.2 percent–49.7 percent) of emergency department

visits for adverse drug events.<sup>136</sup> Among older adults (aged ≥65 years), three drug classes (anticoagulants, diabetic agents, and opioid analgesics) have been implicated in an estimated 59.9 percent (95 percent CI, 56.8 percent–62.9 percent) of ED visits for adverse drug events.<sup>137</sup> Further, antipsychotic medications have been identified as a drug class for which there is a need for increased outreach and educational efforts to reduce use among older adults.

*Comment:* One commenter was concerned with the addition of the High-Risk Drug Classes: Use and Indication data elements, noting that providers should be granted clinical judgment to effectively treat patients without CMS monitoring of medications used for treatment.

*Response:* The proposed SPADEs attempt to collect information about individual patients to understand clinical acuity and to populate a core set of information that can be exchanged with the patient across care transitions. The intent of these data elements is not to monitor prescribing practices, but rather to assess the extent to which indications are noted for medications in certain drug classes.

*Comment:* A few commenters noted that the High-Risk Drug Class: Use and Indication data elements seemed redundant with other SPADEs (that is, IV Medications) and measures (that is, Provision of Current Reconciled Medication List to Subsequent Provider at Discharge), or duplicative of existing standards in the Hospital CoPs related to procurement, preparation, and administration of drugs, which creates unnecessary burden.

*Response:* The High-Risk Drugs: Use and Indications data element captures unique information compared to the other SPADEs and measures to which the commenters referred. With regard to the reference to the measure Provision of Current Reconciled Medication List to Subsequent Provider at Discharge, we wish to clarify that the High-Risk Drug Classes: Use and Indication data elements capture medications taken by any route and focuses on a select set of drug classes, not the act of communicating a complete medication list. To the extent that the activities captured by the High-Risk Drugs: Use and Indications data element are already being performed by providers as part of

<sup>135</sup> Chang A, Schyve PM, Croteau RJ, O’Leary DS, Loeb JM. The JCAHO patient safety event taxonomy: A standardized terminology and classification schema for near misses and adverse events. *Int J Qual Health Care*. 2005;17(2):95–105.

<sup>136</sup> Shehab N, Lovegrove MC, Geller AI, Rose KO, Weidle NJ, Budnitz DS. US emergency department visits for outpatient adverse drug events, 2013–2014. *JAMA* 2016;316(2):2115–2125.

<sup>137</sup> Shehab N, Lovegrove MC, Geller AI, Rose KO, Weidle NJ, Budnitz DS. US emergency department visits for outpatient adverse drug events, 2013–2014. *JAMA* 2016;316(2):2115–2125.

the Hospital CoPs, we believe that reporting of this data elements should be easily integrated into existing workflow.

*Comment:* One commenter noted that medication indications are typically documented in narrative notes by the medical staff and would therefore be difficult to collect.

*Response:* We maintain that collecting information on the presence of indications in the medical record is clinically important information that can inform care planning and support care transitions. It is the responsibility of IRF providers to record patient data in a way that is useful and appropriate to meet clinical and administrative needs. It is possible that the adoption of this SPADE and related reporting requirement will promote a more efficient method for documenting the clinical indication for each medication.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the High-Risk Drug Classes: Use and Indication data element as standardized patient assessment data beginning with the FY 2022 IRF QRP as proposed.

### 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.

In this section 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.<sup>138</sup> 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.<sup>139 140 141</sup>

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 sought comment that applies specifically to the standardized patient assessment data for the category of medical conditions and co-morbidities. We did not receive any comments on the category of medical conditions and co-morbidities.

<sup>138</sup> 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>.

<sup>139</sup> 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>.

<sup>140</sup> 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.

<sup>141</sup> 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.

Final decisions on the SPADEs are given below, following more detailed comments on each SPADE proposal.

- 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 sought comment on whether or not we should add these pain items in light of those concerns. Commenters were asked to address to what extent the collection of the SPADEs described below through patient queries might encourage providers to prescribe opioids.

In the FY 2020 IRF PPS proposed rule (84 FR 17314 through 17316), we proposed 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.<sup>142</sup> 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.<sup>143</sup> 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.<sup>144</sup>

<sup>142</sup> Institute of Medicine. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*. Washington (DC): National Academies Press (US); 2011. <http://www.ncbi.nlm.nih.gov/books/NBK91497/>.

<sup>143</sup> 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>.

<sup>144</sup> National Academies. *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid*

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.<sup>145</sup> 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 the proposed rule we have also proposed a SPADE that assess for the use of, as well as importantly the indication for the 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,<sup>146 147 148</sup> 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, stretching and strengthening exercises, chiropractic, electrical stimulation, radiotherapy, and ultrasound.<sup>149 150 151</sup>

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 the dosage regimens in 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,<sup>152</sup> and consistent with HHS’s 5-Point Strategy To Combat the Opioid Crisis<sup>153</sup> 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 affects 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

(2010). *Archives Internal Medicine*, 170(22):1979–1986.

<sup>149</sup> 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.

<sup>150</sup> Kligler, B., Bair, M.J., Banerjee, 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>.

<sup>151</sup> 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.

<sup>152</sup> Society for Post-Acute and Long-Term Care Medicine (AMDA). (2018). Opioids in Nursing Homes: Position Statement. <https://paltc.org/opioids%20in%20nursing%20homes>.

<sup>153</sup> <https://www.hhs.gov/opioids/about-the-epidemic/hhs-response/index.html>.

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 “Final 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

Use. Washington DC: National Academies of Sciences, Engineering, and Medicine.; 2017.

<sup>145</sup> National Pain Strategy: A Comprehensive Population-Health Level Strategy for Pain. [https://iprc.nih.gov/sites/default/files/HHSNational\\_Pain\\_Strategy\\_508C.pdf](https://iprc.nih.gov/sites/default/files/HHSNational_Pain_Strategy_508C.pdf).

<sup>146</sup> 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.

<sup>147</sup> Fine, P. G. (2009). Chronic Pain Management in Older Adults: Special Considerations. *Journal of Pain and Symptom Management*, 38(2): S4–S14.

<sup>148</sup> Solomon, D. H., Rassen, J. A., Glynn, R. J., Garneau, K., Levin, R., Lee, J., & Schneeweiss, S.

April 26 to June 26, 2017. The items we sought comment on were modified from 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 "Final 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 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 noted 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 proposed 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.

Commenters submitted the following comments related to our proposal to adopt the Pain Interference (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities) data elements.

*Comment:* A few commenters noted support for the Pain Interference data

element, noting that the data element will provide a useful and more accurate assessment of a patient's ability to function, and that understanding the impact of pain on therapy and other activities, including sleep, can improve the quality of care, which in turn will support providers in their ability to provide effective pain management services.

*Response:* We thank the commenters for their support of the Pain Interference data element.

*Comment:* A commenter noted that the proposed Pain Interference SPADEs document pain frequency, but stated that it is important to identify both pain frequency and pain intensity.

*Response:* We wish to clarify, the Pain Interference interview data elements question the patient on the frequency with which pain interferes with sleep, therapy, or non-therapy activities. These data elements therefore combine the concepts of frequency and intensity, with the measure of intensity being interference with the named activities. Self-reported measures of pain intensity are often criticized for being infeasible to standardize. In these data elements, we use interference with activities as an alternative to inquiring about intensity.

*Comment:* A commenter expressed concerns about the suitability of the Pain Interference data elements for use in patients with cognitive and communication deficits and recommended CMS consider the use of non-verbal means to allow patients to respond to SPADEs related to pain.

*Response:* We appreciate the commenter's concern surrounding pain assessment with patients with cognitive and communication deficits. The Pain Interference interview SPADEs require that a patient be able to communicate, whether verbally, in writing, or using another method; assessors may use non-verbal means to administer the questions (for example, providing the questions and response in writing for a patient with severe hearing impairment). Patients who are unable to communicate by any means would not be required to complete the Pain Interference interview SPADEs. However, evidence suggests that pain presence can be reliably assessed in non-communicative patients through structural observational protocols. To that end, we tested observational pain presence elements in the National Beta Test, but have chosen not to propose those data elements as SPADEs at this time. We will take the commenter's concern into consideration as the SPADEs are monitored and refined in the future.

*Comment:* A commenter expressed concerns about how CMS might use these data elements, noting particular concern that collection of these data elements may inappropriately translate into an assessment of quality, and that data collection on this topic could create incentives that directly or indirectly interfere with treatment decisions.

*Response:* We appreciate the commenter's concern related to wanting to understand how we will use the SPADEs in the future. We intend to continue to communicate and collaborate with stakeholders about how the SPADEs will be used in the IRF QRP, as those plans are developed, by soliciting input during the development process and establishing use of the SPADEs in payment and quality programs through future rulemaking.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Pain Interference (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities) data elements as standardized patient assessment data beginning with the FY 2022 IRF QRP as proposed.

#### 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 sought comment on our proposals to collect as standardized patient assessment data the following data with respect to impairments. We did not receive any comments on the category of impairments.

Final decisions on the SPADEs are given below, following more detailed comments on each SPADE proposal.

- Hearing

In the FY 2020 IRF PPS proposed rule (84 FR 17317 through 17318), we proposed 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.<sup>154</sup> <sup>155</sup> Treatment and accommodation of hearing impairment led to improved health outcomes including, but not limited to, quality of life.<sup>156</sup> For example, hearing loss in elderly individuals has been associated with depression and cognitive impairment,<sup>157</sup> <sup>158</sup> <sup>159</sup> higher rates of incident cognitive impairment and cognitive decline,<sup>160</sup> and less time in occupational therapy.<sup>161</sup> 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 "Final Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements," available at [https://www.cms.gov/Medicare/Quality-](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-)

<sup>154</sup> 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.

<sup>155</sup> Hawkins K, Bottone FG, Jr., Ozmkowski 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.

<sup>156</sup> 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.

<sup>157</sup> 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.

<sup>158</sup> 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.

<sup>159</sup> Hawkins K, Bottone FG, Jr., Ozmkowski 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.

<sup>160</sup> 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.

<sup>161</sup> 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.

*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 “Final 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 noted 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 patient’s score on this assessment would change between the start and end of the IRF stay. Therefore, we proposed that IRFs that submit the Hearing data element with respect to admission will be deemed to have submitted with respect to both admission and discharge.

Taking together the importance of assessing for hearing, stakeholder input, and strong test results, we proposed 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.

Commenters submitted the following comments related to our proposal for the Hearing data element.

*Comment:* A few commenters supported the collection of information on hearing impairment. One of these commenters also suggested that CMS consider how hearing impairment impacts a patient’s ability to respond to the assessment tool in general.

*Response:* We thank the commenters for their support of the Hearing data element. We intend to reinforce assessment tips and item rationale through training, open door forums, and future rulemaking efforts.

In the existing guidance manual for the IRF–PAI, we offer tips for administration that direct assessors to take appropriate steps to accommodate sensory and communication impairments when conducting the assessment.

*Comment:* Some commenters expressed concern that severely impaired hearing occurs infrequently in IRF patients, thereby limiting the utility of the data collected.

*Response:* The Hearing SPADE consists of one data element completed by the assessor based primarily on interacting with the patient and reviewing the medical record. Given the low burden of reporting the Hearing data element, and despite severe hearing impairment occurring in a small proportion of IRF patients, we believe it is important to systematically assess for hearing impairment in order to improve clinical care and care transitions.

*Comment:* One commenter recommended adding “unable to assess” as a response option, which the commenter believes would be the appropriate choice if the patient is comatose or is unable to effectively answer questions related to an assessment of their hearing.

*Response:* We appreciate the commenter’s recommendation. The assessment of hearing is completed based on observing the patient during assessment, patient interactions with others, reviewing medical record documentation, and consulting with patient’s family and other staff, in addition to interviewing the patient, so it can be completed when the patient is unable to effectively answer questions related to an assessment of their hearing.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Hearing data element as standardized patient assessment data beginning with the FY 2022 IRF QRP as proposed.

- Vision

In the FY 2020 IRF PPS proposed rule (84 FR 17318 through 17319), we proposed 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.<sup>162</sup> 163 164 165 166 167 168

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 proposed 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 "Final 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 "Final 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>.

We also held SODFs 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 noted 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

<sup>162</sup> 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.

<sup>163</sup> 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.

<sup>164</sup> Keepnews D, Capitman JA, Rosati RJ. Measuring patient-level clinical outcomes of home health care. *J Nurs Scholarsh*. 2004;36(1):79–85.

<sup>165</sup> 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.

<sup>166</sup> 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.

<sup>167</sup> Rovner BW, Ganguli M. Depression and disability associated with impaired vision: The MoVies Project. *J Am Geriatr Soc*. 1998;46(5):617–619.

<sup>168</sup> 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.

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 proposed that IRFs that submit the Vision data element with respect to admission will be deemed to have submitted with respect to both admissions and discharge.

Taking together the importance of assessing for vision, stakeholder input, and strong test results, we proposed 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.

Commenters submitted the following comments related to the proposed rule’s discussion of the Vision data element.

*Comment:* A few commenters supported the collection of information on vision impairment. One of the commenters noted that the collection of information on vision impairment would support the identification and appropriate treatment of vision problems, which they stated were prevalent and undertreated.

*Response:* We thank the commenters for their support.

*Comment:* One commenter recommended that a doctor of optometry should play a lead role in conducting vision assessments, and that vision assessments done by other clinicians should also obtain the patient’s own assessment of his or her vision, such as used by the Centers for Disease Control and Prevention (CDC) Behavioral Risk Factors Surveillance System survey, which questions patients “Do you have serious difficulty seeing, even when wearing glasses?” This commenter expressed concerns about the proposed SPADE being subjective and risks of mis-categorizing patients.

*Response:* We appreciate the commenter’s recommendation about how to assess for vision impairment. We do not require that a certain type of clinician complete assessments; the SPADEs have been developed so that any clinician who is trained in the

administration of the assessment will be able to administer it correctly. The proposed item relies on the assessor’s evaluation of the patient’s vision, which has the advantage of reducing burden placed on the patient. We will take the recommendation to use patient-reported vision impairment assessment into consideration in the development of future assessments.

*Comment:* Some commenters expressed concern that severely impaired vision occurs infrequently in IRF patients, thereby limiting the utility of the data collected.

*Response:* The Vision SPADE consists of one data element completed by the assessor based primarily on interacting with the patient and reviewing the medical record. Given the low burden of the Vision data element, and despite severe vision impairment occurring in a small proportion of IRF patients, we believe it is important to systematically assess for vision impairment in order to improve clinical care and care transitions.

*Comment:* A commenter recommended that CMS require a vision assessment at discharge, noting that vision impairment could be related to challenges in medication management and compliance with written follow-up instructions for care.

*Response:* We appreciate the commenter’s feedback. We agree that adequate vision—or the accommodations and assistive technology needed to compensate for vision impairment—is important to patient safety in the community, in part for the reasons the commenter mentions. In the FY 2020 IRF PPS proposed rule (84 FR 17292), we proposed that IRFs that submitted the Vision SPADE with respect to admission will be deemed to have submitted with respect to both admission and discharge; we stated that it is unlikely that the assessment of this SPADEs at admission would differ from the assessment at discharge. Vision assessment, collected via the Vision SPADE with respect to admission, will provide information that will support the patient’s care while in the IRF. Out of consideration for the burden of data collection, and with an understanding that significant clinical changes to a patient’s vision will be documented in the medical record as part of routine clinical practice, we are finalizing our proposal that IRFs that submit the Vision SPADE with respect to admission will be deemed to have submitted with respect to both admission and discharge. We note that during the discharge planning process, it is incumbent on IRF providers to

make reasonable assurances that the patient’s needs will be met in the next care setting, including in the home.

*Comment:* One commenter recommended adding “unable to assess” as a response option, which the commenter believes would be the appropriate choice if the patient is comatose or is unable to effectively answer questions related to an assessment of their vision.

*Response:* We appreciate the commenter’s recommendation. However, the assessment of vision is completed based on consulting with patient’s family and other staff, observing the patient including requesting the patient to read text or examine pictures or numbers in addition to interviewing the patient about their vision abilities. These other sources/methods can be used to complete the assessment of vision when the patient is unable to effectively answer questions related to an assessment of their vision.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Vision data element as standardized patient assessment data beginning with the FY 2022 IRF QRP as proposed.

#### 4. New Category: Social Determinants of Health

##### a. Social Determinants of Health Data Collection To Inform Measures and Other Purposes

Section 2(d)(2)(A) 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. Paragraph (C) of section 2(d)(2) of the IMPACT Act further requires the Secretary to carry out periodic analyses, at least every 3 years, based on the factors referred to paragraph (A) so as to monitor changes in possible relationships. Paragraph (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 paragraph (A) and for periodic analyses in such paragraph (C)). Accordingly we proposed to use our authority under paragraph (B) of section 2(d)(2) of the IMPACT Act to establish a new data source for information to

meet the requirements of paragraphs (A) and (C) of section 2(d)(2) of the IMPACT Act. In this rule, we proposed to collect and access data about social determinants of health (SDOH) in order to perform CMS' responsibilities under paragraphs (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 proposed 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 rule.

We also proposed 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 IX.G.4.b. of this final rule. Paragraphs (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."<sup>169</sup> 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>.

Each of the data elements we proposed 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.<sup>170</sup>

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.<sup>171</sup> Using NASEM's

<sup>169</sup> 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.

<sup>170</sup> Social Determinants of Health. Healthy People 2020. <https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health>. (February 2019).

<sup>171</sup> U.S. Department of Health and Human Services, Office of the Assistant Secretary for

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 PAC 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-medicare-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 paragraph (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 sections (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.

Planning and Evaluation. 2016. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Payment Programs. Washington, DC.

Paragraph 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 proposed 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 IX.G.4.b. of this final rule, under section 2(d)(2) of the IMPACT Act would be independent of our proposal below (in section IX.G.4.b. of this final 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 proposed 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.4.b.(1) of this rule; (2) Ethnicity, as described in section VII.G.4.b.(1) of this rule; (3) Preferred Language, as described in section VII.G.4.b.(2) of this rule; (4) Interpreter Services, as described in section VII.G.4.b.(2) of this rule; (5) Health Literacy, as described in section VII.G.4.b.(3) of this rule; (6) Transportation, as described in section VII.G.4.b.(4) of this rule; and (7) Social Isolation, as described in section VII.G.4.b.(5) of this rule. These data elements are discussed in more detail below in section VII.G.4.b of this rule. A detailed discussion of the comments we received, along with our responses is included in each section.

#### 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 proposed 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 also proposed 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 proposed 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 PAC settings.

All of the Social Determinants of Health data elements we proposed 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 proposed to assess some of the factors relevant for patients receiving PAC 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.

We proposed 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,<sup>172</sup> 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

<sup>172</sup> Health Leads. Available at <https://healthleadsusa.org/>.

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>.

We solicited comment on these proposals.

Commenters submitted the following comments related to the proposed rule's discussion of SDOH SPADEs. A discussion of these comments, along with our responses, appears below.

*Comment:* One commenter supported the incorporation of SDOH in the IRF QRP, in the interest of promoting access and assuring high-quality care for all beneficiaries. The commenter also encouraged CMS to be mindful of meaningful data collection and the potential impact for data overload. Since SDOH have impacts far beyond the post-acute care setting, the commenter cautioned data collection that cannot be readily gathered, shared, or replicated beyond the PAC setting.

The commenter also encouraged CMS to consider leveraging data points collected during primary care visits by using social risk factor data captured during those encounters. They pointed out that the ability to have a hospital's or physician's EHR also collect, capture, and exchange segments of this information is powerful. The commenter recommended that CMS take a holistic view of SDOH across the care continuum so that all care settings may gather, collect or leverage this data efficiently and in way that maximizes its impact.

*Response:* We agree that collecting SDOH data elements can be useful in identifying and addressing health disparities. We also agree that CMS should be mindful that data elements selected are useful. The proposed SDOH SPADEs are aligned with SDOH identified in the 2016 NASEM report, which was commissioned by ASPE. Regarding the commenter's suggestion that CMS consider how it can align existing and future SDOH data collection to minimize burden on providers, we agree that it is important to minimize duplication of effort and will take this under advisement for future policy development.

*Comment:* One commenter recommended that CMS consider admission assessment for certain SPADEs as also fulfilling the discharge assessment requirement. The commenter supported the inclusion of the SDOH SPADEs and recommended that CMS require these items be assessed at some point during the patient's stay instead of during the admission assessment time window. The commenter recommended that any SDOH SPADEs finalized should be assessed at any point during the stay.

*Response:* We disagree with the commenters regarding SDOH SPADEs should be assessed at any point during the stay. Each of the SDOH SPADE data elements will assist with care planning when the patient is admitted. It is important for providers to identify a patient's needs in order to better inform the patient's care decisions made during and after the stay, including a patient's unique risk factors and treatment preferences.

*Comment:* Commenters were generally in favor of the concept of collecting SDOH data elements and provided that, if implemented appropriately, the data could be useful in identifying and addressing health care disparities, as well as refining the risk adjustment of outcome measures. However, some of the commenters suggested CMS not to finalize the proposed policy until CMS can address important issues around the potential future uses of these elements and the requirements around data collection for certain elements. The commenters provided that CMS did not state explicitly in the rule whether it anticipates the SDOH SPADEs will be used in adjusting measures and believe that the IMPACT Act's requirements make it likely the SPADEs will be considered for use in future adjustments. The commenters recommended CMS to be circumspect and transparent in its approaches to incorporating the data elements

proposed in payment and quality adjustments, such as by collecting stakeholder feedback before implementing any adjustments.

*Response:* We appreciate the commenters for recognizing that collecting SDOH data elements can be useful in identifying and address health disparities. We intend to use this data to assess the impact that the social determinants of health have on health outcomes. We will continue to work with stakeholders to promote transparency and support providers who serve vulnerable populations, promote high quality care, and refine and further implement SDOH SPADE. We appreciate the comment on collecting stakeholder feedback before implementing any adjustments to measures based on the SDOH SPADE. Collection of this data will help us in identifying potential disparities, conducting analyses, and assessing whether any adjustments are needed. Any future policy development based on this data would be done transparently, and involve solicitation of stakeholder feedback through the notice and comment rulemaking process as appropriate.

*Comment:* Several commenters recommended that CMS include disability status as a SDOH that contributes to overall patient access to care, health status, outcomes, and many other determinants of health since it is already included in some Medicare risk adjustment. The commenters stated that ASPE's report to Congress entitled "Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs" reported that disability is an independent predictor of poor mental and physical health outcomes and that individuals with disabilities may receive lower-quality preventive care.

*Response:* We appreciate the comments and suggestions provided by the commenters. We agree that it is important to understand and meet the needs of patients with disabilities. While disability is not being currently assessed through the SPADE, it is comprehensively assessed as part of existing protocols around care plans and health goals. However, as we continue to evaluate SDOH SPADEs, we will keep commenters' feedback in mind and may consider these suggestions in future rulemaking.

*Comment:* One commenter supported CMS's proposal to collect SDOH data within SPADEs but was concerned that all of these new elements may be burdensome. The commenter recommended that CMS require data collection on race, ethnicity, preferred

language, and interpreter services, and make data collection on health literacy, transportation, and social isolation voluntary for now and have the requirement phased into future rulemaking. The commenter noted that this would give IRFs an opportunity to adjust to the new data collection methods, while signaling their importance as entities that are currently collecting information on SDOH are experiencing various workflow, privacy, and other challenges. The commenter recommended that CMS consider including the collection of housing status in the future as individuals with unmet housing needs, such as homelessness or substandard housing, have higher health care costs and can be at risk for readmissions.

*Response:* We thank the commenter for their comment. As discussed above, section 2(d)(2)(B) of the IMPACT Act requires 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. 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. 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. Regarding the suggestion that CMS consider a housing status SPADE data element in future rulemaking efforts, we appreciate this feedback and will consider this suggestion in future rulemaking efforts on SPADE SDOH data elements.

#### (1) Race and Ethnicity

The persistence of racial and ethnic disparities in health and health care is widely documented, including in PAC settings.<sup>173 174 175 176 177</sup> 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.<sup>178</sup> 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.<sup>179</sup> Studies have also shown that African Americans are significantly more likely than white Americans to die prematurely from heart disease and stroke.<sup>180</sup> 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.<sup>181</sup>

The ability to improve understanding of and address racial and ethnic disparities in PAC outcomes requires 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.<sup>182</sup> The

for Medicare and Medicaid Services; February 28, 2018.

<sup>176</sup> 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.

<sup>177</sup> 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.

<sup>178</sup> National Healthcare Quality and Disparities Reports. (December 2018). Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/research/findings/nhqdr/index.html>.

<sup>179</sup> National Center for Health Statistics. *Health, United States, 2017: With special feature on mortality*. Hyattsville, Maryland. 2018.

<sup>180</sup> HHS. *Heart disease and African Americans*. 2016b. (October 24, 2016). <http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=19>.

<sup>181</sup> 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 at <https://www.ncbi.nlm.nih.gov/books/NBK425844/>.

<sup>182</sup> “Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity

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 proposed 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 proposed 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 proposed 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 proposed to include five response options under the ethnicity data element: (1) Not of Hispanic, Latino/a, or Spanish origin; (2) Mexican, Mexican American,

(Notice of Decision)”. **Federal Register** 62:210 (October 30, 1997) pp. 58782–58790. Available at <https://www.govinfo.gov/content/pkg/FR-1997-10-30/pdf/97-28653.pdf>.

<sup>173</sup> 2017 National Healthcare Quality and Disparities Report. Rockville, MD: Agency for Healthcare Research and Quality; September 2018. AHRQ Pub. No. 18–0033–EF.

<sup>174</sup> 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.

<sup>175</sup> 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

Chicano/a; (3) Puerto Rican; (4) Cuban; and (5) Another Hispanic, Latino, or Spanish Origin. We are including the addition of “of” to the Ethnicity data element to read, “Are you of Hispanic, Latino/a, 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.<sup>183 184 185 186</sup> 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.<sup>187</sup> Standardizing self-reported data collection for race and ethnicity allows for the equal comparison of data across multiple healthcare entities.<sup>188</sup> 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 U.S. 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 “Final 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 proposed to adopt the Race and Ethnicity data elements described above as SPADEs with respect to the proposed Social Determinants of Health category.

Specifically, we proposed to replace the current Race/Ethnicity data element with the proposed Race and Ethnicity data elements on the IRF–PAI. We also proposed that IRFs that submit the Race and Ethnicity data 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.

We solicited comment on these proposals.

Commenters submitted the following comments related to the proposed rule’s discussion of the Race and Ethnicity SPADEs. A discussion of these comments, along with our responses, appears below.

*Comment:* Some commenters noted that the response options for race do not align with those used in other government data, such as the U.S. Census or the Office of Management and Budget (OMB). The commenters also stated these responses are not consistent with the recommendations made in the 2009 Institute of Medicine report. The commenters pointed out that IOM report recommended using broader OMB race categories and granular ethnicities chosen from a national standard set that can be “rolled up” into the broader categories. The commenters stated that it is unclear how CMS chose the 14 response options under the race data element and the five options under the ethnicity element and worried that these response options would add to the confusion that already may exist for patients about what terms like “race” and “ethnicity” mean for the purposes of health care data collection. The commenters also noted that CMS should confer directly with experts on the issue to ensure patient assessments are collecting the right data in the right way before these SDOH SPADEs are finalized.

*Response:* The proposed Race and Ethnicity categories align with and are rolled up into the 1997 OMB minimum data standards and conforming with the 2011 HHS Data Standards as described in the implementation guidance titled “U.S. Department of Health and Human Services Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status” at <https://aspe.hhs.gov/basic-report/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-and-disability-status>. As stated in the proposed rule, the 14 race categories and the 5 ethnicity categories conform with the 2011 HHS Data Standards for person-level data collection, which were developed in fulfillment of section 4302 of the Affordable Care Act that required the Secretary of HHS to establish data collection standards for race, ethnicity, sex, primary language, and disability status. Through the HHS Data Council, which is the principal, senior internal Departmental forum and advisory body to the Secretary on health and human

<sup>183</sup> 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.

<sup>184</sup> 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.

<sup>185</sup> IOM (Institute of Medicine). 2009. *Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement*. Washington, DC: The National Academies Press.

<sup>186</sup> “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.

<sup>187</sup> 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 at <https://www.ncbi.nlm.nih.gov/books/NBK425844/>.

<sup>188</sup> IOM (Institute of Medicine). 2009. *Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement*. Washington, DC: The National Academies Press.

services data policy and coordinates HHS data collection and analysis activities, the Section 4302 Standards Workgroup was formed. The Workgroup included representatives from HHS, the OMB, and the Census Bureau. The Workgroup examined current federal data collection standards, adequacy of prior testing, and quality of the data produced in prior surveys; consulted with statistical agencies and programs; reviewed OMB data collection standards and the Institute of Medicine (IOM) Report Race, Ethnicity, and Language Data Collection: Standardization for Health Care Quality Improvement; sought input from national experts; and built on its members' experience with collecting and analyzing demographic data. As a result of this Workgroup, a set of data collection standards were developed, and then published for public comment. This set of data collection standards is referred to as the 2011 HHS Data Standards.<sup>189</sup> As described in the implementation guidance provided above, the categories of race and ethnicity under the 2011 HHS Data Standards allow for more detailed information to be collected and the additional categories under the 2011 HHS Data Standards can be aggregated into the OMB minimum standards set of categories.

As noted in the FY 2020 IRF PPS proposed rule (84 FR 17321 through 17323), we conferred with experts by conducting a listening session regarding the proposed SDOH data elements regarding 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 Data Standards to better reflect state and local diversity.

*Comment:* A commenter recommended that CMS consider the implications of having PAC providers collect Race and Ethnicity codes that vary from the Race and Ethnicity codes collected by other healthcare providers, specifically acute-care hospitals. The commenter noted that unless all care providers are expected to utilize the uniform 2011 HHS Data Standards, the consistency and accuracy of race and ethnicity data across settings will likely be unreliable and problematic. Another commenter provided that the proposed

list of response options for Race may not include all races that should be reflected, for example, Native African and Middle Eastern. In addition, the item should include "check all that apply" to ensure accurate and complete data collection. The commenter encouraged CMS to refine the list of response options for Race and provide a rationale for the final list of response options.

*Response:* We thank the commenter and agree that it is important to collect race and ethnicity data in a consistent way. The race and ethnicity categories that were proposed align with the 2011 HHS Data Standards and are rolled up into the 1997 OMB minimum data standards, which can be found at <https://aspe.hhs.gov/basic-report/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-and-disability-status>. For example, the 1997 OMB minimum data standard for Hispanic is the roll up category for the following response options on the 2011 HHS Data Standards: Mexican, Mexican American, Chicano/a; Puerto Rican; Cuban; another Hispanic, Latino, or Spanish origin. However, we will take the comment under advisement for future consideration. We also note that the option for "check all that apply" is available for providers to choose from the list of response options.

*Comment:* A commenter supported the opportunities to better account for SDOH in the diagnosis and treatment of patients but is concerned by the specificity of several of the seven proposed element for data collection for example, collection of race by Japanese, Chinese, Korean, etc. The commenter's concern is with the added burden in collecting the level of specificity outlined, and the commenter requested that CMS provide more detailed guidance in the final rule regarding how this information should be collected and shared in compliance with HIPAA. Further, the commenter asked that the agency outlines its expectations for how this newly collected information will be used by Medicare for payment and public reporting.

*Response:* For the Race and Ethnicity SPADE, this data should be completed based on the response of the patient. It is important to ask the patient to select the category or categories that most closely correspond to their race and ethnicity. Respondents should be offered the option of selecting one or more race and ethnicity categories. Observer identification or medical record documentation may not be used. The SDOH data elements that will be collected will assist with care

coordination and with evaluating the impact of disparities. With respect to how the data will be used for payment and public reporting, any potential future use of the data for these purposes would be done through future rulemaking.

SDOH data elements should be treated the same as other data collected on the assessment tool. As to any specific HIPAA questions, we appreciate the commenter's commitment to compliance with the HIPAA requirements, but note that the Office for Civil Rights (OCR) is tasked with implementing and enforcing HIPAA, not CMS. Commenters should consult appropriate counsel in instances in which they are unsure of their HIPAA status, or the permissibility of a disclosure under the HIPAA Privacy Rule. In doing so, commenters may wish to consult 45 CFR 164.103 (definition of "required by law") and § 164.512(a) (allowing "required by law" disclosures).

#### (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).<sup>190</sup> Individuals with LEP have been shown to receive worse care and have poorer health outcomes, including higher readmission rates.<sup>191</sup> <sup>192</sup> <sup>193</sup> 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

<sup>190</sup> U.S. Census Bureau, 2013–2017 American Community Survey 5-Year Estimates.

<sup>191</sup> 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.

<sup>192</sup> 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.

<sup>193</sup> 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.

<sup>189</sup> HHS Data Standards. Available at <https://aspe.hhs.gov/basic-report/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-and-disability-status>.

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.<sup>194</sup>

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.<sup>195</sup> 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 proposed 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 “Final 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 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 proposed 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 proposed to add the current Preferred Language and Interpreter Services data elements from the MDS and LCDS to the IRF-PAI.

We solicited comment on these proposals.

Commenters submitted the following comments related to the proposed rule’s discussion of Preferred Language and Interpreter Services SPADEs. A discussion of these comments, along with our responses, appears below.

*Comment:* Some commenters noted that, if finalized, IRFs should only need to submit data on the race and ethnicity SPADEs with respect to admission and would not need to collect and report again at discharge, as it is unlikely that patient status for these elements will change. The commenters believe that a patient’s preferred language and need for an interpreter also are unlikely to change between admission and discharge; thus, the commenter urged CMS to require collection of these SDOH SPADEs with respect to admission only.

*Response:* We thank the commenters for the comment. With regard to the submission of the Preferred Language SPADE and the Interpreter Services SPADE, we agree with the commenters that it is unlikely that the assessment of Preferred Language and Interpreter

<sup>194</sup> IOM (Institute of Medicine). 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

<sup>195</sup> 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>.

Services at admission would differ from assessment at discharge. As discussed in previous response for Vision and Hearing, we believe that the submission of preferred language and the need for an interpreter is similar to the submission of Race, Ethnicity, Hearing, and Vision SPADES.

We account for this change to the Collection of Information requirements for the IRF QRP in XIV.C of this final rule. Based on the comments received, and for the reasons discussed, we are finalizing that the Preferred Language and Interpreter Services SPADEs be collected as proposed with the modification that we will deem IRFs that submit these two SPADEs with respect to admission to have submitted with respect to both admission and discharge.

### (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.”<sup>196</sup> 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.<sup>197</sup>

Health literacy is prioritized by Healthy People 2020 as an SDOH.<sup>198</sup> 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.<sup>199</sup> 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 questions, “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.<sup>200 201</sup> 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.<sup>202</sup> Furthermore, the S-TOFHLA instrument is proprietary and subject to purchase for individual entities or users.<sup>203</sup> 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 proposed 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.<sup>204</sup> 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.<sup>205</sup> For more information on the proposed Health Literacy data element, we refer readers to the document titled “Final 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 health literacy data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section

[www.peppercornbooks.com/catalog/information.php?info\\_id=5](http://www.peppercornbooks.com/catalog/information.php?info_id=5).

<sup>196</sup> 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.

<sup>205</sup> 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.

<sup>199</sup> 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-medicare-value-based-purchasing-programs>. Washington, DC: 2016.

<sup>200</sup> 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.

<sup>201</sup> 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.

<sup>202</sup> 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 at <https://elcentro.sonhs.miami.edu/research/measures-library/tofhlaindex.html>.

<sup>203</sup> Nurss, J.R., Parker, R.M., Williams, M.V., & Baker, D.W. David W. (2001). TOFHLA. Peppercorn Books & Press. Available at <http://>

<sup>196</sup> 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.

<sup>197</sup> 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.

<sup>198</sup> Social Determinants of Health. Healthy People 2020. <https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health>. (February 2019).

1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we proposed to adopt SILS question described above for the Health Literacy data element as SPADE under the Social Determinants of Health Category. We proposed to add the Health Literacy data element to the IRF-PAL.

We solicited comment on this proposals. A discussion of these comments, along with our responses, appears below.

*Comment:* Some commenters noted that, if finalized, IRFs should only need to submit data on the race and ethnicity SPADEs with respect to admission and would not need to collect and report again at discharge, as it is unlikely that patient status for these elements will change. The commenters believe that a patient's health literacy is unlikely to change between admission and discharge; thus, the commenter urged CMS to require collection of all SDOH SPADEs with respect to admission only.

*Response:* We disagree with the commenters that it is unlikely patient status for health literacy will change from admission to discharge. Unlike the Vision, Hearing, Race, Ethnicity, Preferred Language, and Interpreter Services SPADEs, we believe that the response to this data element may change from admission to discharge for some patients. Health literacy can impact a patient's ability to manage their conditions, and it something that should be taken into account when developing care plans. The collection of the Health Literacy SPADE at discharge is to support patients, whose circumstances may have changed over the duration of their admission, in having the appropriate supports post-discharge. Therefore, the health literacy data element should be collected at both admission and discharge given the impact this could have on health outcomes and care planning.

*Comment:* One commenter stated that the health literacy question could be improved to capture whether the patient can read, understand, and implement/respond to the information. In addition, the commenter stated that the question does not take into account whether a patient's need for help is due to limited vision, which is different from the purpose of the separate Vision Impairment data element. Another possible question the commenter suggested was "How often do you have difficulty?" The commenter suggested that a single construct may not be sufficient for this area, depending on the aspect of health literacy that CMS intends to identify.

*Response:* We thank the commenters for the comment on the health literacy

data element. We agree that knowing whether a patient has a reading or comprehension challenge, or limited vision would be helpful. However, we specifically proposed data elements that have been tested. We were also mindful to try and limit the potential burden of asking additional questions related to health literacy. The SILS Health Literacy data element that we proposed performed well when tested, and it minimizes concerns related to burden by requiring one instead of multiple questions on health literacy.<sup>206 207</sup> If commenters have examples of SDOH questions that have been cognitively tested, we would welcome that feedback as we seek to refine SDOH SPADE data elements in future rulemaking.

#### (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.<sup>208</sup> 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 therefore proposed 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 questions, "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 proposed 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.<sup>209</sup>

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.<sup>210</sup> 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.<sup>211</sup> 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 proposed to adopt the Transportation data element from PRAPARE. More information about

<sup>206</sup> 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.

<sup>207</sup> 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.

<sup>208</sup> 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.

<sup>209</sup> 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](http://www.aha.org/transportation).

<sup>210</sup> 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](http://www.aha.org/transportation).

<sup>211</sup> Northwestern University. (2017). PROMIS Item Bank v. 1.0—Emotional Distress—Anger—Short Form 1.

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 “Final 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 proposed 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.

We solicited comment on these proposals. A discussion of these comments, along with our responses, appears below.

*Comment:* One commenter supported the collection of data to capture the reason(s) transportation affects a patient’s access to health care. The commenter appreciated the inclusion of these items on the IRF-PAI and encouraged exploration of quality measures in this area as transportation is an extremely important instrumental activity of daily living to effectively transition to the community.

*Response:* We thank the commenter and we will consider this feedback as we continue to improve and refine the SPADEs.

*Comment:* Some commenters noted that, if finalized, IRFs should only need to submit data on the race and ethnicity SPADEs with respect to admission and would not need to collect and report again at discharge, as it is unlikely that patient status for these elements will change. The commenters believe that a patient’s access to transportation is unlikely to change between admission and discharge; thus, the commenter suggested CMS to require collection of all SDOH SPADEs with respect to admission only.

*Response:* We disagree with the commenters that stated that access to transportation will always be the same from admission to discharge. Unlike the Vision, Hearing, Race, Ethnicity, Preferred Language, and Interpreter Services SPADEs, we believe that the response to this data element is likely to change from admission to discharge for some patients. For example, a patient could lose a family member or caregiver between admission and discharge, which could impact his or her access to transportation and impact how the patient responds to the access to transportation SPADE data element. Therefore, we believe that the response to this SDOH data element is likely to change from admission to discharge for some patients and we proposed to collect this SPADE data element with respect to both admission and discharge.

As outlined in the FY 2020 IRF PPS proposed rule, multiple studies have demonstrated that access to transportation has an impact on the health of patients (84 FR 17325). Therefore, it is important for providers to be able to identify a patient’s needs when the patient is admitted and when the patient is discharged in order to better inform the patient’s care decisions made during and after the stay, including understanding the patient’s unique risk factors and treatment preferences. Because of this, we are requiring that the Access to Transportation data element be assessed with respect to both admission and discharge.

#### (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.<sup>212 213</sup> Social isolation tends to

<sup>212</sup> 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.

<sup>213</sup> Social Connectedness and Engagement Technology for Long-Term and Post-Acute Care: A Primer and Provider Selection Guide. (2019).

increase with age, is a risk factor for physical and mental illness, and a predictor of mortality.<sup>214 215 216</sup> PAC 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 proposed 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 questions, “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.<sup>217</sup> 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

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>.

<sup>214</sup> 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.

<sup>215</sup> 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.

<sup>216</sup> 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.

<sup>217</sup> Northwestern University. (2017). PROMIS Item Bank v. 1.0—Emotional Distress—Anger—Short Form 1.

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 “Final 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 proposed to adopt the Social Isolation data element described above as SPADE with respect to the proposed Social Determinants of Health category. We proposed to add the Social Isolation data element to the IRF-PAI.

We sought public comment on this proposal. A discussion of these comments, along with our responses, appears below.

*Comment:* Commenters agreed with CMS that SDOH data could provide Medicare with valuable information about the role that non-clinical factors play in PAC patient outcomes and that the addition of the SDOH SPADEs will facilitate communication between PAC settings and other health care providers. A commenter noted that common standards and definitions are important for interoperability and communication across providers and encouraged CMS to ensure that the SDOH elements collected in IRF settings are aligned with future proposed SDOH data collection requirements in other settings. One commenter stated that there is increasing attention on the critical role that social factors play in individual and population health and that addressing health-related social needs through enhanced clinical-community linkages can improve health outcomes and reduce costs. Another commenter was also pleased that CMS is looking at SDOH and believes it is a positive step toward identifying disparities in health care.

*Response:* We thank the commenters for the comments.

*Comment:* Some commenters noted that, if finalized, IRFs should only need to submit data on the race and ethnicity

SPADEs with respect to admission and would not need to collect and report again at discharge, as it is unlikely that patient status for these elements will change. The commenters believe that a patient’s response to social isolation is unlikely to change between admission and discharge; thus, the commenter suggested CMS to require collection of all SDOH SPADEs with respect to admission only.

*Response:* We disagree with the commenters that stated that the response to the Social Isolation data element will be the same from admission to discharge. Unlike the Vision, Hearing, Race, Ethnicity, Preferred Language, and Interpreter Services SPADEs, we believe that the response to this data element is likely to change from admission to discharge for some patients. For example, a patient could lose a family member or caregiver between admission and discharge, which could impact their response to the Social Isolation data element. Therefore, we proposed to collect this SPADE data element with respect to both admission and discharge. As outlined in the FY 2020 IRF PPS proposed rule, multiple studies have demonstrated that social isolation has an impact on the health of patients (84 FR 17325 through 17326). Therefore, it is important for providers to be able to identify a patient’s needs when the patient is admitted and when the patient is discharged in order to better inform the patient’s care decisions made during and after the stay, including understanding the patient’s unique risk factors and treatment preferences. Because of this, we are requiring that the Social Isolation data element be assessed at both admission and discharge.

*Comment:* One commenter stated that the proposed question on social isolation may have a very different answer based on the time horizon considered by the beneficiary as beneficiaries who are newly admitted to an IRF may have experienced differing levels of social isolation over the preceding week due to interactions with health care providers, emergency providers, and friends or family visiting due to hospitalization. The commenter believes this question could be improved by adding a timeframe to the question. For example, “How often have you felt lonely or isolated from those around you in the past 6 months?”

*Response:* We thank the commenter for this comment. The Social Isolation data element assesses whether a patient has experienced social isolation in the past 6 months to a year. The social isolation question proposed is currently

part of the Accountable Health Communities (AHC) Screening Tool. The AHC item was selected from the Patient-Reported Outcomes Measurement Information System (PROMIS®) Item Bank on Emotional Distress.

*Comment:* A commenter suggested that collecting SDOH SPADEs that have no clinical value, such as transportation and social isolation during an assigned period of either admission or discharge, is a significant concern. The commenter stated that at admission, the focus should be on assessing the patient’s medical needs and plan of care, and at discharge, the focus shifts to patient’s transition plan and caregiver education. As there are already multiple required assessments on the IRF-PAI, the SDOH SPADEs would add burden and recommended that any SDOH SPADEs finalized should be assessed at any point during the stay.

*Response:* We disagree with the commenters that the Social Isolation and Transportation data elements have no value. As proposed in the transportation and social isolation section, multiple studies have demonstrated that access to transportation and social isolation have an impact on the health of patients.<sup>218 219</sup> For example, access to transportation is important to medication access. Similarly, social isolation is a predictor of mortality. Therefore, it is important for providers to identify a patient’s needs both at admission and discharge in order to better inform the patient’s care decisions made during and after the stay, including a patient’s unique risk factors and treatment preferences. To minimize burden, we proposed to collect this data element with respect to admission and discharge, rather than more frequently.

After consideration of the public comments, we are finalizing our proposals to collect SDOH data for the purposes of section 2(d)(2)(B) of the IMPACT Act and section 1899B(b)(1)(B)(vi) of the Act as follows. With regard to Race, Ethnicity, Health Literacy, Transportation, and Social Isolation, we are finalizing our proposals as proposed. In response to stakeholder comments, we are revising our proposed policies and finalizing

<sup>218</sup> 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.

<sup>219</sup> 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.

that IRFs that submit the Preferred Language and Interpreter Services SPADEs with respect to admission will be deemed to have submitted with respect to both admission and discharge.

#### *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 proposed to designate that system as the data submission system for the IRF QRP beginning October 1, 2019. We proposed to revise § 412.634(a)(1) by replacing “Certification and Survey Provider Enhanced Reports (CASPER)” with “CMS designated data submission”. We proposed 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 proposed to revise § 412.634(d)(5) by replacing reference to the “QIES ASAP” with “CMS designated data submission”. We proposed to revise § 412.634(f)(1) by replacing “QIES” with “CMS designated data submission system”. In addition, we proposed 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 invited public comment on our proposals.

*Comment:* One commenter supported this proposal and recommended that CMS begin educating and preparing IRFs for the transition as soon as possible.

*Response:* We thank the commenter for their support and appreciate the importance of educating for this transition. Information regarding the transition to iQIES and instructions for onboarding has been provided to IRFs and will be ongoing. Training resources are currently available on You-Tube at [https://go.cms.gov/iQIES\\_Training](https://go.cms.gov/iQIES_Training) and

additional help content for users is available within iQIES. Ongoing technical support via email is also available at [help@QTSO.com](mailto:help@QTSO.com).

After consideration of the public comments, we are finalizing our proposal to revise § 412.634(a)(1), § 412.634(d)(1), § 412.634(d)(5), and § 412.634(f)(1) as proposed. We are also finalizing our proposal to notify the public of any future changes to the CMS designated system using subregulatory mechanisms, such as website postings, listserv messaging, and webinars.

##### 3. 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 final rule, we proposed 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 proposed that IRFs would report the data on those measures using the IRF-PAI. IRFs would be required to collect data on both measures for Medicare Part A and Medicare Advantage 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 sought public comment on this proposal and did not receive any comments.

We are finalizing our proposal that IRFs report the data on 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 using the IRF-PAI as proposed. IRFs will be required to collect data on both measures for Medicare Part A and Medicare Advantage patients beginning with patients discharged on or after October 1, 2020.

##### 4. Schedule for Reporting Standardized Patient Assessment Data Elements Beginning With the FY 2022 IRF QRP

As discussed in section IV.F. of the proposed rule, we proposed to adopt SPADEs beginning with the FY 2022 IRF QRP. We proposed 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 Medicare Part A and

Medicare Advantage 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 sought public comment on this proposal and did not receive any comments.

We are finalizing our proposal that IRFs must submit the SPADEs for all Medicare Part A and Medicare Advantage patients discharged on or after October 1, 2020, with respect to both admission and discharge, using the IRF-PAI. IRFs that submit data with respect to admission for the Hearing, Vision, Preferred Language, Interpreter Services, Race, and Ethnicity SPADEs will be considered to have submitted data with respect to discharges.

##### 5. 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 website,<sup>220</sup> 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.<sup>221</sup> 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

<sup>220</sup> 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>.

<sup>221</sup> 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](http://www.qualityforum.org/Publications/2012/02/MAP_Coordination_Strategy_for_Post-Acute_Care_and_Long-Term_Care_Performance_Measurement.aspx).

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.<sup>222</sup>

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.

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 proposed 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 proposed 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 sought public comment on this proposal and received several comments, which are discussed below.

*Comment:* Many commenters, including MedPAC, supported the proposal to expand the reporting of quality measures to all patients regardless of payer, agreeing that quality care should be a goal for all patients. Several commenters agreed that most providers already complete an IRF-PAI for all patients. MedPAC also cautioned that any future Medicare payment adjustments related to performance should be based only on outcomes for Medicare beneficiaries. One commenter stated that this approach is consistent with other quality programs and offers consumers a fuller picture of quality of care. One commenter recommended including quality data about all payers on IRF Compare, and another commenter supported the proposal but suggested CMS to allow adequate time to review and validate data before it is made public and allow data on IRF Compare to be analyzed by payer.

*Response:* We thank commenters for their support and appreciate suggestions for implementing this policy.

*Comment:* A few commenters requested additional details about how this proposal would be implemented. One commenter suggested that CMS verify comprehensive data submission on all patients to avoid "cherry-picking" patients. A few commenters recommended that CMS delay this proposal and study how this additional data affects quality measure performance.

*Response:* We appreciate the commenters' request for more details regarding the implementation of this proposal, how data submission will be verified to avoid cherry-picking, and how this data will affect quality measure performance. We acknowledge the commenters' concerns about the

proposal's implementation timeline and the request to delay the proposal; however instead of delaying, we plan to use the comments received during this rulemaking cycle to bring a new all-payer policy proposal in the future. Therefore, after consideration of the public comments we received on these issues, we have decided that at this time, we will not finalize this proposal. We agree that it would be useful to assess further how to best implement the collection of data for all payers for the IRF QRP.

*Comment:* Many commenters had concerns about the burden of collecting quality data on all patients regardless of payer, citing that it contradicted the Patients over Paperwork initiative. One commenter suggested that CMS make this requirement voluntary and to conduct an analysis on the administrative burden on IRFs. Another commenter suggested that the Collection of Information section should contain an estimate of burden required for this reporting.

*Response:* We do not believe that the intent of this policy contradicts the Patients over Paperwork initiative, which aims to simplify the documentation required for our programs. However, the all payer proposal would have imposed a new reporting burden on IRFs. We are sensitive to the issue of burden associated with data collection and acknowledge the commenters' concerns about the additional burden required to collect quality data on all patients. Although we believe that the reporting of all-payer data under the IRF QRP would add value to the program and provide a more accurate representation of the quality provided by IRFs, we believe we need to better quantify the new reporting burden on IRFs from this proposal for stakeholders to submit comments. Therefore, after consideration of the public comments, we received on these issues, we have decided that at this time, we will not finalize this proposal. We agree that this burden should be accounted for and we will estimate this burden in future rulemaking.

*Comment:* One commenter questioned whether IRFs support this proposal. Another commenter was concerned that this proposal would add complexity to CMS' administration of the IRF QRP compliance determination process. One commenter was concerned that quality data would be skewed because younger, non-Medicare patients have more room for improvement compared to older patients.

*Response:* We do not believe this will add complexity to the IRF QRP

<sup>222</sup> 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.

compliance determination process, since adding more patients will not change the overall process that we follow with regard to determining compliance. With regard to IRF support for this proposal, we sought input on this topic in the FY 2018 IRF PPS proposed rule (82 FR 20740) and we received several supportive comments. With regard to the commenter's concerns that quality data would be skewed because younger non-Medicare patients have more room for improvement, we note that risk adjustment is currently used for many quality measures, including measures that focus on improvement, such as the functional outcome measures. We take patient characteristics, such as age, into consideration when developing measures, and these are included as risk adjusters for the functional outcome measures.

*Comment:* Several commenters did not support the proposal, citing concerns about patient privacy. Some commenters suggested that collecting quality data from non-Medicare beneficiaries would be a violation of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) since it is not required for reimbursement purposes. Another commenter was concerned that CMS' collection of, and possible disclosing of, sensitive health information from non-Medicare patients without consent may violate the Privacy Act of 1974, the E-Government Act of 2002, and other state level privacy acts. The commenter suggests amending § 412.608(a) to require the clinician at the IRF to provide the Privacy Act Statement and other information to non-Medicare patients.

Other commenters questioned how CMS would keep this non-Medicare data secure and were concerned that CMS could work with other payers to de-identify this data. A few commenters recommended informing non-Medicare beneficiaries of this reporting and to use only de-identified data. A few commenters requested more details from CMS about the scope of data collection, including non-quality information on the IRF-PAI.

*Response:* We appreciate the commenters' concerns but disagree that this proposal is a violation of HIPAA, Privacy Act of 1974, and e-Government Act of 2002. IRF-PAI data is collected under an existing system of records notice (66 FR 56682). Any disclosure of the data will be made in accordance with the Privacy Act and those routine uses outlined in the SORN. Medicare patients are currently given a Privacy Act Statement and would be given to

every patient under the IRF QRP. Section 208 of the e-Government Act of 2002 requires federal agencies to perform Privacy Impact Assessments when acquiring or developing new information technology or making substantial changes to existing information technology that involves the collection maintenance, or dissemination of information in identifiable form. Because we are not acquiring or developing new information technology, or making substantial changes to existing information technology under this proposal, we disagree that this policy violates the e-Government Act.

With regard to questions about how CMS would keep data non-Medicare data secure, we safeguard the IRF-PAI data in a secure data system. The system limits data access to authorized users and monitors such users to ensure against unauthorized data access or disclosures. This system conforms to all applicable federal laws and regulations as well as federal government, Department of Health & Human Services (HHS), and CMS policies and standards as they relate to information security and data privacy. The applicable laws and regulations include, but are not limited to: The Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002; the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003; and the corresponding implementing regulations. With regard to the scope of data collection, IRFs would be required to submit quality measure and standardized patient assessment data elements required by the IRF QRP. After consideration of the public comments we received on these issues, we have decided that at this time, we will not finalize this proposal. We appreciate concerns raised by providers and will take them into consideration for future rulemaking.

*Comment:* One commenter questioned whether CMS has the statutory authority to require IRFs to submit IRF-PAI data for the IRF QRP for all patients, regardless of payer, citing that it is inconsistent with section 1886(j)(2)(D) of the Act because data from non-Medicare IRF patients are not "necessary" for administering the IRF PPS. The commenter further noted that § 412.604(c) currently requires IRFs to complete an IRF-PAI for all Medicare Part A and Part C patients that an IRF admits or discharges and does not

address reporting for non-Medicare patients.

*Response:* We believe that we generally have authority to collect all payer data for the IRF QRP under section 1886(j)(7) of the Act. We also note that with respect to the data submitted in accordance with section 1886(j)(7)(F) of the Act, the statute expressly requires that data on quality measures specified under section 1899B(c)(1) of the Act be submitted using the IRF PAI, to the extent possible, and that SPADE required under section 1899B(b)(1) of the Act be submitted using the IRF PAI. No all payer data collected for the IRF QRP would be used for purposes of administering the IRF PPS.

We appreciate the support offered by some commenters for our proposal to collect data on all IRF patients regardless of payer so as to ensure that the IRF QRP makes publicly available information regarding the quality of the services furnished to Medicare beneficiaries, as well as to the IRF population as a whole. However, we also acknowledge the concerns raised by some commenters with respect to the administrative challenges of implementing all payer data collection, the need to account for the burden related to this policy, as well as the need for us to provide further detail and training to IRFs. We continue to believe that the collection of quality data to include all patients would help to ensure that Medicare patients receive the same quality of care as other patients who are treated by IRFs.

Therefore, after careful consideration of the public comments we received, we will not finalize the proposal to expand the reporting of IRF quality data to include all patients, regardless of payer, at this time. We plan to use the comments we received on this proposal to help inform a future all payer proposal.

#### *I. 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 the proposed rule, we proposed 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 proposed 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 proposed 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 sought public comment on these proposals and received several, which are summarized below.

*Comment:* Several commenters supported the proposal to begin publicly displaying data for the Drug Regimen Review Conducted With Follow-Up for Identified Issues—PAC IRF QRP measure in CY 2020 or as soon as technically feasible, including the exception for IRFs with fewer than 20 eligible cases. One commenter clarified that its support is contingent on the measure not utilizing performance categories.

*Response:* We appreciate the commenter's support.

After consideration of the public comments, we are finalizing our proposal 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.

#### J. 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 payment update status. Therefore, we proposed 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 sought public comment on this proposal and received several comments.

*Comment:* One commenter supported this proposal, but suggested that CMS make this information available to stakeholders upon request in the interest of transparency.

*Response:* We thank commenters for their support. At this time, we do not plan to make the list of compliant IRFs available upon request, in alignment with other QRPs that do not provide this list. We believe stakeholders can find sufficient quality information about IRFs on the IRF compare website.

*Comment:* Several commenters did not support the proposal removal of the list of compliant IRFs. One commenter agreed that the list was not relevant to IRF providers in reviewing their own compliance status, but stated that it could be of interest to patients and other IRFs. Other commenters recommended posting the list because it is helpful for large health systems to quickly determine which hospitals are compliant. One commenter further suggested that the list continue to be posted in a standardized manner across the various QRPs to improve transparency.

*Response:* We acknowledge commenters' concerns about removing the requirement to post the list of compliant IRFs. Patients and consumers can still find information about IRF quality on the IRF Compare website. We do not believe that removing this list will have a negative impact for IRFs, since the list does not give any new information to IRF providers or health providers about their own compliance status. We also note that other QRPs do not require posting of a list of compliant facilities.

After consideration of the comments, we are finalizing our proposal and will no longer publish a list of compliant IRFs on the IRF QRP website, beginning with the FY 2020 payment determination.

#### 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 proposed 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 invited 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, which are summarized below.

*Comment:* Some commenters suggested that CMS provide flexibility in its application of the IRF QRP payment penalty for IRFs who make a good-faith effort to comply and submit quality reporting data.

*Response:* We interpret the commenter's suggestion that we take into consideration case by case exceptions and apply leniency for providers have attempted but failed to submit their quality reporting data for the IRF QRP. We are unable to provide flexibility with respect to the 2 percent payment penalty; as noted previously, section 1886(j)(7) of the Act requires the Secretary to reduce the annual increase factor for IRFs that fail to comply with the quality data submission requirements. While we did not seek comment on flexibilities on which the penalty is applied, we note that we have provided flexibility where the failure of the IRF to comply with the requirements of the IRF QRP stemmed from circumstances beyond its control. For example, we have finalized policies that grant exceptions or extensions for IRFs if we determine that a systemic problem with one of our data collection systems affected the ability of IRFs to submit data (79 FR 45920). We have also

adopted policies (78 FR 47920) that allow us to grant exemptions or extensions to an IRF if it has experienced an extraordinary circumstance beyond its control. In addition, we set the reporting compliance threshold at 95 percent

rather than at 100 percent to data to account for the rare instances when assessment data collection and submission maybe impossible, such as when patients have been discharged emergently, or against medical advice.

Table 18 shows the calculation of the 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 18: Calculations to Determine the 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 (2.9 percent), reduced by 0.4 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 1.0050
Budget Neutrality Factor for the Wage Index and Labor-Related Share	X 1.0031
Budget Neutrality Factor for the Revisions to the CMGs and CMG Relative Weights	X 1.0010
Adjusted FY 2020 Standard Payment Conversion Factor	= \$ 16,167

After consideration of the comments, we are finalizing our proposal 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.

#### X. Miscellaneous Comments

We received several comments that were outside the scope of the FY 2020 IRF PPS proposed rule. Specifically, we received comments regarding the processes for updating the IRF facility-level adjustment factors and the transparency of these updates, the application of a cost-of-living adjustment for IRFs located in Alaska and Hawaii, the need for CMS education and instruction on the appropriate IGC/ICD coding on the IRF-PAI, re-evaluating and phasing out the 60 percent rule as criteria for IRF admission, and federal funding for universal health care. We thank commenters for bringing these issues to our attention, and we will take these comments into consideration for potential policy refinements.

#### XI. Provisions of the Final Regulations

In this final rule, we are adopting the provisions set forth in the FY 2020 IRF PPS proposed rule (84 FR 17244).

Specifically:

- We will adopt an unweighted motor score to assign patients to CMGs, 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 (FYs 2017 and 2018) using the Quality Indicator items in the IRF-PAI. This includes revisions to the CMG

relative weights and average LOS values for FY 2020, in a budget neutral manner, as discussed in section IV. of this final rule.

- We will rebase and revise the IRF market basket to reflect a 2016 base year rather than the current 2012 base year as discussed in section VI. of this FY 2020 IRF PPS final rule.

- We will update the IRF PPS payment rates for FY 2020 by the market basket increase factor, based upon the most current data available, with a productivity adjustment required by section 1886(j)(3)(C)(ii)(I) of the Act, as described in section VI. of this final rule.

- We will update to the IRF wage index to use the concurrent FY IPPS wage index and the FY 2020 labor-related share in a budget-neutral manner, as described in section VI. of this final rule.

- The facility-level adjustments will remain frozen at the FY 2014 levels for FY 2015 and all subsequent years, as discussed in section V. of this final rule.

- We will calculate the final IRF standard payment conversion factor for FY 2020, as discussed in section VI. of this final rule.

- We will update the outlier threshold amount for FY 2020, as discussed in section VII. of this final rule.

- We will update the CCR ceiling and urban/rural average CCRs for FY 2020, as discussed in section VII. of this final rule.

- We will 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, as discussed in section VIII. of this final rule.

- We will adopt updates requirements to the IRF QRP, as discussed in section IX. of this final rule.

#### XII. 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.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

This final 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 July 15, 2019, there are approximately 1,122 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 2018 National Occupational Employment and Wage Estimates ([http://www.bls.gov/oes/current/oes\\_nat.htm](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 19.

**TABLE 19: 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 final rule, we are adopting 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 1.2 minute addition in clinical staff time to report data per patient stay. We estimate 411,622 discharges from 1,122 IRFs annually. This equates to an increase of 8,232 hours in burden for all IRFs (0.02 hours per assessment  $\times$  411,622 discharges). Given 0.7 minutes of RN time at \$70.72 per hour and 0.5 minutes of LVN time at \$43.96 per hour, we estimate that the total cost will be increased by \$437 per IRF annually, or \$490,314 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 finalizing our proposal to add the standardized patient assessment data elements described in section VIII.F of this final rule 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 7.8 minutes on admission, and 10.95 minutes on discharge, for a total of 18.8 minutes of additional clinical staff time to report data per patient stay. Note that this is a decrease from the proposed 11.1 minutes at discharge because of the changes in section XIII.G.4.2 of this final rule. We estimate 411,622 discharges from 1,122 IRFs annually. This equates to an increase of 122,995 hours in

burden for all IRFs (0.3 hours per assessment  $\times$  409,982 discharges). Given 11.3 minutes of RN time at \$70.72 per hour and 7.5 minutes of LVN time at \$43.96 per hour, we estimate that the total cost will be increased by \$6,902 per IRF annually, or \$7,744,044 for all IRFs. 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 newly adopted IRF QRP quality measures and standardized patient assessment data elements will result in a burden addition of \$7,339 per IRF annually, and \$8,234,450 for all IRFs annually.

### XIII. Regulatory Impact Analysis

#### A. Statement of Need

This final 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 CMGs, and a description of the methodology and data used in computing the prospective payment rates for that fiscal year.

This final 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 MFP adjustment to the market basket increase factor. The productivity adjustment applies to FYs from 2012 forward.

Furthermore, this final rule also adopts policy changes under the statutory discretion afforded to the Secretary under section 1886(j)(7) of the Act. Specifically, we are rebasing and revising the IRF market basket to reflect a 2016 base year rather than the current

2012 base year, revising the CMGs, making 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 and updating 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 final rule by comparing the estimated payments in FY 2020 with those in FY 2019. This analysis results in an estimated \$210 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 QRP result in an estimated \$8.2 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](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 20, we estimate that the net revenue impact of this final rule on all IRFs is to increase estimated payments by approximately 2.5 percent. The rates and policies set forth in this final 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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. As discussed in detail below in this section, the rates and policies set forth in this final 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 1,122 IRFs for which data were available.

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–04, enacted 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 final 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 final 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 final rule is considered an E.O. 13771 regulatory 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 final rule updates to the IRF PPS rates contained in the FY 2019 IRF PPS final rule (83 FR 38514). Specifically, this final rule updates the CMG relative weights and average LOS values, the wage index, and the outlier threshold for high-cost cases. This final 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 final rule rebases and revises the IRF market basket to reflect a 2016 base year rather than the current 2012 base year, revises the CMGs based on FYs 2017 and 2018 data and amends the regulatory language to clarify 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 final rule will be a net estimated increase of \$210 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 IX.K. of this final rule). The impact analysis in Table 20 of this final 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 adopting standard annual revisions described in this final 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 \$210 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. Outlier payments are estimated to remain at 3 percent in FY 2020. Therefore, we estimate that these updates will result in a net increase in estimated payments of \$210 million from FY 2019 to FY 2020.

The effects of the updates that impact IRF PPS payment rates are shown in Table 20. The following updates that affect the IRF PPS payment rates are discussed separately below:

- The effects of the update to the outlier threshold amount, from approximately 3.0 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 annual market basket update (using the IRF market basket) to IRF PPS payment rates, as required by sections 1886(j)(3)(A)(i) and (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 budget-neutral labor-related share and wage index adjustment, as required under section 1886(j)(6) of the Act.

- The effects of the budget-neutral changes to the CMGs, relative weights and average LOS values, under the authority of section 1886(j)(2)(C)(i) of the Act.

- The total change in estimated payments based on the FY 2020 payment changes relative to the estimated FY 2019 payments.

### 3. Description of Table 20

Table 20 shows the overall impact on the 1,122 IRFs included in the analysis.

The next 12 rows of Table 20 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 975 IRFs located in urban areas included in our analysis. Among these, there are 697 IRF units of hospitals located in urban areas and 278 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 616 non-profit IRFs. Among these, there are 526 urban IRFs and 90 rural IRFs. There are 113 government-owned IRFs. Among these, there are 92 urban IRFs and 21 rural IRFs.

The remaining four parts of Table 20 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 20. 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 adjustment to the outlier threshold amount.
- Column (5) shows the estimated effect of the update to the IRF labor-related share and wage index, in a budget-neutral manner.
- Column (6) shows the estimated effect of the update to the CMGs, relative weights, and average LOS values, in a budget-neutral manner.
- Column (7) compares our estimates of the payments per discharge, incorporating all of the policies reflected in this final rule for FY 2020 to our estimates of payments per discharge in FY 2019.

The average estimated increase for all IRFs is approximately 2.5 percent. This estimated net increase includes the effects of the IRF market basket increase factor for FY 2020 of 2.9 percent, reduced by a productivity adjustment of 0.4 percentage point in accordance with section 1886(j)(3)(C)(ii)(I) of the Act. There is no change in estimated IRF outlier payments from the 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 20: IRF Impact Table for FY 2020 (Columns 4 through 7 in percentage)**

Facility Classification (1)	Number of IRFs (2)	Number of Cases (3)	Outlier (4)	FY 2020 CBSA wage index and labor-share (5)	CMG Weights (6)	Total Percent Change <sup>1</sup> (7)
Total	1,122	411,622	0.0	0.0	0.0	2.5
Urban unit	697	167,770	0.0	0.1	2.3	5.0
Rural unit	136	21,883	0.0	0.3	2.8	5.7
Urban hospital	278	217,445	0.0	-0.1	-2.1	0.2
Rural hospital	11	4,524	0.0	-0.9	-3.7	-2.1
Urban For-Profit	357	211,142	0.0	-0.2	-1.7	0.6
Rural For-Profit	36	8,217	0.0	-0.3	0.2	2.4
Urban Non-Profit	526	151,927	0.0	0.2	1.4	4.1
Rural Non-Profit	90	15,018	0.0	0.4	2.0	5.0
Urban Government	92	22,146	0.0	0.1	2.7	5.4
Rural Government	21	3,172	0.0	0.3	3.9	6.8
Urban	975	385,215	0.0	0.0	-0.1	2.4
Rural	147	26,407	0.0	0.1	1.7	4.4
<b>Urban by region</b>						
Urban New England	29	16,298	0.0	-0.1	-2.2	0.1
Urban Middle Atlantic	135	51,771	0.0	0.0	-1.4	1.1
Urban South Atlantic	147	77,544	0.0	-0.4	-0.5	1.6
Urban East North Central	167	50,728	0.0	-0.3	2.2	4.4
Urban East South Central	56	28,030	0.0	-0.7	-0.8	1.0
Urban West North Central	74	20,958	0.0	0.1	0.6	3.2
Urban West South Central	184	84,286	0.0	0.3	-0.4	2.3
Urban Mountain	84	30,427	0.0	-0.8	-0.9	0.8
Urban Pacific	99	25,173	0.0	2.0	2.0	6.6
<b>Rural by region</b>						
Rural New England	5	1,321	0.0	-2.4	-3.1	-3.1
Rural Middle Atlantic	12	1,294	0.0	0.0	1.0	3.6
Rural South Atlantic	16	3,647	0.0	0.4	-2.2	0.7
Rural East North Central	23	4,094	0.0	0.2	1.8	4.6
Rural East South Central	21	4,547	0.0	-0.1	3.4	5.8
Rural West North Central	22	3,223	0.0	0.3	2.1	5.0
Rural West South Central	40	7,361	0.0	0.5	3.6	6.8
Rural Mountain	5	627	0.0	0.8	2.2	5.6
Rural Pacific	3	293	0.0	0.2	2.8	5.6
<b>Teaching status</b>						
Non-teaching	1,015	363,012	0.0	0.0	-0.2	2.3
Resident to ADC less than 10%	61	34,980	0.0	0.1	0.6	3.3
Resident to ADC 10%-19%	33	12,061	0.0	0.0	2.3	4.9
Resident to ADC greater than 19%	13	1,569	0.0	-0.3	3.4	5.7
<b>Disproportionate share patient percentage (DSH PP)</b>						
DSH PP = 0%	29	5,153	0.0	-0.6	-1.5	0.3
DSH PP <5%	134	58,240	0.0	-0.1	-1.8	0.6
DSH PP 5%-10%	303	131,572	0.0	-0.2	-0.4	1.9
DSH PP 10%-20%	381	139,294	0.0	-0.1	0.1	2.5
DSH PP greater than 20%	275	77,363	0.0	0.4	1.7	4.7

<sup>1</sup>This column includes the impact of the updates in columns (4), (5), and (6) above, and of the IRF market basket increase factor for FY 2020 (2.9 percent), reduced by 0.4 percentage point for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act.

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## 4. Impact of the Update to the Outlier Threshold Amount

The estimated effects of the update to the outlier threshold adjustment are presented in column 4 of Table 20. 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 the FY 2020 IRF PPS proposed rule (84 FR 17244), we used 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. As we typically do between the proposed and final rules each year, we updated our FY 2018 IRF claims data to ensure that we are using the most recent available data in setting IRF payments. Therefore, based on updated analysis of the most recent IRF claims data for this final rule, we now estimate that IRF outlier payments as a percentage of total IRF payments as 3.0 in FY 2019. Thus, we are adjusting the outlier threshold amount in this final rule to maintain total estimated outlier payments equal to 3 percent of total estimated payments in FY 2020.

The impact of this outlier adjustment update (as shown in column 4 of Table 20) is to maintain estimated overall payments to IRFs at 3 percent.

## 5. Impact of the CBSA Wage Index and Labor-Related Share

In column 5 of Table 20, we present the effects of the budget-neutral update of the wage index and labor-related share. The 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 changes in the two have a combined effect on payments to providers. As discussed in section VI.E. of this final rule, we are updating the labor-related share from 70.5 percent in FY 2019 to 72.7 percent in FY 2020.

## 6. Impact of the Update to the CMG Relative Weights and Average LOS Values

In column 6 of Table 20, we present the effects of the budget-neutral update of the CMGs, relative weights and average LOS values. In the aggregate, we do not estimate that these 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 final rule, we discuss the 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 final rule, we are finalizing our proposal 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 finalizing our proposal to add standardized patient assessment data elements, as discussed in section IV.G of this final rule. We describe the estimated burden and cost reductions for both of these measures in section VIII.C of this final rule. In summary, the changes to the IRF QRP will result in a burden addition of \$7,339 per IRF annually, and \$8,234,450 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.

## 8. Effects of the Amending § 412.622(a)(3)(iv) To Clarify the Definition of a Rehabilitation Physician

As discussed in section VIII. of this final rule, we are 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. We do not expect this to have any effect on the quality of care that beneficiaries receive in IRFs because we continue to require that the rehabilitation physicians caring for patients in IRFs be licensed physicians with specialized training and experience in inpatient rehabilitation. We expect IRFs to continue ensuring that the rehabilitation physicians meet these requirements. Although we do not currently collect data from IRFs on the physicians specialties that are providing

care to patients in IRFs, we do not expect this to change as a result of the amendments we are making to § 412.622(a)(3)(iv). However, we will continue to monitor the quality of care beneficiaries receive in IRFs, and will initiate appropriate actions through future rulemaking if we observe any declines in quality of care in IRFs.

As this is merely clarifying our existing policy regarding the definition of a rehabilitation physician in § 412.622(a)(3)(iv), we do not expect this to result in any financial impacts for the Medicare contractors, IRFs, other providers, or for the Medicare program. However, we expect that this clarification may ease some administrative burden for IRFs and for Medicare contractors by making it easier for IRF providers to document their decisions regarding the licensed physicians in their facilities that meet the regulatory definition of a rehabilitation physician and for the Medicare contractors to continue to accept the IRFs' decisions in this regard. We are unable at this time to quantify how much administrative burden may have existed because of the previous ambiguity surrounding the definition of a rehabilitation physician, but we are hopeful that this clarification will alleviate any administrative burden that might have existed before.

We expect this clarification to enhance Medicare's program integrity efforts in this area by eliminating uncertainty surrounding the definition of a rehabilitation physician.

*D. Alternatives Considered*

The following is a discussion of the alternatives considered for the IRF PPS updates contained in this final 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 adopting a market basket increase factor for FY 2020 that is based on a rebased and revised 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 final 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 are updating the IRF prospective payments in this final rule by 2.5 percent (which equals the 2.9 percent estimated IRF market basket increase factor for FY 2020 reduced by a 0.4 percentage point 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 2 years of data (FYs 2017 and 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. As described in the FY 2020 IRF PPS proposed rule (84 FR 17244, 17249 through 17260), we explored the use of a weighted motor score, as requested by stakeholders. Our analysis showed that weighting the motor score would improve the accuracy of payments under the IRF PPS. The improved accuracy combined with the requests from stakeholders to explore a weighted methodology led us to propose to use a weighted motor score to assign patients to CMGs beginning on October 1, 2019. However, in light of the many concerned stakeholder comments on the FY 2020 IRF PPS proposed rule that requested that we go back to an unweighted motor score methodology until we can more fully analyze a weighted motor score, the fact that the improvement in accuracy using the weighted motor score is small, and the greater simplicity achieved through the use of an unweighted motor score, we are finalizing an unweighted motor score, in which each of the 18 items have a weight of 1, beginning October 1, 2019. We will continue to analyze weighted motor score approaches and will consider possible revisions to the motor score for future rulemaking.

We considered not removing the item GG0170A1 Roll left and right from the composition of the motor score. However, this item was found to be very collinear with other items in the motor

score and did not behave as expected in the models. Therefore, we believe it is appropriate to remove this item from the construction of the 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 1-year lag of the IPPS wage index. However, we believe that updating the IRF wage index based on the concurrent fiscal year's IPPS wage index will better align the data across acute and PAC settings in support of our efforts to move toward more unified Medicare payments across PAC settings.

We considered maintaining the existing outlier threshold amount for FY 2020. However, the outlier threshold must be adjusted to reflect changes in estimated costs and payments for IRFs in FY 2020. Consequently, we are adjusting the outlier threshold amount in this final rule to maintain total outlier payments equal to 3 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. Instead, we considered addressing this issue through subregulatory means, such as issuing guidance to the Medicare contractors. However, we believe that it is important to clarify this definition in regulation to ensure that IRF providers and Medicare contractors have a shared understanding of these regulatory requirements and to make certain that there is no room for further ambiguity on this point.

In addition, we considered addressing this issue by amending § 412.622(a)(3)(iv) to add further specificity to the definition of a rehabilitation physician. However, we did not take this approach because we continue to believe that the IRFs are in the best position to make the determination as to which licensed physicians meet the requirements for purposes of § 412.622, and we did not

want to inadvertently affect access to IRF care for beneficiaries. However, we will continue to monitor this policy and engage with stakeholders to determine if further specificity of these requirements may be warranted in the future.

#### E. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on the FY 2020 IRF PPS proposed rule will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this final rule. It is possible that not all commenters reviewed the FY 2020 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 final rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We 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](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 final rule. For each IRF that reviews the rule, the estimated cost is \$218.72 (2 hours × \$109.36). Therefore, we estimate that the total cost of reviewing this regulation is \$274,931.04 (\$218.72 × 1,257 reviewers).

We received one comment on the proposed methodology for estimating the total cost of reviewing this regulation which is summarized below.  
*Comment:* One commenter suggested that CMS should take into consideration the number of times the proposed rule has been downloaded in estimating the cost of reviewing this regulation.

*Response:* The regulatory review cost is an estimate that makes several assumptions such as average reading speed and number of the people who

read the document, etc. For more than 2 years, we have used the number of comments received as a proxy for the number of staff members who review the document. This assumption is well accepted by the general public. The number of comments received is a more reasonable proxy than the number of downloads since those who provide comments must actually read the rule,

as those that download the rule may not read the rule.

**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 21, we have prepared an accounting statement showing the

classification of the expenditures associated with the provisions of this final rule. Table 21 provides our best estimate of the increase in Medicare payments under the IRF PPS as a result of the updates presented in this final rule based on the data for 1,122 IRFs in our database. In addition, Table 21 presents the costs associated with the new IRF QRP requirements for FY 2020.

**TABLE 21: 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
	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	\$8.2 million

**G. Conclusion**

Overall, the estimated payments per discharge for IRFs in FY 2020 are projected to increase by 2.5 percent, compared with the estimated payments in FY 2019, as reflected in column 7 of Table 20.

IRF payments per discharge are estimated to increase by 2.4 percent in urban areas and 4.4 percent in rural areas, compared with estimated FY 2019 payments. Payments per discharge to rehabilitation units are estimated to increase 5.0 percent in urban areas and 5.7 percent in rural areas. Payments per discharge to freestanding rehabilitation hospitals are estimated to increase 0.2 percent in urban areas and decrease 2.1 percent in rural areas.

Overall, IRFs are estimated to experience a net increase in payments as a result of the policies in this final rule. The largest payment increase is estimated to be a 6.8 percent increase for rural government IRFs and rural IRFs located in the West South Central region. 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 amends 42 CFR chapter IV as set forth below:

**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 revising paragraphs (a)(3)(iv), (a)(4)(i)(A), (a)(4)(iii)(A), and (a)(5)(i) and adding paragraph (c) to 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: 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: July 23, 2019.

**Seema Verma,**

*Administrator, Centers for Medicare & Medicaid Services.*

Dated: July 25, 2019.

**Alex M. Azar II,**

*Secretary, Department of Health and Human Services.*

[FR Doc. 2019-16603 Filed 7-31-19; 4:15 pm]

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